Date: 08th September, 2025

To, Manager - Listing Compliance **National Stock Exchange of India Limited** 'Exchange Plaza'. C-1, Block G, Bandra Kurla Complex, Bandra (E), Mumbai - 400 051 SYMBOL: JSLL	**To,** Head of the Department, Department of Listing Operation, **BSE Limited** Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai 400001 SCRIP Code: 544476

Subject: Intimation under Regulation 30 of SEBI (LODR) Regulations, 2015 – Approval of Clinical Trial of Anti-Diabetes Efficacy of SDM02 TABLETS, Shuddhi XS Syrup, Petshuddhi Churna and Shuddhi Dr. B P Care tablets.

Dear Sir/Madam,

Pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, we wish to inform you that Jeena Sikho Lifecare Limited has received approval for conducting a clinical trial on the following products:

1. **Anti-Diabetes Efficacy of SDM02 Tablets** – Pre-clinical study conducted at MIET, Meerut, on streptozotocin-induced diabetic rats. The tablets were found effective with no mortality or adverse effects at the tested dose.

2. **Shuddhi XS Syrup** – Clinical trial on 60 subjects with constipation conducted at CCFT Laboratories, Meerut. 92% reported relief in constipation and abdominal pain, with no adverse events.

3. **Petshuddhi Churna** – Retrospective clinical study on 100 patient records conducted at Hospital & Institute of Integrated Medical Sciences, Meerut. Significant improvement observed in bowel movement, stool consistency, and abdominal discomfort. No adverse events reported.

4. **Shuddhi Dr. B P Care Tablets** – Clinical trial on 60 hypertensive patients conducted at CCFT Laboratories, Meerut. Significant reduction in systolic and diastolic blood pressure and heart rate was observed within 2–3 hours and sustained for 6 hours. No adverse events reported.

Sr No.	Tablets	Date of Final Report	Principal Investigator	Trial Site	Primary Sponsor	Clinical Research Organization
1	Anti-Diabetes Efficacy of Sdm02 Tablets	05 Jul 2024	Dr. Vipin Kumar Garg	Pharmacology Department, Department of Pharmaceutical Technology, MIET Meerut	Jeena Sikho Lifecare Limited & Mittal Ayurved Sansthan	Mittal Global Clinical Trial Services

Registered Office Address:
SCO-11, Kalgidhar Enclave, Baltana, Zirakpur, Punjab-140604, 01762-513185
CIN NO.: L52601PB2017PLC046545

Corporate Office Address:
B-26, Opp. Metro Pillar No. 223, Rohtak Road, New Multan Nagar, Delhi - 110056
Email ID.: cs@jeenasikho.com | www.jeenasikho.com

2	Shuddhi XS Syrup	12-Jun-25	Dr Mansoor Riyaz	CCFT Laboratories, Meerut	Jeena Sikho Lifecare Limited	Mittal Global Clinical Trial Services (MGCTS)
3	Petshuddhi Churna	13-Jun-25	Dr Monu Pathak	Hospital & Institute of Integrated Medical Sciences, Meerut	Jeena Sikho Lifecare Limited	-
4	Shuddhi Dr. B P Care Tablets	27-Jul-25	Dr Mansoor Riyaz	CCFT Laboratories, Meerut	Jeena Sikho Lifecare Limited	Mittal Global Clinical Trial Services (MGCTS)

This development is in line with the Company's ongoing commitment towards structured scientific evaluation of products to establish safety and efficacy. The outcomes of these studies are expected to support future product validation.

The copies of the Clinical Trial Reports are enclosed and also being made available on the Company's website www.jeenasikho.com.

The above is for your information and records.

Thanking you,

Yours faithfully,
For Jeena Sikho Lifecare Limited

MANISH GROVER Digitally signed by MANISH GROVER Date: 2025.09.08 13:01:05 +05'30'

Manish Grover
Managing Director
DIN: 07557886
Place: Zirakpur, Punjab
Date: 08-09-2025

Registered Office Address:
SCO-11, Kalgidhar Enclave, Baltana, Zirakpur,
Punjab-140604, 01762-513185
CIN NO.: L52601PB2017PLC046545

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MEERUT INSTITUTE OF ENGINEERING & TECHNOLOGY

(MIET Meerut)

CPCSEA Registration Number:
711/PO/Re/S/02/CPCSEA (Ministry of Environment, & Forest, Government of India)

ANTI-DIABETES EFFICACY OF SDM02 TABLETS

SPONSOR

JEENA SIKHO LIFECARE LIMITED &
MITTAL AYURVED SANSTHAN

CLINICAL RESEARCH ORGANIZATION

MITTAL GLOBAL CLINICAL TRIAL SERVICES (MGCTS)

TEST LABORATORY

PHARMACOLOGY DEPARTMENT, DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY, MIET Meerut
NH-58, Delhi-Roorkee Highway, Baghpat Bypass Road Crossing, Meerut, U.P. – 250005

PROJECT NO	**: 2024-06-289**
REPORT NO.	**: MIET/DPT/2024-06/289/Diabetes**
DATE	**: 05-07-2024**

Test Compound : SDM02 Tablets
SPONSOR : Jeena Sikho Lifecare Ltd & Mittal Ayurved Sansthan
CRO : Mittal Global Clinical Trial Services (MGCTS)
STUDY : ANTI_DIABETES EFFICACY OF SDM02 Tablets
PROJECT NO : 2024-06-289
REPORT NO : MIET/DPT/2024-06/289/Diabetes

CONTENTS OF THE REPORT

Test Compound	**: SDM02 Tablets**
SPONSOR	**: Jeena Sikho Lifecare Ltd & Mittal Ayurved Sansthan**
CRO	**: Mittal Global Clinical Trial Services (MGCTS)**
STUDY	**: ANTI_DIABETES EFFICACY OF SDM02 Tablets**
PROJECT NO	**: 2024-06-289**
REPORT NO	**: MIET/DPT/2024-06/289/Diabetes**

1. STATEMENT OF COMPLIANCE

I, the undersigned hereby declare that **Project No. 2024-06-289/ Report No. MIET/DPT/2024-06/289/Diabetes**; entitled "***Anti-Diabetes Efficacy of SDM02 TABLETS"*** was performed in accordance to the standard procedure of Pharmacology Department, Department of Pharmaceutical Technology, MIET Meerut, UP, as well as the approved study plan.

I hereby attest the authenticity of the study and guarantee that this report is a true and accurate record of the results obtained and shall not be reproduced except in full, without the written approval of the Sponsor.

This study was conducted inaccordance to the Good Laboratory Practices (GLP).

All original raw data including documentation, the draft report, a copy of the final report and the representative test sample are archived at the Pharmacology Department, Department of Pharmaceutical Technology, MIET Meerut, UP. There were no circumstances that may have affected the quality and integrity of the study.

The sponsor of the study is responsible for the necessary evaluation of the test sample concerning the chemicals, purity, identity, stability and other required data.

Study Director **05-07-2024**
Mr. Ankit Chaudhary (M.Pharm) Date

Test Compound	**: SDM02 Tablets**
SPONSOR	**: Jeena Sikho Lifecare Ltd & Mittal Ayurved Sansthan**
CRO	**: Mittal Global Clinical Trial Services (MGCTS)**
STUDY	**: ANTI_DIABETES EFFICACY OF SDM02 Tablets**
PROJECT NO	**: 2024-06-289**
REPORT NO	**: MIET/DPT/2024-06/289/Diabetes**

2. STATEMENT BY TEST FACILITY MANAGEMENT

Management of the test facility has made available all the resources to the Principle Investigator necessary for conduct of the present study in compliance with the principles of GLP.

I, the undersigned, take overall responsibility for the reliability of the work described in the report with accordance to GLP.

Test Facility Management **05-07-2024**
Dr. Vipin Kumar Garg (M.Pharm, PhD) Date

Test Compound	**: SDM02 Tablets**
SPONSOR	**: Jeena Sikho Lifecare Ltd & Mittal Ayurved Sansthan**
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3. QUALITY ASSURANCE REPORT

This **Project No. 2024-06-289**, **Report No. MIET/DPT/2024-06/289/Diabetes** entitled **"*Anti-Diabetes Efficacy of SDM02 TABLETS***" (ISO Guideline 10993 – 11) was subjected to inspection by Quality Assurance Unit.

This report had been audited by the Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed. In each case, the outcome of the QA evaluation is reported to the Principle Investigator and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and schedule of this study were as follows:

Standard Test Method Compliance Audit	: 10-06-2024
Animal Preparation	: 11-06-2024
Test Material Preparation	: 16-06-2024
Application of test compound	: 17-06-2024 to 23-06-2024
Assessment of Response	: 21 Days (10-06-2024 to 30-06-2024)
Draft Report Audit	: 02-07-2024
Final Report Date	: 05-07-2024

FOR QUALITY ASSURANCE **05-07-2024**
Ms. Garima Agarwal Date

Test Compound	**: SDM02 Tablets**
SPONSOR	**: Jeena Sikho Lifecare Ltd & Mittal Ayurved Sansthan**
CRO	**: Mittal Global Clinical Trial Services (MGCTS)**
STUDY	**: ANTI_DIABETES EFFICACY OF SDM02 Tablets**
PROJECT NO	**: 2024-06-289**
REPORT NO	**: MIET/DPT/2024-06/289/Diabetes**

4. STUDY PERSONNEL

Study Director	**:** Mr. Ankit Chaudhary (M.Pharm, Pharmacology)
Study Personnel	**:** Ms. Aditi Giri (M.Pharm, Pharmacology)
Veterinarian	: Dr. Sonia Sharma (MVSc)
Study Managers	: Ms. Garima Agarwal (M.Pharm)

5. SUMMARY

The study was conducted in accordance with the previously reported literature to evaluate the Anti-Diabetes Efficacy of SDM02 TABLETS in streptozotocin induced diabetic rats.

The test sample was administered through the oral route at pre-specified fixed-dose 2g/kg volume in either sex wistar rats (8-12 weeks). The body weight of animals was measured at day 0 (before the drug administration) and on days 7, 14 and 21 of the study. The rate of mortality and general behavior of the animals were observed continuously for the initial 1, 4, and 24 h after the drug administration and then daily for 21 days. Cage side observations included variations in the skin and fur, eyes, and sleep time at night. Particular attention was directed to observations of tremor, convulsions, salivation, diarrhea, lethargy, sleep, and coma. Also, respiratory, circulatory, autonomic, and central nervous systems and somatomotor activity were examined.

In the study, no mortality was observed up to 21 days. No toxic symptoms were found in rats 2g/kg at dose according to their body weight. No abnormalities were been observed in general clinical observations or gross necropsy. The rats were found to behave normally with no variation in locomotor, behavioral, neurological, or secretary patterns. No significant changes were observed in the body weight of rats.

Considering the data obtained from the study, the SDM02 TABLET at dose of 2g/kg is found to be effective.

6. INTRODUCTION

A. Purpose of the Study:

The test article identified below was evaluated to determine the Anti-Diabetes efficacy of the SDM02 TABLETS following oral administration to rats.

B. Testing Guidelines:

The study was conducted based on the International Organization for Standardization (ISO) 10993, Biological Evaluation of Medical Devices, Part 11- Test for Systemic Toxicity,and previous reported literatures.

References of literature reported

- Mestry, S. N., Dhodi, J. B., Kumbhar, S. B., & Juvekar, A. R. (2016). Attenuation of diabetic nephropathy in streptozotocin-induced diabetic rats by *Punica granatum* Linn. leaves extract. *Journal of traditional and complementary medicine*, *7*(3), 273–280. https://doi.org/10.1016/j.jtcme.2016.06.008
- Molehin, O. R., Oloyede, O. I., & Adefegha, S. A. (2018). *Streptozotocin-induced diabetes in rats: effects of White Butterfly (Clerodendrum volubile) leaves on blood glucose levels, lipid profile and antioxidant status.* *Toxicology Mechanisms and Methods, 1–14.* doi:10.1080/15376516.2018.1479476
- Ahmad, U., & Ahmad, R. S. (2018). Anti diabetic property of aqueous extract of Stevia rebaudiana Bertoni leaves in Streptozotocin-induced diabetes in albino rats. *BMC complementary and alternative medicine*, *18*(1), 179. https://doi.org/10.1186/s12906-018-2245-2

7. MATERIALS

Sample Details

The test article provided by the sponsor was identified and handled as follows:

Test Compound	: SDM02 TABLETs
Batch No	: 02
Mfg Date	: 04/2024
Physical Appearance	: Grey color solid dosage form
Expiry Date	: 3 yrs from mfg date
Storage Condition	: Room Temperature
Control Article	: NA
Control Article Stability Testing	: NA

Sample Preparation:

The sample was directly used in different dose volumes.

Test System

Species	: Wistar rats
Source	: Lala Lajpat Rai University
Strain	: Albino
Sex	: Female
Body Weight Range	: 180-250 gm
Acclimatization	: Minimum 5 days
No. of Animals	: 18 Rats

Identification Method: Marked with a permanent marker on the tail.

Animal Management
Husbandry:
The conditions conformed to the MIET Standard Operating System that is based on "*Guide for theCare and Use of Experimental Animals*"

Test Compound	**: SDM02 Tablets**
SPONSOR	**: Jeena Sikho Lifecare Ltd & Mittal Ayurved Sansthan**
CRO	**: Mittal Global Clinical Trial Services (MGCTS)**
STUDY	**: ANTI_DIABETES EFFICACY OF SDM02 Tablets**
PROJECT NO	**: 2024-06-289**
REPORT NO	**: MIET/DPT/2024-06/289/Diabetes**

Food:
A commercially available Rat feed was provided daily

Water:
Portable water was provided *ad libitum* through species appropriate water container ordelivered through an automatic watering system.

Environmental conditions:
Air conditioned rooms with 10-15 air changes per hour, Temperature between 22 ± 3°C, relative humidity 40 – 60% and illumination cycle set to 12 hours artificial fluorescent light and 12 hours dark.

Selection:
Only healthy previously unused animals were selected.

Personnel:
Associates involved were appropriately qualified and well trained.

Veterinary Care:
Standard veterinary medical care was provided in the study.

IAEC:
This procedure has been approved by MIET's Institutional Animal Ethical Committee and is reviewed at least half-yearly by the same committee.

8. METHODS

Preparation of Animals:

18 Wistar rats were randomly selected, weighed, and marked individually for identification. A total of three groups were formed containing six rats in each group. The animals were kept in the cages for five days prior to dosing to allow for acclimatization to the laboratory conditions.

Preparation of test drug:

The test drug was directly suspended in distilled water.

Drug administration:

Animals were kept on overnight fasting before the drug administration and three to four hours post-drug administration. During that time, the animals had free access to the water. Before the drug administration, the animals were weighed. Diabetes was induced following single-dose administration of streptozotocin at a dose of 45mg/kg via the *i.p.* route. The test sample was administered at a pre-specified fixed-dose volume (2g/kg) via oral route daily for two weeks.

Mortality observation:

The numbers of animal deaths were observed at day 0 before drug administration and at days 7, 14, and 21 after drug administration.

General Clinical observation:

Post-drug administration, the animals were continuously observed for muscle activity (Locomotion, muscle coordination, tremor and convulsive episode), Visual place response, and secretory activity (Lacrimation, and salivation). Also, respiratory and heart rate were examined.

Biochemical Parameters:

At the end of study, all the rats were sacrificed for the Biochemical Parameters estimation.

Body weight Measurement:

The body weight was recorded at day 0, 7, 14 and 21 of the study using electric balance.

Gross Necropsy:

At the end of the observation period the survived animals were sacrificed by an over dosageof pentobarbital and were subjected to gross necropsy. All gross pathological changes were observed and pancreas and kidney were isolated for histopathological analysis.

9. Acceptance Criteria and Statistical Analysis

According to the previous literature reported, the number of animal mortalities and evident toxicity, the hazard class was classified to the category of Globally Harmonized Classification System.

Test Compound : SDM02 Tablets
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10. RESULTS & DISCUSSION

Mortality:
No mortality was observed in any animals until 21 days post drug administration.

Clinical signs:
No abnormalities were observed in any animals until 21 days after the drug administration.

Body Weight:
No significant variation has been observed. Weight gain or weight loss in the study cannot be considered a sign of evident toxicity as no abnormalities were observed in clinical and gross necropsy findings.

Macroscopic Findings:
No abnormalities were observed in any animals at 2g/kg dose.

Table:

Dose (mg/kg)	Animal No.	Mortality Observed	Initial Body weight	Body weight post drug administration			Macroscopic Findings (Abnormalities detected)
			Day 0	Day 7	Day 14	Day 21	
Control Group	1	No	220.4	219.8	218.5	218.2	None
	2	No	224.5	225.8	223.8	223.5	None
	3	No	221.6	222.4	223.4	224.8	None
	4	No	219.8	217.6	219.5	220.5	None
	5	No	222.5	223.5	225.8	224.7	None
	6	No	225.4	224.3	223.5	221.8	None
STZ induced Group	1	No	224.9	211.5	210.5	204.3	None
	2	No	218.7	213.5	211.8	210.9	None
	3	No	220.8	214.8	215.6	214.8	None
	4	No	222.8	210.9	208.9	206.4	None
	5	No	223.9	209.9	211.9	209.5	None
	6	No	226.8	210.4	212.8	210.2	None
STZ + Test Drug	1	No	217.5	213.8	215.9	216.7	None
	2	No	220.9	212.9	213.5	215.4	None
	3	No	223.1	217.8	218.4	218.9	None

	4	No	227.7	216.7	217.4	218.9	None
	5	No	228.9	218.4	220.4	220.8	None
	6	No	225.9	219.4	220.4	221.3	None

Biochemical Parameters:

Diabetes was induced after the single injection of streptozotocin at the dose of 45mg/kg. Significant toxicity was observed in the toxic group when compared to the control rats. Following this treatment was started at herbal drug was administered at the dose of 2g/kg via oral route. Blood glucose level was measured from tail vein using glucose meter (ACCU-CHEK advantage), seven days after induction. Rats with blood glucose level above 14 mmol/L were considered as diabetic and were used for further study by initiating the treatment. Pooled 24 h urine was also evaluated.

Group	Blood Glucose level (mmol/L)			
	Day 0 (Before Injection)	Day 7	Day 14	Day 21
Control	4.35 ± 0.30	4.23 ± 0.37	4.31 ± 0.33	4.55 ± 0.39
STZ induced rats	4.33 ± 0.36	24.35 ± 0.61	24.68 ± 0.75	24.83 ± 0.86
STZ + Test Drug	4.39 ± 0.34	24.60 ± 0.83	23.52 ± 0.76	19.44 ± 1.08

Group	Urine Albumin gm/24h	Urine Creatinine mg/24h
Control	0.08 ± 0.01	21.91 ± 0.74
STZ induced rats	0.43 ± 0.06	12.52 ± 0.72
STZ + Test Drug	0.24 ± 0.06	15.42 ± 0.49

11. ARCHIVE

On completion of the study, the raw data and other material, sample of the test substance and the study report are being retained for 09 years at the Pharmacology Department, Department of Pharmaceutical Technology, MIET Meerut, UP.

Test Compound	**: SDM02 Tablets**
SPONSOR	**: Jeena Sikho Lifecare Ltd & Mittal Ayurved Sansthan**
CRO	**: Mittal Global Clinical Trial Services (MGCTS)**
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PROJECT NO	**: 2024-06-289**
REPORT NO	**: MIET/DPT/2024-06/289/Diabetes**

12. CERTIFICATE

This is to certify that the "***Anti-Diabetes Efficacy of SDM02 TABLETS***" sponsored by **JEENA SIKHO LIFECARE LIMITED** and **MITTAL AYURVED SANSTHAN** and the testing material for the study was provided by Clinical Research Organization: **MITTAL GLOBAL CLINICAL TRIAL SERVICES (MGCTS)** was performed according to the International Organization for Standardization 10993: Biological Evaluation of Medical Devices Part 11: and previous reported literature. **The test sample at the dose of 2g/kg was found to be effective in reducing the blood sugar, supporting urine Albumin, and creatinine excretion function.**

Note: Results and conclusions apply only to the test article tested. Any extrapolation of thesedata to other samples is the sponsor's responsibility.

Ankit Chaudhary

_____

Study Director **05-07-2024**
Mr. Ankit Chaudhary Date

13. ANNEXURE – I: REFERENCES

- International Organization for Standardization (ISO) 10993, Biological evaluation ofMedical Devices Part – 11, Test for Systemic Toxicity (2017)
- Mestry, S. N., Dhodi, J. B., Kumbhar, S. B., & Juvekar, A. R. (2016). Attenuation of diabetic nephropathy in streptozotocin-induced diabetic rats by *Punica granatum* Linn. leaves extract. *Journal of traditional and complementary medicine*, *7*(3), 273–280. https://doi.org/10.1016/j.jtcme.2016.06.008
- Molehin, O. R., Oloyede, O. I., & Adefegha, S. A. (2018). *Streptozotocin-induced diabetes in rats: effects of White Butterfly (Clerodendrum volubile) leaves on blood glucose levels, lipid profile and antioxidant status. Toxicology Mechanisms and Methods, 1–14.* doi:10.1080/15376516.2018.1479476
- Ahmad, U., & Ahmad, R. S. (2018). Anti diabetic property of aqueous extract of Stevia rebaudiana Bertoni leaves in Streptozotocin-induced diabetes in albino rats. *BMC complementary and alternative medicine*, *18*(1), 179. https://doi.org/10.1186/s12906-018-2245-2

SPONSOR
JEENA SIKHO LIFECARE LIMITED

CLINICAL RESEARCH ORGANIZATION
MITTAL GLOBAL CLINICAL TRIAL SERVICES (MGCTS)

MGCTS/24/443

Study Title: "An open Label, Single arm Clinical Study to Evaluate the efficacy of Shuddhi XS Syrup in patients having Constipation."

Clinical Study Report

Title Page

Study Title: An open Label, Single arm Clinical Study to Evaluate the efficacy of Shuddhi XS Syrup in patients having Constipation.

Protocol No.	MGCTS/24/443
Version Number and Date	1.0 DATED 19 Dec 2024
Investigational Product	Shuddhi XS Syrup
Name & Address of Sponsor	Jeena Sikho Lifecare Limited
Name & Affiliation of the Investigator (s)	Name: Dr Mansoor Designation: Principal Investigator Affiliation: CCFT Laboratories E-mail: mansoor25riyaz@gmail.com
Date of First patient in the study	19 April 2025
Date of Last patient follow up	23 May 2025
No. of patients	60
Report Number	MGCTS/24/443
Date of the draft report	11 June 2025
Date of Final Report	12 June 2025

Confidential

The information in this document is confidential and is to be used only in connection with matters authorized by Jeena Sikho Lifecare Limited no part of it is to be disclosed to the others without prior written permission from Jeena Sikho Lifecare Limited. This study was performed in accordance with ICH E6 R2, Schedule-Y (2017) and Ethical Principles as per the Declaration of Helsinki (2013) including archiving of all the essential documents.

INVESTIGATOR(S) SIGNATURE(S)

A Clinical study titled: “An open Label, Single arm Clinical Study to Evaluate the efficacy of Shuddhi XS Syrup in patients having Constipation.”

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name: Dr. Mansoor Riyaz **Designation:** Principle Investigator CCFT Laboratories, Meerut	 12-06-2025 SIGNATURE & DATE

STATEMENT OF COMPLAINCE

"An open Label, Single arm Clinical Study to Evaluate the efficacy of Shuddhi XS Syrup in patients having Constipation."

This study was conducted in compliance with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

Name	**Designation & Address**	**Signature**	**Date (DD MM YYYY)**
PUNEET MITTAL	Director- Clinical Research, MGCTS, Mittal Building 121-B, Mansarovar Ind Estate, Panchli, Baghpat Road, Meerut-250002, India		12-06-2025

STATEMENT OF COMPLAINCE

(DATA SAFETY MONITORING BOARD)

A Clinical study titled: "An open Label, Single arm Clinical Study to Evaluate the efficacy of Shuddhi XS Syrup in patients having Constipation."

This study was verified and reviewed independently according with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

S. No	Name and Designation	Signature	Date (DD MM YYYY)
1	NIDHI DIXIT Study Director CCFT- Meerut		12-06-2025
2	Ms. Sheetal, Data Management Associate CCFT- Meerut		12-06-2025

REPORT SUMMARY:

Title of the Study	An open Label, Single arm Clinical Study to Evaluate the efficacy of Shuddhi XS Syrup in patients having Constipation.
Name of Investigational product	Shuddhi XS Syrup
Name of Sponsor	Jeena Sikho Lifecare Limited
SITE	1st Floor room 3, CCFT laboratories, AR multispecialty hospital and research center, Delhi Road, Meerut UTTAR PRADESH
Investigator (s)	Dr. Mansoor Riyaz
Study Objective	**Primary objective:** The primary objective is to study the efficacy and safety of DR. Shuddhi XS Syrup with- • Subject Self-Assessment
Study Phase	NA
Study Design	An open label single arm study. Each participant entering the trial will be assigned to a regimen of investigational product, and advised to take general precautions as needed. Patients will be assigned to investigational product for 1 day, following up on 2nd day. The Bristol Stool Form assessment was conducted during Visit 1, and the subject's self-assessment was completed during Visit 2  **Subject Self-Assessment**

	1. Do you agree that this syrup helps relieve constipation? 2. Do you agree that it increases the frequency of your bowel movements? 3. Have you noticed an improvement in abdominal pain? 4. Do you agree that your stool becomes looser after taking the syrup? 5. Do you agree that this syrup does not taste bad? 6. Do you agree that this syrup works quickly? 7. Do you agree that this syrup does not cause any sensitivity?
Sample Size	60 Subjects
Study Inclusion Criteria	**Inclusion Criteria** Subjects must meet all the following criteria to be eligible for participation in the trial: 1. Subject from 18-65 years of age. 2. Subject having problem in passing stool. 3. Subjects that are able to give written informed consent in a manner approved by the institutional ethics committee and comply with the requirements of the study. 4. Subject willing to avoid participation in any other interventional clinical trial for the duration of the study.
Study Exclusion Criteria	**Exclusive Criteria:** • Have used, are using, or are planning to use immunosuppressive or immunomodulatory medication (i.e., biologics), including oral or parenteral corticosteroids. • Subjects that have participated in any other interventional clinical trial in the previous 90 days. • Heart patients will no enrolled. • Subjects with known sensitivity to any of the constituents of the investigational product. • Any clinically significant systemic or cutaneous disease, which may interfere with study treatment or procedures.

	• Chronic illness which may influence the outcome of the study. • Pregnant/nursing mothers
Test Product Study Product, Dose	**Test Product**: Shuddhi XS Syrup **Dose:** 20ml shot before bedtime **Route of Administration:** Oral
Clinical assessment and Laboratory Assessment	• Subject Self- Assessment) • Bristol Stool Form
Outcome Measures	**Primary Outcome Measures:** **Efficacy:** • Change in Subject Self- Assessment [Timeframe 1-2days] **Safety**: • Adverse Events • Tolerability of Shuddhi XS Syrup
SAFETY EVALUATION	Incidence of AE
Statistical Analysis	The study was done as a consumer test based on patient/subjects evaluation only, and therefore the results will be represented as % of population observing the change, and not parameter based, therefore, the actual trial statistics is not applicable for the same.
Ethical Conduct of the study	The study was initiated after written approval from the hospital's Committee. The trial was conducted as per ICH E6 R2 Guidelines, Schedule Y (2017), Declaration of Helsinki (Brazil, 2013) and in accordance with other applicable guidelines.
Efficacy and Safety Results	Out of 60 subjects screened, none were found dropout, no screen failure. 60 subjects who underwent the full trial period. The mean age of the subjects was 37.3 years in the study. The mean height of the subjects was 158.63 cm. The mean weight of the subjects was 60.42 kg. The BMI of the subjects were 24.09. A total of 40 female, and 20 male subjects were enrolled in the study. Data from 60 patients who completed the study were analyzed. A special assessment was done in the first visit for the Bristol stool

	scale to identify and group as per the type of stool. 47% of the study subjects had stool like Separate hard lumps, like nuts – hard to pass, 27% had sausage shape stool, 23% had stool which was Like a sausage but with cracks on the surface, and rest 3% had smooth textured stool. The assessment for efficacy involved a set of questions asked to each study subject. Each question had a Boolean response of Yes, and No, and the results are represented as percentage of users observing the change. 92% of the users observed that the syrup helps relieving the constipation. 82% users agree that it increases the frequency of their bowel movements. 92% users noticed an improvement in the abdominal pain. 87% users felt their stool to loosen after taking the syrup. 55% users liked the taste of the test product. 92% users felt that it works quickly. 85% users observed no sensitivity post taking the test product. No adverse event was reported during the study. Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication. There were no protocol violations and deviations reported. There were no patients who lost to follow up. None of the patients withdrawn the consent.
Conclusion	In conclusion, Shuddhi XS Syrup showed laxative properties, making stool smooth and more frequent along with reduction in the constipation related pain. No, adverse events were observed during the study.
Date of Report	12 June 2025

Contents

List of Abbreviations

Abbreviation	Definition
AE	Adverse event
ANOVA	Analysis of variance
AUC	Area under the curve
BOCF	Baseline observation carried forward
CI	Confidence interval
CRO	Contract Research Organisation
ECG	Electrocardiogram
CRF	Electronic case report form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
IP	Investigational product
IEC	Institutional Ethics Committee
ITT	Intent to treat
MI	Multiple imputation
MedDRA	Medical Dictionary for Regulatory Activities
OTC	Over the counter
PP	Per protocol
PRO	Patient-reported outcome
QOL	Quality of Life
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SD	Standard deviation
SGA	Subject's global assessment
SUSAR	Suspected unexpected serious adverse reaction
TC	Telephone call
UPT	Urine pregnancy test

Patient Information and Consent

All patients provided written informed consent to participate in the study prior to being screened. The patient information sheet detailed the procedures involved in the study (aims, methodology, potential risks and anticipated benefits) and the investigator explained these to each patient. The patient signed the consent form to indicate that the information had been explained and understood. The patients were allowed to take ample time to consider the information presented before signing and dating the informed consent form to indicate that they fully understood the information, and willingly volunteered to participate in the study. The patients were given a copy of the signed informed consent form for their information. The original informed consent documents were kept in a confidential file in the Investigators site record.

Investigators and Study Administrative Structure

Sponsor	Jeena Sikho Lifecare Limited
Principal Investigator (S)	Dr. Mansoor Riyaz
ETHICS COMMITTEE (S)	INSITUTIONAL ETHICS COMMITTEE
SITE(S) ADDRESS	1st Floor room 3, CCFT laboratories, AR multispecialty hospital and research center, Delhi Road Meerut UTTAR PRADESH
NAME AND ADDRESS OF LABORATORY	SAME AS ABOVE

1. INTRODUCTION

1.1. Background

Constipation is a common digestive condition characterized by infrequent, difficult, or painful bowel movements. It often involves passing hard or dry stools and may be accompanied by abdominal discomfort or bloating. Causes can include a low-fiber diet, dehydration, lack of physical activity, or certain medications. While occasional constipation is usually not serious, chronic cases may require medical evaluation to rule out underlying issues. Maintaining a healthy diet, staying hydrated, and exercising regularly can help prevent and manage constipation effectively.

1.2. Rationale of the Trial

To determine the benefits from Dr. Shuddhi XS Syrup with these following ingredients:

1. Cassia fistula
2. Cassia senna
3. Phyllanthus emblica
4. Terminalia chebula
5. Terminalia bellirica
6. Stevia rebaudiana

1.3. Benefit-risk Assessment

The subject population will be composed of healthy volunteers.

The active ingredients in the investigational products are known to be effective for the skin hydration and barrier function. The safety and efficacy profiles for marketed products with these ingredients are well known.

It would be safe to assume that the risk factor in this clinical trial is minimal. However, the trial is designed to record any adverse event that may take place as well as handle any complication that may arise during the trial.

2. TRIAL OBJECTIVES AND PURPOSE

2.1. Primary objective

The primary objective is to study the efficacy and safety of DR. Shuddhi XS Syrup with-

- Subject Self-Assessment

3. TRIAL DESIGN

3.1. Overall Trial Design

An In-vivo study

Each participant entering the trial will be assigned to a regimen of investigational product, and advised to take general precautions as needed.

Patients will be assigned to this study for 1 day in which Day 0 (Visit 1/Screening) done for screening purpose and handover the IP to the Subjects, and measure Bristol Stool Form.

The next visits- day 2, only Subject Self-Assessment will be measured.

3.2. Trial Endpoints

3.2.1. Endpoints

Efficacy:

Primary Outcome Measures:

<u>Efficacy</u>:

- Change in Subject Self- Assessment [Timeframe 1-2days]

<u>Safety</u>:

- Adverse Events
- Tolerability of Shuddhi XS Syrup

4. SELECTION OF TRIAL POPULATION

4.1. Subject Population

Subjects (60 in no.) were enrolled for the primary analysis. An individual subject was allowed to participate in the trial one time only.

Each potential subject signed and date an informed consent document before any trial-specified procedures was performed. Subjects were provided authorization for use of their personal data in accordance with the applicable regulations regarding privacy and data protection.

4.2. Inclusion Criteria

Subjects must meet all the following criteria to be eligible for participation in the trial:

- Subject from 18-65 years of age.
- Subject having problem in passing stool.
- Subjects that are able to give written informed consent in a manner approved by the Institutional ethics committee and comply with the requirements of the study.
- Subject willing to avoid participation in any other interventional clinical trial for the duration of the study.

4.3. Exclusion Criteria

- Have used, are using, or are planning to use immunosuppressive or immunomodulatory medication (i.e., biologics), including oral or parenteral corticosteroids.
- Subjects that have participated in any other interventional clinical trial in the previous 90 days.
- Heart patients will no enrolled.
- Subjects with known sensitivity to any of the constituents of the investigational product.
- Any clinically significant systemic or cutaneous disease, which may interfere with study treatment or procedures.
- Chronic illness which may influence the outcome of the study.
- Pregnant/nursing mothers

4.4. Discontinuation of Treatment

In accordance with legal requirements and International Conference on Harmonization (ICH) – Good Clinical Practice (GCP) guidelines, every subject has the right to refuse Further participation in this trial at any time and without providing. A subject's participation is to be terminated immediately upon his/her request. The investigator should seek to obtain the reason and record this on the electronic case report form (eCRF) whenever possible.

If, at the time of refusal, a trial product has already been administered, the investigator should advise the subject on follow-up safety evaluations.

In the case of an SAE or development of a condition that would have met the trial safety-related exclusion criteria, the subject should be evaluated by the investigator. The investigator should use his/her discretion to determine whether the subject should continue

treatment with the IP.

A subject may be withdrawn from the trial at any time at the discretion of the investigator. The reasons for early termination are to be fully documented on the CRF.

In addition, sponsor reserves the right to end or suspend the trial at any time.

If a subject withdraws from the trial, all efforts will be made to complete a final evaluation if possible. The withdrawal procedures for subjects who withdraw during the treatment period are the same as those for the End of Treatment visit. Subjects discontinued for an AE will be monitored until the AE is resolved, a reasonable explanation is provided for the event, or the subject is referred to his/her own primary medical doctor. The specific AE in question will be recorded on the appropriate CRF.

4.5. Replacement Policy

After trial enrolment has been completed, subjects who prematurely discontinue the trial after were not replaced.

5. TRIAL TREATMENTS

5.1. Investigational Product

Shuddhi XS Syrup

5.2. Dosing Regimen

20ml shot during bedtime.

5.3. Dose Modification

Subjects classified as clear at on actual visits may stop the treatment at the investigator's discretion. They should remain in the trial and attend visits up to whole trial.

5.4. Packaging, Labeling, and Storage

Medication labels for the IPs will comply with the legal requirements of the country where the trial is performed and be printed in the local language.

The IPs will be supplied by the **Jeena Sikho Lifecare Limited** designated vendor and stored securely at the site under the control of the investigator. The temperature will be monitored and documented.

The cream was supplied to the clinical site. The product to be protected from sunlight,

stored in a cool and dry place at a temperature of 25°C (below 77°F) at the site, and below 25°C (below 77°F) after dispensing to the subject however the product must not be refrigerated.

5.5. Prior, Concomitant, and Prohibited Therapy

All medications, including over-the-counter (OTC) drugs, taken within 30 days prior to the start of the trial were recorded at Screening. Thereafter, a record of all medications and supportive therapy taken during the course of the trial was made. Information regarding the total daily dose, route of administration, start and discontinuation dates, and indication were recorded on the subject's CRF.

5.5.1. Washout of Prohibited Medications Prior to Enrollment

A washout period of up to 2 weeks was completed if the subject has been treated with any medication as specified in the exclusion criteria.

5.5.2. Prohibited Medications during the Trial

Use of any medication that would exclude the subject from participation in the trial (as specified in Section 5.2 Exclusion Criteria) is also prohibited during the treatment which includes medications in the following categories:

Patients should not use any form of the topical interventions

5.5.3. Rescue Medication

In case the patient does not respond to the treatment, any other medication as judged by the Investigator would be better for the subject will be given to subjects. No other concomitant medicine will be allowed except study drug and rescue medication throughout study duration.

5.6. Treatment Compliance

Records of trial product used and dosages administered were kept during the trial. The trial monitor has noted product accountability during site visits and at the completion of the trial.

At all on-treatment visits, the subjects were asked if he/she has used the medication as prescribed. If this is not the case, the degree and nature of noncompliance was specified. In addition, subjects were asked to complete a dosing diary during the treatment period as a

measure of treatment compliance.

Subjects who are consistently noncompliant were counseled.

Subjects were asked to return all used and unused bottles in the outer box at each visit. All returned bottles that had been dispensed to a subject were weighed to determine the amount of the IP used per treatment phase.

6. VISIT SCHEDULE AND ASSESSMENTS

Trial Procedures

The visit schedule and assessments are summarized in Table 1.

Visit	Screening and Visit1(Baseline-Day0/1)	Visit 2 (Follow up-Day 2)
Informed consent	X	
Inclusion/ exclusion criteria	X	
Demographics, medical history	X	
Concomitant medication	X	
Concurrent diagnoses	X	
Physical Exam	X	
Vital signs	X	
Pregnancy test	X	
Subject Self-Assessment		X
Bristol Stool Form Scale	X	
Dispensing IP	X	
AE \ SAE Reporting		
Compliance	X	
Return of all trial Materials		

Table 1: Visit Schedule and Assessments

6.1 Trial Visits and Assessments

Visit 1/Baseline (Day 0):

Screening procedures should be completed no more than 1 days prior to Visit 1/ (Day 0).Visit 1/Screening and Visit 1/Baseline can occur on the same day if no washout of prohibited medications is required. The following screening procedures will be performed at the screening visit:

- Review trial information with subject and obtain written informed consent.
- Review inclusion and exclusion criteria with the subject to determine the subject's eligibility.
- Collect medical history;
    - other allergic history if the subject received concomitant medication for this condition
    - If subject participated in skin related study within last two months
- Review and record any current medical diagnoses.
- Perform the following assessments:
    - Bristol Stool Form Assessment
- Perform a urine pregnancy test (UPT) in female subjects of childbearing potential and instruct these female subjects to use approved form(s) of contraception.
- If the Visit 1Screening or Visit 1/Baseline (Day 0) procedures are being performed on the same day, perform the procedures specified in Table 1:

Visit 2/Day2

Take Vital signs (Body temperature systolic and diastolic blood pressure and heart rate and pulse rate).

Perform the following assessments:

- Subject Self-Assessment

Early Termination

If a subject withdraws from the trial prior to the Visit 2 (End of Treatment) visit, the subject is to return to the site for assessment of any post exposure AE.

Unscheduled Visit and Telephone Calls

An unscheduled visit may be performed at any time during the trial if judged necessary by the Investigator, such as for a severe reaction and clinically significant AE. Details of the event must be recorded in the subject's records.

Investigator Assessments

The investigator assessments are to be performed by a dermatologist, a dermatologist with at least 1 year of experience in dermatology. For dermatologist and dermatologist Assistants who do not fulfill the requirement regarding dermatologist experience and other state licensed professionals who have the ability to diagnose, treat and prescribe medications, the person must be preapproved by the sponsor. The assessments are to be performed as specified in the visit schedule (Table 1).

Assessment of Safety Adverse Events

Adverse Events Assessments

The investigator or designee was responsible for obtaining, assessing, and documenting all AEs during the study. Adverse Events information were collected from the time of the signature of the informed consent form until the end of the study. An AE is an untoward medical occurrence in any subject during the trial which does not necessarily have a causal relationship with the trial drug treatment.

All were will be documented in the CRF, including a description of each AE, AE relationship to trial product administration, start and stop dates, seriousness, severity, action taken and outcome.

Any AE that meets the serious criteria must be reported on the CRF and on a separate SAEs report form. SAEs must be reported to the Ethics Committee within 24 hours of awareness.

Throughout the trial, the occurrence of AEs should be sought by nondirective questioning of the subject at each visit during the trial. Information on AEs can also be obtained from signs and symptoms detected during examination, observations made by the trial site personnel, or spontaneous reports from subjects. Pre-existing conditions that worsen during the trial should also be recorded as AEs.

AEs requiring therapy must be treated with recognized standards of medical care to protect the health and well-being of the subject. Treatment due to an AE will be recorded in the subject's records and on the appropriate CRF.

Any AE that is considered related to the trial product must be followed by the investigator until it is resolved or until the medical condition of the subject is stable; all relevant follow-up information will be reported to the Sponsor/CRO or designee.

The outcome of an AE was classified as recovered, recovered with squeal, recovering/resolving, ongoing, or death.

No AE were observed in the study in either of the arms.

Timing

AEs were collected/assessed from the time of the signature of the informed consent form by the subject and first trial-related activity performed.

Severity of Adverse Events

The investigator is to classify the severity (intensity) of an AE according to the following definitions:

- Mild – The subject was aware of the signs and symptoms but the signs and symptoms were easily tolerated and does not interfere with daily activity.
- Moderate – The signs and symptoms were sufficient to restrict, but did not prevent, usual daily activity for the subject. The subject is still able to function.
- Severe – The subject was unable to perform usual daily activity.

The maximum intensity of an AE (mild, moderate, or severe) will be assessed taking into account the possible range of intensity of the symptom(s).

Relationship of an Adverse Event to Trial Treatment

The investigator is responsible to assess the relationship of an AE to the IP using good clinical judgment and the following definitions:

Not Related	The AE is clearly explained by another cause not related to the trial product administration; the temporal relationship of the AE to IP administration makes a causal relationship unlikely, or, concomitant medication, therapeutics interventions, or underlying condition providea sufficient explanation for the observed AE
Possibly Related	The AE and administration of trial product are temporally related, but the AE can be explained equally well by causes other than the trial product administration
Probably Related	The AE and use of trial product are temporally related, and the AE is more likely explained by trial product administration than by other causes
Definitely Related	The AE and trial product administration are related in time, and a direct association can be demonstrated. Concomitant medication, therapeutics interventions, or underlying conditions do not provide a sufficient explanation for the observed AE

Unexpected Adverse Events

Any AE assessed as related to the IP will be assessed for expectedness by the sponsor or designee. An AE is considered ―unexpected‖ if its nature or severity is not consistent with information in the Investigator's Brochure.

―Unexpected as used in this definition, also refers to AEs that are mentioned in the Investigator's Brochure or product prescribing information as occurring with a class of drugs or as anticipated from the pharmacological properties of the drug, but are not specifically mentioned as occurring with the particular drug under investigation.

Trial Medication Overdose

An overdose of the IP, i.e., a dose that is higher than the highest dose under clinical investigation or the known therapeutic dose, will be fully documented even if no

toxic effects were observed and will be considered as an AE.

Serious Adverse Event

An SAE is any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect, or is an important medical event?
- Other serious or important medical event

The death of a subject enrolled in a trial is per se not an event, but an outcome. Any event resulting in a fatal outcome must be fully documented and reported, regardless of the causality relationship to the IP.

Any medical important events that may not result in death, be life-threatening, or require hospitalization may be considered an SAE when, based on appropriate medical judgment, jeopardize the subject, or the subject may require medical or surgical intervention to prevent one of the outcomes listed in the above definitions.

Any pre-planned hospitalizations that are known at the time of signing the ICF will not be recorded as SAEs, however they will be recorded as AEs only.

Any SAE, whether or not deemed drug-related or expected, must be reported immediately to the Sponsor or designee as soon as it becomes known to the investigator and not later than within 24 hours of his/her knowledge of the occurrence of an SAE). The investigator will document such events in the best possible detail on the SAE Report Form.

A suspected unexpected serious adverse reaction (SUSAR) is an SAE that is both unexpected (not consistent with the current Investigator's Brochure) and for which there is evidence to suggest a causal relationship between the drug and the SAE. The Institutional Ethics Committee (IEC) will be informed of SUSARS according to local requirements. All investigators participating in the trial will also be notified of unexpected SAEs. The sponsor or designee will report SAEs and other events requiring expedited reporting to regulatory authorities as required.

Investigator instructions for reporting SAEs.

Vital Signs

At all the visits, the investigator or designee will take measurements of vital signs, including blood pressure and heart rate (pulse) with the subject in the sitting position with approximately5 minutes rest prior to measurement. The same arm is to be used for all measurements.

Physical Examination

At Visit 1/Baseline the investigator or designee will complete a general physical examination including measurements of height (at screening only) and weight (with indoor clothing and without shoes) and on visit 2, the investigator also takes all the vitals and examine any delayed erythema response on the site.

During the trial, any new clinically significant findings of signs/symptoms that could indicate systemic safety will be reported as AEs.

Appropriateness of Measurements

The assessments to be used in this trial are the standardized and most widely accepted methods for acne testing as per guidelines.

7. Statistical Methods and Analytical Plans

Prior to the analysis of the final study data, a detailed Statistical Analysis Plan (SAP) was written describing all analyses that will be performed. Data was analyzed using a combination of NCSS & R software version 2.15.0 (R Development core team, R Foundation for statistical computing, Vienna, Austria) with appropriate statistical test. The SAP may contain any modifications to the analysis plan described below.

7.1. Data Sets Analyzed

All eligible patients who are included into the study and receive single dose on same day of the study

7.2. Demographic and Baseline Characteristics

The following demographic variables at screening were summarized by dose level: race, gender, age, height and weight.

7.3. Analysis of Endpoints

All data will be expressed as percentage of subjects with improvement in the condition, with no statistical Safety and tolerability data was summarized by treatment group.

Adverse event rates were coded by body system and MedDra classification term. Adverse events were tabulated by treatment group and include the number of patients for whom the event occurred, the rate of occurrence, and the severity and relationship to study drug.

7.4. Sample Size

Sample size for this protocol is 60. The eligible patients will be assigned to study drug randomly and there is no need of randomization in it.

8. CHANGES IN THE PLANNED TRIAL

8.1. Protocol Amendments

Except for administrative changes, any changes or additions to this clinical trial protocol require a written protocol amendment that must be approved by the IEC before implementation.

These requirements for approval should in no way prevent any immediate action from being taken by the investigator or SPONSOR/CRO in the interests of preserving the safety of all subjects included in the trial. If an immediate change to the protocol is felt to be necessary by the investigator and is implemented for safety reasons, SPONSOR/CRO or designee should be notified and the IEC should be informed according to their reporting requirements.

8.2. Termination or Suspension of the Trial

SPONSOR/CRO reserves the right to terminate or suspend the trial at any time. In case of premature termination or suspension of the trial, the contract research organization (CRO) project manager has to promptly inform the investigators, regulatory authorities, and s about the premature termination or suspension, including the reason for it. In terminating the trial, SPONSOR/CRO and the investigator should ensure that adequate consideration is given to the protection of the subjects' interests.

9. DATA HANDLING AND RECORD KEEPING

9.1. Recording of Data

9.1.1. Source Documents

Source data are all the information in original records and copies of original records of clinical findings, observations, or other activities in the trial, which are necessary for the reconstruction and evaluation of the trial. The identification of any data to be recorded directly on the CRFs is to be considered source data.

Trial data collection procedures must ensure that each data element can be traced with a high level of confidence from its originator or recorder to its representation in the trial database and then to its place in the analysis and report of trial results. Once recorded, the trial data must be protected from unauthorized modification or deletion, and all authorized modifications and deletions must be securely linked in the permanent record with their author, time of change, and reason for change (i.e., the audit trail must be maintained).

The investigator should permit trial-related monitoring, audit(s), IEC review(s) and regulatory inspection(s), with direct access to all the required source records.

The principal investigator should certify the data to be accurate and complete and release the data for transmittal to SPONSOR/CRO or designee.

Source records need to be preserved for the maximum period of time permitted by local requirements. For each subject enrolled, the investigator will indicate in the source record(s) that the subject participated in the trial.

9.1.2. Case Report Forms

The primary data collection tool for the trial is a CRF designed specifically for the trial. For each subject enrolled in the trial, a CRF was completed by the trial coordinator and signed by the investigator or his/her designate.

The investigator was responsible for ensuring the accuracy of all data entered in the CRFs. All CRFs are to be completed in a timely manner.

Errors occurring in the CRFs were queried. Queries raised by data reviewers must be addressed by site personnel.

On request, the investigator should provide the SPONSOR/CRO with additional data relating to the trial, or copies of relevant source records, duly anonymized (i.e., subject's name is redacted).

9.2. Retention of Documents

The investigator should take responsibility for maintaining adequate and accurate source documents of all observations and data generated during this trial, including any data clarification forms received from the SPONSOR/CRO or designee. Such documentation is subject to inspection by the sponsor or its agents, the FDA and/or other regulatory agencies. The investigator is responsible for retention of essential documents including the Investigator Trial File until SPONSOR/CRO informs the investigator that the documents are no longer to be retained or longer if required by local regulations.

10. QUALITY CONTROL AND QUALITY ASSURANCE

10.1. Direct Access to Source Documents

As specified in the investigator's agreement, the investigator agrees to allow trial-related monitoring, audit(s), IEC review(s) and regulatory inspection(s), with direct access to all the required source records, and to allocate his/her time and the time of his/her staff to the auditor/inspector to discuss findings and any issues.

10.2. Monitoring Procedures

The Clinical Trial Monitor will contact and/or visit the investigator site periodically to verify the adherence to the protocol, the maintenance of trial-related source records, and the completeness and accuracy of all CRF entries compared to source data. The investigator will cooperate with the trial monitor to ensure that any discrepancies that may be identified are resolved.

10.3. Audit and Inspection

The investigator has made all the trial-related source data and records available to a quality assurance auditor mandated by the sponsor, or to domestic or foreign regulatory inspectors, after reasonable notice. The main purposes of an audit or inspection are to confirm that the rights and well-being of the subjects have been adequately protected, and that all data relevant for the evaluation of the IP have

been processed and reported in compliance with GCP/ICH and applicable regulatory requirements.

The investigator has to notify the SPONSOR/CRO or designee immediately of any inspection by regulatory authorities.

11. ETHICS

11.1. Ethical Conduct of the Trial

This trial must be carried out in compliance with the protocol and the applicable laws and regulatory requirements of the appropriate regulatory agency. The trial must be conducted in accordance with the ethical principles originating from the Declaration of Helsinki and amendments and the ICH-GCP guidelines.

11.2. Institutional Ethics Committee (IEC)

This protocol, the proposed informed consent form, and other information for subjects must be reviewed and approved by an IEC, before the start of the trial, in compliance with local regulations. This committee must also approve any amendments to the protocol, other than administrative ones, before initiation of the amendment procedures. This protocol was approved dated 24 December 2024 by ARMHRC Institutional Ethics Committee.

11.3. Subject Information and Consent

Before participation in the trial, each subject or guardian is required to provide written consent to participate in the trial. No trial-specific procedures should be performed before a subject’s informed consent is obtained.

11.4. Disclosure and Confidentiality

11.4.1. Confidentiality of Trial Documentation

By signing the protocol, the investigator agrees to keep all information provided by the sponsor in strict confidence and to request similar confidentiality from his/her staff and the or IEC. Trial documents provided by the trial sponsor (i.e., protocols, Investigators' Brochures, CRFs and other material) should be stored appropriately to ensure their confidentiality. The information provided by the sponsor to the investigator may not be disclosed to others without direct written authorization from the sponsor, except to the extent necessary to obtain informed consent from subjects who wish to participate in the trial.

11.4.2. Privacy of Individual Health Information

The investigator should undertake to protect the privacy of all individually identifiable health information except as specifically authorized by each individual subject through the written informed consent. The Informed Consent document should include a request of the subject's consent to release the collected data for research purposes in such a way that the individual's identity remains masked. While all data records should be identified by the corresponding subject number, the identity of the subject will be held in confidential source documents at the trial site. All trial personnel with access to this information are legally bound not to disclose such information.

11.5. Reporting of Serious Adverse Events and Pregnancies

11.5.1. Contact Person(s) and Number(s)

SAEs and pregnancies must be reported immediately (i.e., not later than 24 hours after first knowledge). The SAE or pregnancy report should be e-mailed or texted to IEC and Sponsor using the following phone number:

Name: Markandey Tiwari

Phone: +91 81270 80666

11.5.2. Reporting Procedures

Serious Adverse Events

For each SAE, the investigator should complete a Serious Adverse Event Report Form and assess the relationship of each SAE to trial treatment. The completed form(s) should be sent electronically to the UBC using the SAE Reporting fax number within 24 hours of first knowledge of the SAE.

Follow-up reports regarding the status of the SAE and the subject's subsequent course should be submitted until the SAE has subsided, the condition stabilized (in the case of persistent impairment), the subject receives alternative therapy, or the subject dies. The form and fax confirmation should be retained. Contacts for reporting SAEs, pregnancies and other safety concerns are provided to each site.

12. INSURANCE

SPONSOR/CRO has taken out appropriate insurance policies covering the subjects in the clinical trial in accordance with applicable laws and regulations.

13. PUBLICATION POLICY

The clinical trial information should be posted on www.ctri.nic.in or www.clinical trial.gov and in accordance with applicable regulations.

All publications (e.g., manuscripts, abstracts, oral/slide presentations, book chapters) based on this trial must be submitted to SPONSOR/CRO for review, as specified in the Clinical Trial Agreement between the institution, investigator, and SPONSOR/CRO or its designee.

14. Results

14.1. Subject disposition:

Out of 60 subjects screened, None were found dropout, no screen failure. 60 subjects who underwent the full trial period.

S. No	Variable	Number of subjects
1.	No. of subjects screened for study	60
2.	No. of subject's screen failure	0
3.	No. of subjects enrolled in the study	60
4.	Number of subjects completed the Study	60
5.	Dropout	60

Table 2: Patient disposition details

S. No	Schedule	Dates
1.	First subject ICF date	19 April 2025
2.	Last subject ICF date	22 May 2025
3.	First subject screening date	19 April 2025
4.	Last subject screening start date	22 May 2025
5.	Date of first subject completed study	20 April 2025
6.	Date of Last subject completed study	23 May 2025

Table 3: Study dates/schedules:

Subjects disposition chart

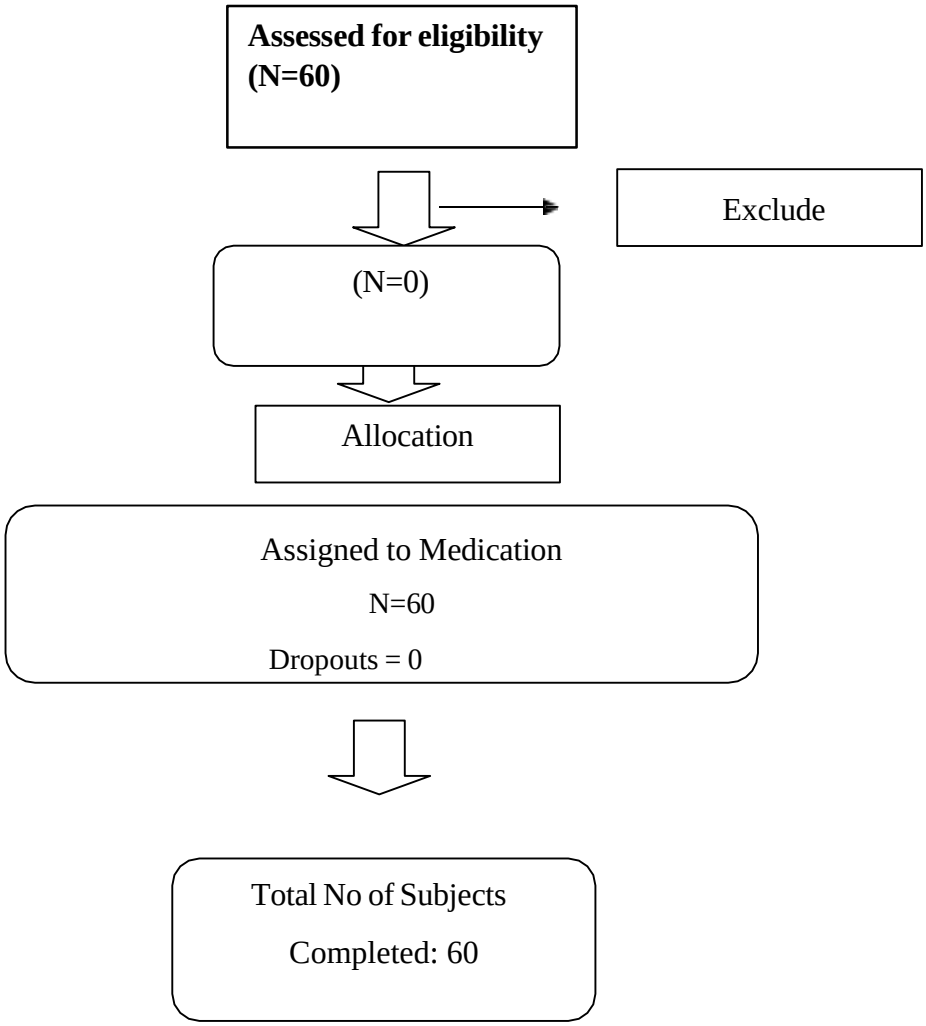
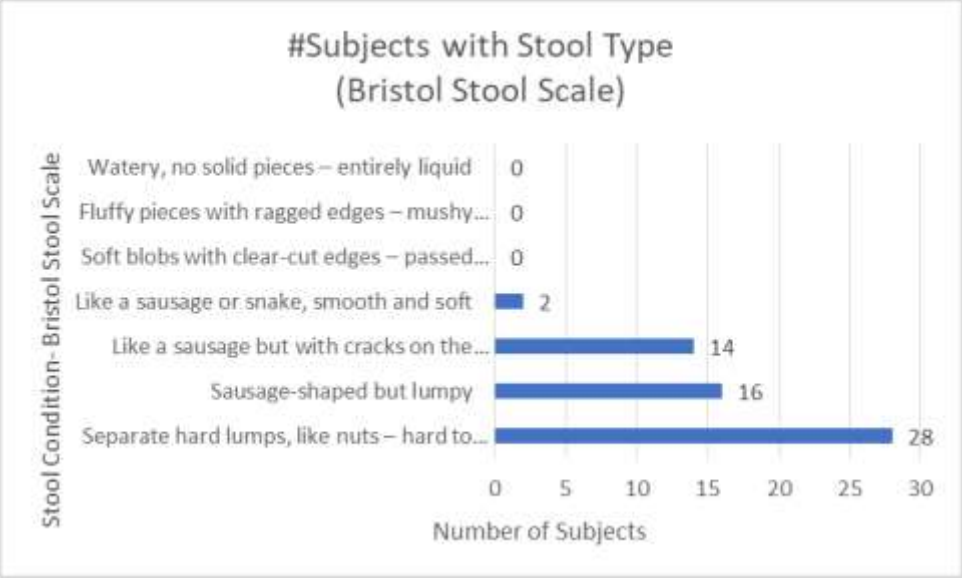


Figure 1: Subject disposition chart details

14.2. Demographic and Other Baseline Characteristics

The mean age of the subjects was 37.3 years in the study. The mean height of the subjects was 158.63 cm. The mean weight of the subjects was 60.42 kg. The BMI of the subjects were 24.09. A total of 40 female, and 20 male subjects were enrolled in the study.

A special assessment was done in the first visit for the Bristol stool scale to identify and group as per the type of stool.



47% of the study subjects had stool like Separate hard lumps, like nuts – hard to pass, 27% had sausage shape stool, 23% had stool which was Like a sausage but with cracks on the surface, and rest 3% had smooth textured stool.

14.3. Efficacy Evaluations

Data sets Analyzed. Data from 60 patients who completed the study were analyzed.

Treatments	Test Product(s)
Total screened	60
Enrolled	60
No. of patients completed	60

Table 4: Data sets analyzed

Efficacy Results and Tabulations of Individual Patient Data

14.3.1. Change in Subject's Global Assessment (Questionnaire):

The assessment involved a set of questions asked to each study subject. Each question had a Boolean response of Yes, and No, and the results are represented as percentage of users observing the change.

Below were the data points and results.

	Questionnaire	%users
Subject's Self-Assessment	**Do you agree that this syrup helps relieve constipation?**	92%
	Do you agree that it increases the frequency of your bowel movements?	82%
	Have you noticed an improvement in abdominal pain?	92%
	Do you agree that your stool loosens after taking the syrup?	87%
	Do you agree that this syrup does not taste bad?	55%
	Do you agree that this syrup works quickly?	92%
	Do you agree that this syrup does not cause any sensitivity?	85%

- 92% of the users observed that the syrup helps relieving the constipation.
- 82% users agree that it increases the frequency of their bowel movements.
- 92% users noticed an improvement in the abdominal pain.
- 87% users felt their stool to loosen after taking the syrup.
- 55% users liked the taste of the test product.
- 92% users felt that it works quickly
- 85% users observed no sensitivity post taking the test product.

14.3.10 Adverse events and other safety assessments:

The adverse events reported was none during the treatment. No such issue reported.

S. No.	AE	Test (N=60)
1	No. of AEs	0
2	SAE	0

Table 6: Adverse Events list

As per the protocol the r esults are represented as % of Panel found No-side effects; i.e, 100% of subjects found No-side effects.

14.3.12. Other concomitant medications:

All standard treatments were given to the subjects as deemed necessary by the Investigator. Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

15. Discussion:

Out of 60 subjects screened, none were found dropout, no screen failure. 60 subjects who underwent the full trial period.

The mean age of the subjects was 37.3 years in the study. The mean height of the subjects was 158.63 cm. The mean weight of the subjects was 60.42 kg. The BMI of the subjects were 24.09. A total of 40 female, and 20 male subjects were enrolled in the study. Data from 60 patients who completed the study were analyzed.

A special assessment was done in the first visit for the Bristol stool scale to identify and group as per the type of stool. 47% of the study subjects had stool like Separate hard lumps, like nuts – hard to pass, 27% had sausage shape stool, 23% had stool which was Like a sausage but with cracks on the surface, and rest 3% had smooth textured stool.

The assessment for efficacy involved a set of questions asked to each study subject. Each question had a Boolean response of Yes, and No, and the results are represented as percentage of users observing the change. 92% of the users observed that the syrup helps relieving the constipation. 82% users agree that it increases the frequency of their bowel movements. 92% users noticed an improvement in the abdominal pain. 87% users felt their stool to loosen after taking the syrup. 55% users liked the taste of the test product. 92% users felt that it works quickly. 85% users observed no sensitivity post taking the test product.

No adverse event was reported during the study.

Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

There were no protocol violations and deviations reported. There were no patients who lost to follow up.

None of the patients withdrawn the consent.

16. Conclusion:

In conclusion, Shuddhi XS Syrup showed laxative properties, making stool smooth and more frequent along with reduction in the constipation related pain.. No, adverse events were observed during the study.

17. Reference List

1. Pediatric and Adolescent Sexuality and Gynecology: Principles for the Primary Care Clinician. Hatim A. Omar, Donald E. Greydanus, Artemis K. Tsitsika, Dilip R. Patel, & Joav Merrick, (Eds.).
p. 317-411

Clinical Study Report

Title Page

Study Title: "A Retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation"

Protocol No.	MGCTSR6
Version Number and Date	Version 1.0 dated 02 June 2025
Investigational Product	Petshuddhi Churna
Name & Address of Sponsor	Jeena Sikho Lifecare Limited, Panchkula, India
Name & Affiliation of the Investigator(s)	Dr. Monu Pathak Hospital & Institute of Integrated Medical Sciences, Meerut
No. of patients/records	100
Report Number	MGCTS/CT/R6
Date of the draft report	13 June 2025

Confidential

The information in this document is confidential and is to be used only in connection with matters authorized by Jeena Sikho Lifecare Limited and Mittal Global Clinical Trial Services and no part of it is to be disclosed to the others without prior written permission from the either organization. This study was performed in accordance with NDCT Rules 2019, ICHGCP E6 (R2), Schedule-Y (2017) and Ethical Principles as per the Declaration of Helsinki (2013) including archiving of all the essential documents

INVESTIGATOR(S) SIGNATURE(S)

Study Title:

A Retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Dr. Monu Pathak Principal Investigator Hospital & Institute of Integrated Medical Sciences, Meerut	*Monu Pathak* **13 June 2025** **SIGNATURE & DATE**

STATEMENT OF COMPLAINCE

A Clinical study titled: "A Retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation".

This study was conducted in compliance with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

Name	**Designation & Address**	**Signature**	**Date** **(DD MMM YYYY)**
PUNEET MITTAL	Director- Clinical Research, MGCTS, Mittal Building 121-B, Mansarovar Ind Estate, Panchli, Baghpat Road, Meerut-250002, India		13 June 2025

STATEMENT OF COMPLAINCE
(DATA SAFETY MONITORING BOARD)

A Clinical study titled: "A Retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation"

This study was verified and reviewed independently according with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

S. No	Name and Designation	Signature	Date (DD MMM YYYY)
2	**Ms. Nidhi Dixit** **Study Director,** **MGCTS- Meerut**		12 June 2025
3	**Sheetal** **Data Management Associate** **MGCTS- Meerut**		12 June 2025

1. REPORT SUMMARY:

Title of the Study	A Retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation
Investigational Product	Petshuddhi Churna
Name of Sponsor	Jeena Sikho Lifecare Limited
Investigator (s)	**Dr. Monu Pathak** Principal Investigator Hospital & Institute of Integrated Medical Sciences, Meerut
Study Objective	**Primary objective:** • The primary objective was to evaluate the efficacy of Petshuddhi Churna for patients with Constipation.
Study Phase	NA
Study Design	This trial was a retrospective study to assess the efficacy of Petshuddhi Churna when administered for up to 30 days to adults with Constipation. The Investigator's consent was taken prior to accessing the patient case files who was on the treatment of Petshuddhi Churna for 30 days in the past 3 months. The case records with the data for Abdominal Discomfort, Stool Consistency and Complete Bowel movement were only considered. Patient case records must have data from day 1(Visit 1), and day 30 (visit 2) to be considered for analysis in this study.
Number of subjects	100

Study Inclusion Criteria	Subject records were included based on the following criteria. 1. Subjects of either sex 2. Age 18 - 65 years (both inclusive) 3. Chronic Constipation Subjects 4. Subject record has Abdominal Discomfort data for baseline and day 30 5. Subject record has Stool consistency and total defecation for baseline and day 30
Study Exclusion Criteria	Subject records were excluded based on the following criteria. 1. Were pregnant or breast-feeding. 2. Patients requiring the use of antibiotics either in medicine form of natural (e.g. grapefruit seed extract, olive leaf extract, oil of oregano, colloidal silver and highly concentrated garlic preparations) 3. Patients requiring treatments with non-permitted medication (i.e. 5- HT3 antagonist, spasmolytics, anticholinergics, cholestyramine, anti- flatulence agents, metoclopramide, gastric-anti secretory agents (proton pump inhibitors; for indications other than Gastroesophageal Reflux Disease (GERD)), narcotics, anti-diarrheal drugs, and systemic steroids) 4. Patient had a potential central nervous system cause of constipation (e.g., Parkinson's disease, spinal cord injury, and multiple sclerosis). 5. Patient had untreated hypothyroidism or treated hypothyroidism for which the dose of thyroid hormone had not been stable for at least 6 weeks at the time of the Screening. 6. Have used immunosuppressive or immunomodulatory medication (i.e., biologics), including oral orparenteral corticosteroids.
Test Product, Dose	**Test Product:** Petshuddhi Churna, 1 tsp daily during bedtime **Route of Administration:** Oral

Study Methodology	The Investigator's consent was taken prior to accessing the patient case files who was on the treatment of Petshuddhi Churna for 30 days in the past 3 months. The case records with the data for Abdominal Discomfort, Stool Consistency and Complete Bowel movement were only considered. Patient case records must have data from day 1(Visit 1), and day 30 (visit 2) to be considered for analysis in this study. The study had the following visits **Visit 1 (Day 1):** Beginning of Study(Dispensing to the Subject) **Visit 2 (Day 30):** End of Study
Primary Outcome	• Effectiveness of Petshuddhi Churna in decreasing constipation Symptoms as Differences in abdominal discomfort, stool consistency and complete defecation.
Secondary Outcome	NA
Statistical Analysis	Prior to the analysis of the final studied data, a detailed statistical analysis planned (sap) had been written describing all analyses that had been performed. Data had been analyzed used NCSS software appropriate statistical test.
Ethical Conduct of the study	The study was initiated after written approval from the hospital's Institutional Ethics Committee. The trial was conducted as per NDCT Rule 2019, ICH GCP E6 R2 Guidelines, Schedule Y (2017), Declaration of Helsinki (Brazil, 2013) and in accordance with other applicable guidelines.
Efficacy Results	Age of the cases in this study ranged from 20 to 65 years with average age 38.16 years among treatment group. 50% of the cases among the treatment group were male and 50% female. Average BMI of the patients among treatment group was 22.93 Kg/m2. Complete Spontaneous Bowel Movement: 8% of the cases among the treatment group at baseline had complete spontaneous bowel movement. After 30 days of treatment 84% of the cases among treatment group complete spontaneous bowel movement. This

	indicates that Petshuddhi Churna helps in complete defecation. Average abdominal discomfort score at baseline among the treatment group was 4.92 which was indicative of Medium abdominal discomfort. After 30 days of treatment the abdominal discomfort score among the treatment group was 1.42 showing clinically significant improvement in the abdominal discomfort when compared to the baseline. This indicates that the abdominal discomfort reduces to a good level when used for 30 days regularly. Average stool consistency score at baseline among the treatment group was 1.78 which was indicative of stool consistency like a sausage with cracks. After 30 days of treatment the mean stool consistency score among the treatment group was 2.90 which was indicative of stool consistency like a sausage but crumby and smooth on the surface which was significant from the baseline. This indicates that that stool consistency gets better when you use Petshuddhi Churna for 30 days. The test and reference product were well tolerated by the patients. No adverse event was reported during the study. All the vital signs were found normal at baseline and the end visit. Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication. There were no protocol violations and deviations reported. No death, serious or severe adverse events were reported during the conduct of the study.
Conclusion	Petshuddhi Churna was effective in maintaining and treating the constipation symptoms. In conclusion, there was significant change from the baseline till the end of the treatment among most of the efficacy parameters observed. Petshuddhi Churna was effective in maintaining and treating the constipation symptoms, such as Complete spontaneous Bowel Movement, Abdominal Discomfort and Stool Consistency. No adverse events were reported by the patients after using Petshuddhi Churna indicating that it was well tolerated and thus safe to use.
Date of Report	13 June 2025

Table of Contents

2. List of Abbreviations

Abbreviation	Definition
AE	Adverse event
ANOVA	Analysis of variance
AUC	Area under the curve
COA	Certificate of Analysis
CI	Confidence interval
CRO	Contract Research Organization
DCGI	Drug Controller General of India
eCRF	Electronic case report form
ED	Early Discontinuation
END	Endoscopy
EoT	End of Treatment
EoS	End of Study
EMEA	European Medicines Evaluation Agency
gm	Gram
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
FDA	Food and Drug Administration
Hrs.	Hours
ICD	Informed Consent Document
ICH	International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
IEC	Institutional Ethics Committee
IMP	Investigational Medicinal Product
IP	Investigational product
IRB	Institutional Review Board
Kg	Kilograms
Ltd.	Limited

MedDRA	Medical Dictionary for Regulatory Activities
mg/dL	milligram/deciliter
mL	Milliliter
No.	Number
NICE	National Institute for Health and Care Excellence
OTC	Over the counter
QA	Quality Assurance
QOL	Quality of Life
PRO	Patient-reported outcome
SAE	Serious Adverse Event
SAP	Statistical analysis plan
SD	Standard Deviation
SOP	Standard Operating Procedure
SUSAR	Suspected unexpected serious adverse reaction
TC	Telephone call
U	Units
ULN	Upper limit of normal
UPT	Urine Pregnancy Test
USV	Unscheduled Visit
°C	Degree Celsius
°F	Degree Fahrenheit
%	Percent

3. ETHICS

3.1. Independent Ethics Committee (IEC) or Institutional Review Board(IRB)

The study documents [Protocol, CRF, final CTA, CV, MRC and Undertaking of Investigator] were reviewed by the Institutional Ethics Committee for each center, as listed in Appendix.

Site ID	Name of Investigator	Site	Ethics Committee
A	Dr. Monu Pathak	Hospital & Institute of Integrated Medical Sciences, Meerut	ARMHRC institutional Ethics Committee, Meerut- UP

3.2. Ethical Conduct of the Study

The study was conducted as per requirements of ICMR Guidelines for Biomedical Research on Human Subjects, International Conference on Harmonization (Step 5) 'Guidance on Good Clinical Practice', New Drugs and Clinical Trials Rules (2019) of India, Declaration of Helsinki (Fortaleza, Brazil, October 2013) and with procedures oriented to Good Laboratory Practice, EMEA guideline and applicable regulatory guidelines, guideline ethical requirements of directive 2001/20/EC and applicable regulatory guidelines.

3.3. Patient Information and Consent

All patients provided written informed consent to participate in the study prior to being screened. The patient information sheet detailed the procedures involved in the study (aims, methodology, potential risks and anticipated benefits) and the investigator explained these to each patient. The patient signed the consent form to indicate that the information had been explained and understood. The patients were allowed to take ample time to consider the information presented before signing and dating theinformed consent form to indicate that they fully understood the information, and willingly volunteered to participate in the study. The patients were given a copy of thesigned informed consent form for their information. The original informed consent documents were kept in a confidential file in the Investigators site record.

4. Investigators and Study Administrative Structure

Sponsor	Jeena Sikho Lifecare Limited, Panchkula
Principal Investigator (S)	Dr. Monu Pathak Hospital & Institute of Integrated Medical Sciences, Meerut
ETHICS COMMITTEE (S)	ARMHRC Institutional Ethics Committee
SITE(S) ADDRESS	Hospital & Institute of Integrated Medical Sciences, Meerut
REPORT GENERATION	Ms. Nidhi Dixit

5. INTRODUCTION

Constipation is a functional gastrointestinal (GI) disorder characterized by recurrent symptoms of abdominal discomfort, accompanied by slow bowel function and a feeling of bloating, moderate to severe cases of constipation, an overall deterioration in quality of life (QOL) is often present. Gut microbiota plays important role in the maintenance of gut homeostasis by direct bactericidal effect and the evolution of both innate and adaptive immune system. Gut microbiota plays important role in pathogenesis of constipation. This is evident from the fact that constipation occurs more frequently after intestinal infections and antibiotic treatment. Considering the relationship between gut microbiota and inflammation of gut, selective manipulation of gut microbiota by sennosides and other herbs appears to be an ideal treatment modality for constipation.

Petshuddhi Churna is a combination of proven herbs in Ayurveda which includes,

- Cassia angustifolia
- Emblica officinalis
- Terminalia bellerica
- Terminalia chebula
- Operculina turpenthum
- Aegle marmelos
- Cassia fistula
- Trachyspermum ammi
- Zingiber oficinale
- Foeniculum vulgare
- Rosa centifolia
- Syzygium aromaticum
- Black Salt (Kali muriaticum)

The assessment of efficacy was done as retrospective based on the existing case reports obtained from the existing patient base from the test site.

6. STUDY OBJECTIVES

6.1. Primary objective:

- The primary objective was to study the efficacy of Petshuddhi Churnafor patients with Constipation by assessing Symptoms as Differences in abdominal discomfort, stool consistency and complete defecation.

6.2. Secondary Objective:

The secondary objectives were:

- To study the satety of Petshuddhi Churna

7. INVESTIGATIONAL PLAN

7.1. Overall Study Design and Plan-Description

This trial was a retrospective clinical study to assess the efficacy of Petshuddhi Churna when administered for up to 30 days to adults with Constipation

The Investigator's consent was taken prior to accessing the patient case files who was on the treatment of Petshuddhi Churna for 30 days in the past 3 months. The case records with the data for Abdominal Discomfort, Stool Consistency and Complete Bowel movement were only considered. Patient case records must have data from day 1(Visit 1), and day 30 (visit 2) to be considered for analysis in this study.

The study had the following visits

Visit 1 (Day 1): Beginning of Study(Dispensing to the Subject)

Visit 2 (Day 30): End of Study

7.2. Mode of Administration:

Only the case records were considered where each study patient self-administered **Orally** one of test product once daily preferably at the same time every day for 30 days.

Primary endpoint and Secondary endpoint assessment was performed at Visit 2 (Day 30). Being retrospective study, no regular safety check was performed as part of the process.

8. Discussion of Study Design

The primary efficacy endpoint for the study was to measure the overall symptoms relief by assessing differences in abdominal discomfort, stool consistency and complete defecation.

8.1. Selection of Study Population

The patient's records were selected by an Investigator based on inclusion and exclusion criteria.

8.1.1. Inclusion criteria

Subject records were included based on the following criteria.:

1. Subjects of either sex
2. Age 18 - 65 years (both inclusive)
3. Chronic Constipation Subjects
4. Subject record has Abdominal Discomfort data for baseline and day 30
5. Subject record has Stool consistency and total defecation for baseline and day 30

It was investigator's responsibility to ensure that the subjects records are in compliance with the inclusion criteria.

8.1.2. Exclusion criteria

Subject records were excluded based on the following criteria:

1. Were pregnant or breast-feeding.
2. Patients requiring the use of antibiotics either in medicine form of natural (e.g. grapefruit seed extract, olive leaf extract, oil of oregano, colloidal silver and highly concentrated garlic preparations)
3. Patients requiring treatments with non-permitted medication (i.e. 5- HT3 antagonist, spasmolytics, anticholinergics, cholestyramine, anti- flatulence agents, metoclopramide, gastric-anti secretory agents (proton pump inhibitors; for indications other than Gastroesophageal Reflux Disease (GERD)), narcotics, anti-diarrheal drugs, and systemic steroids)
4. Patient had a potential central nervous system cause of constipation (e.g.,

Parkinson's disease, spinal cord injury, and multiple sclerosis).

5. Patient had untreated hypothyroidism or treated hypothyroidism for which the dose of thyroid hormone had not been stable for at least 6 weeks at the time of the Screening.
6. Have used immunosuppressive or immunomodulatory medication (i.e., biologics), including oral or parenteral corticosteroids.

8.2. Treatments

8.2.1. Treatments administered

Test product (T): Petshuddhi Churna

8.2.2. Mode of Administration:

Oral, once daily preferably at the same time(bedtime) every day for 30 days.

8.2.3. Identity of investigational product(s)

Table 1: Identity of Investigational Test Product

Test product	:	Petshuddhi Churna
Manufactured by	:	Jeena Sikho Lifecare Limited, Germany
Lot No.	:	PS01
Manufacturing Date	:	March 2025

8.2.4. Selection of doses in the study

The subject records where the patient took a dosage of one once daily for 30 days were considered.

8.3. Prior and concomitant therapy

8.3.1. Concomitant medications:

Any allowed concomitant medication being taken by the patient was continued on same dose during the study. Administration of any other constipation medications was not permitted after screening till the end of study.

8.3.2. Prohibited Medications

- Treatments like 5-HT3 antagonist, spasmolytics, anticholinergic, cholestyramine, anti-flatulence agents, metoclopramide, gastric-anti secretory agents (proton pump inhibitors; for indications other than Gastro esophageal Reflux Disease (GERD)), narcotics, anti-diarrheal drugs, and systemic steroids)
- Use of immunosuppressive or immunomodulatory medications (i.e., biologics), including oral or parenteral corticosteroids
- All opioids are prohibited unless for occasional rescue medication purposes. In case of uncertainty regarding prohibited medications please contact the medical monitor.

Concomitant medications taken during washout period were documented in the source data.

Note: This list of drugs was not exhaustive. However, any drug which was not mentioned above and having a possible on study drug efficacy and safety, was confirmed with medical monitor or medical expert.

8.3.3. Treatment compliance

Being a retrospective study, only the subject records with all data is considered to maintain the treatment compliance.

9. EFFICACY VARIABLES

9.1. Efficacy Measurements Assessed

9.1.1. Efficacy measurement:

The primary efficacy endpoint for this study was the effectiveness of Petshuddhi Churna in decreasing constipation Symptoms along with the following:

- Differences in Abdominal Discomfort measured on 10 point scale[0-9]
- Change in stool consistency with 5 point scale[1-5]
- Number of patients with complete defecation.

9.1.2. Description of Data Capture

1) Demographic data, body weight and body height.
2) Abdomen Discomfort
3) Completeness Bowel Movement, and Stool Consistency
4) Appropriateness of measurements

The efficacy assessments performed in the study were considered as medical standard and were widely used in comparable studies with the objective to determine the effect of a therapeutic intervention in Constipation.

9.1.3. Primary Efficacy Variable(s)

The primary efficacy endpoint was effectiveness of Petshuddhi Churna in decreasing constipation Symptoms from baseline to day 30.

- Differences in abdominal discomfort over the study period from the baseline to day 30
- Differences in Stool Consistency from the baseline to day 30
- Differences in number of subjects with a feeling of incomplete defecation the study period from the baseline to day 30

9.1.4. Drug Concentration Measurements:

Not applicable

9.2. Data Quality Assurance

The Quality Assurance department of MGCTS conducted site audits to check the compliance of study conduct with the Protocol, SOPs and applicable regulatory requirements.

The clinical raw data generated during the study at site was reviewed by monitor(s) and QA personnel. During the QA audit visit clinical raw data such as source data and other related records were audited retrospectively to assess the adherence of the activities and reported data to the applicable SOPs and the Protocol.

The clinical and biostatistics raw data such as Database extract, NCSS Output and NCSS Summary Report and other related data were audited retrospectively to assess the adherence of the activities and reported data to the applicable SOPs and the Protocol.

The observations noted during the audit of the various phases were compiled and sent to the concerned personnel of the respective departments. The concerns were discussed and followed up until resolution. Upon resolution of all concerns / issues, the Quality Assurance Authentication was issued.

9.3. Statistical Methods Planned in the Protocol and Determination of Sample Size

9.3.1. Statistical and analytical plans

All statistical analysis was done using NCSS V 11.0 or higher.

For continuous variables, the summary statistics was the number of observations, mean, standard deviation, median, minimum and maximum values. Categorical values were summarized using frequencies and percentages.

9.3.2. Primary Efficacy Endpoint:

The primary endpoint was analyzed using an analysis of covariance (ANCOVA) model with change in score from baseline as a response variable, treatment as fixed effects, and baseline score as a covariate.

For the primary efficacy, 95% confidence interval for the difference of means (μT-μR) between the test and Placebo products was constructed for PP population.

9.3.3. Determination of sample size

P0P1	Alpha	Beta	Cut-Off R + 1	N	Actual Alpha	Actual Beta	
0.035	0.200	0.010	0.050	6	100	0.008	0.048

References

A'Hern, R. P. A. 2001. 'Sample size tables for exact single-stage phase II designs.' Statistics in Medicine,
Volume 20, pages 859-866.

Fleming, T. R. 1982. 'One-sample multiple testing procedure for Phase II clinical trials.' Biometrics, Volume

38, pages 143-151.

Report Definitions

P0 is the maximum response proportion of a poor drug.

P1 is the minimum response proportion of a good drug.

N is the sample size.

If the number of responses ≥ R+1, P0 is rejected.

If the number of responses ≤ R, P1 is rejected.

Alpha is the probability of rejecting that P ≤ P0 when this is true.

Beta is the probability of rejecting that P ≥ P1 when this is true.

Summary Statements

A study requires 100 subjects to decide whether the proportion responding, P, is less than or equal to 0.035 or greater than or equal to 0.200. If the number of responses is 6 or more, the hypothesis that P ≤ 0.035 is rejected with a target error rate of 0.010 and an actual error rate of 0.008. If the number of responses is 5 or less, the hypothesis that P ≥ 0.200 is rejected with a target error rate of 0.050 and an actual error rate of 0.048.

Dropout-Inflated Sample Size

Dropout Rate	Sample Size N	Dropout-Inflated Enrollment Sample Size N'	Expected Number of Dropouts D
00%	100	100	00

Definitions

Dropout Rate (DR) is the percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e. will be treated as "missing").

N is the evaluable sample size at which power is computed. If N subjects are evaluated out of the N' subjects that are enrolled in the study, the design will achieve the stated power.

N' is the total number of subjects that should be enrolled in the study in order to end up with N

Evaluable subjects, based on the assumed dropout rate. After solving for N, N' is calculated by inflating N using the formula N' = N / (1 - DR), with N' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C.,

Shao, J., and Wang, H. (2008) pages 39-40.)

D is the expected number of dropouts. D = N' - N.

Power (Probability of Rejecting $P \leq P0$ when $P \geq P1$): 0.95

Alpha (Probability of Rejecting $P \leq P0$ when $P \leq P0$): 0.01

P0 (Maximum Response Rate of a Poor Treatment): 0.035

P1 (Minimum Response Rate of a Good Treatment): 0.2

9.4. Changes in the Conduct of Study or Planned Analyses

The study was conducted as per IEC approved protocol, errata 01 of protocol and all the related study plans. There was no change in the design and conduct of the study.

10. STUDY PATIENTS

10.1. Disposition of Patients

Out of the 115 patient records that were screened, 100 were selected as per the inclusion & exclusion criteria with complete data to analyze. The PP population included all the completers with no major protocol violations that would affect the treatment evaluation (Test product N=100).

Table 1: List of Patients Disposition

Parameters	**No. of cases**
Total no. of patients records identified	115
Total no. of patients dropped out due to non-compliance	15
No. of patients included	100
No. of patients in Treatment group	100

10.2. Protocol Deviations

No protocol deviations were reported during the study conduct.

11. EFFICACY EVALUATION

11.1. Data Sets Analyzed

All included patients (N=100) who have received all 30 days dosage of study drug were considered for the efficacy assessment. The PP population (N=100) that was used for the main analysis of the primary endpoint with no major deviations that would affect the treatment evaluation.

11.2. Demographic and Other Baseline Characteristics

A total of 100 patient records were considered into the study. Weight, BMI, height and age of each patient were recorded during screening.

Table2: Demographic profile

Parameters	**Treatment Group (N = 100)**
@Age (Yrs.)	
Mean	38.16
SD	11.77
Range	20 – 65
#Gender (%)	
Male	50 (50.0)
Female	50 (50.0)
@Height (CM)	
Mean	162.61
SD	11.47
Range	121.92 – 179.83
@Weight (Kg)	
Mean	60.39

SD Range	9.01 33.5 – 5.00
@BMI Mean SD Range	 22.93 3.599 17.91 – 41.04

Above data shows that age of the cases in this study ranged from 20 to 65 years. Among the cases in the treatment group, the average age was 38.16 years.

50% of the cases among the treatment group were males and 50% of the cases among the treatment group were females.

Average height of the patients among treatment group was 162.61cm. Average weight of the patients among treatment group was 60.39 Kg.

Mean BMI of the patients among treatment group was 22.93 Kg/m^2.

Note: The PP population included all patients who met all inclusion/exclusion criteria and did not have any major protocol violation that was affect the treatment evaluation.

12. EFFICACY RESULTS AND TABULATIONS OF PATIENT DATA

12.1. KEY EFFICACY ASSESSMENTS

Table 3: Changes in Complete Spontaneous Bowel Movement (Complete Defecation)

Visit	**Treatment Group (N = 100)**	
	Yes (%)	**No (%)**
Baseline (Visit 1)	8 (8)	92 (92)
Visit 2	84 (84)	16 (16)
P values (Baseline vs. Visit 2)	<0.001	

By Chi-square test, p <0.05 Significant

8% of the cases among the treatment group at baseline had complete spontaneous

bowel movement. After 30 days of treatment 84% of the cases among treatment group complete spontaneous bowel movement.

Clinically significant improvement was observed among the test cases.

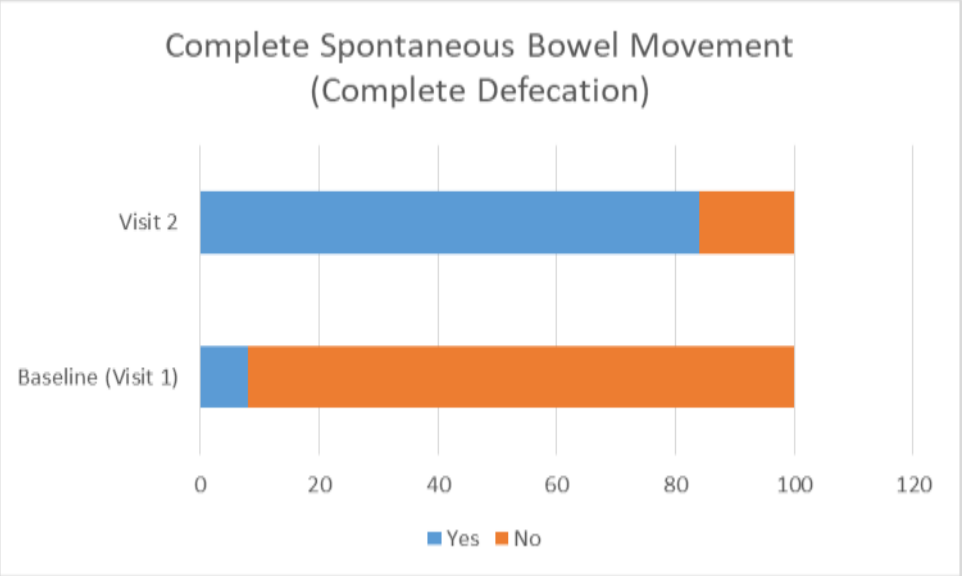


Figure 1: Changes in Complete Spontaneous Bowel Movement

Table5: Mean Change in Patient Assessment of Abdominal Discomfort

Visit	**Treatment Group (N = 100)**
Baseline (Visit 1)	4.92
Visit 2	1.42
P values (Baseline vs. Visit 2)	<0.001

By t test, p <0.05 Significant

As per this data average abdominal discomfort score at baseline among the treatment group was 4.92 which was indicative of Medium abdominal discomfort. After 30 days of treatment the abdominal discomfort score among the treatment group was 1.42 showing clinically significant improvement in the abdominal discomfort when compared to the baseline.

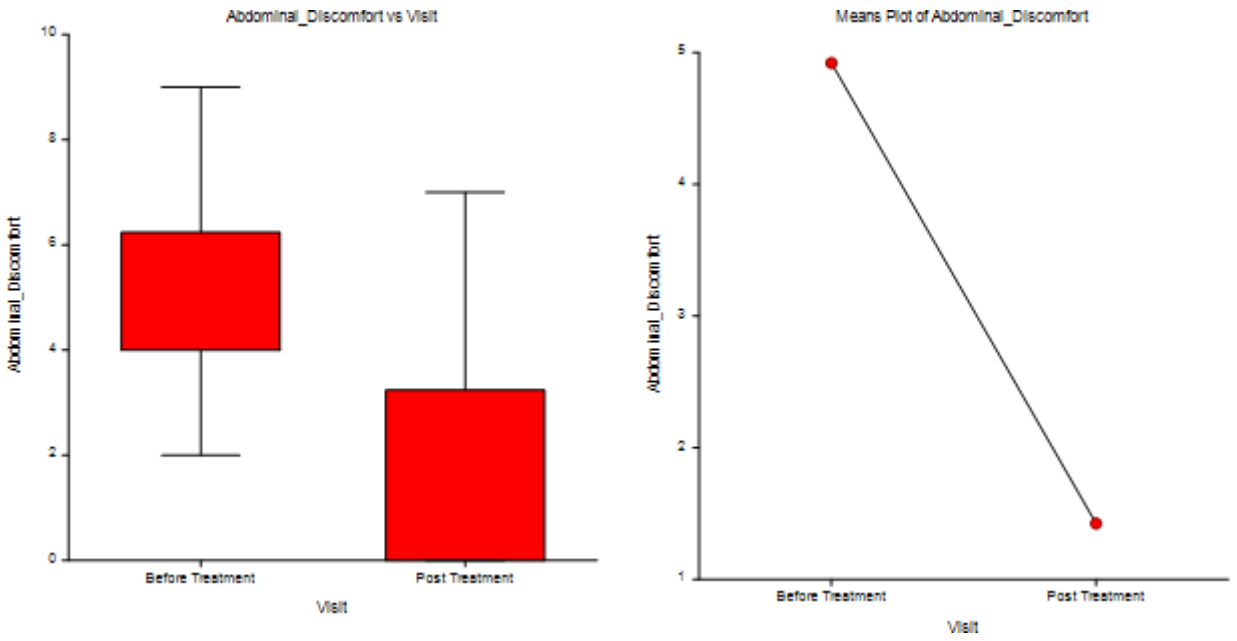


Figure 3: Mean Change in Patient Assessment of Abdominal Discomfort

Table6: Mean Change in Stool Consistency score

Visit	**Treatment Group (N = 100)**
Baseline (Visit 1)	1.78
Visit 2	2.90
P values (Baseline vs. Visit 2)	<0.001

By t test, p <0.05 Significant

The study shows that average stool consistency score at baseline among the treatment group was 1.78 which was indicative of stool consistency like a sausage with cracks. After 30 days of treatment the mean stool consistency score among the treatment group was 2.90 which was indicative of stool consistency like a sausage but crumby and smoother on the surface which was significant from the baseline.

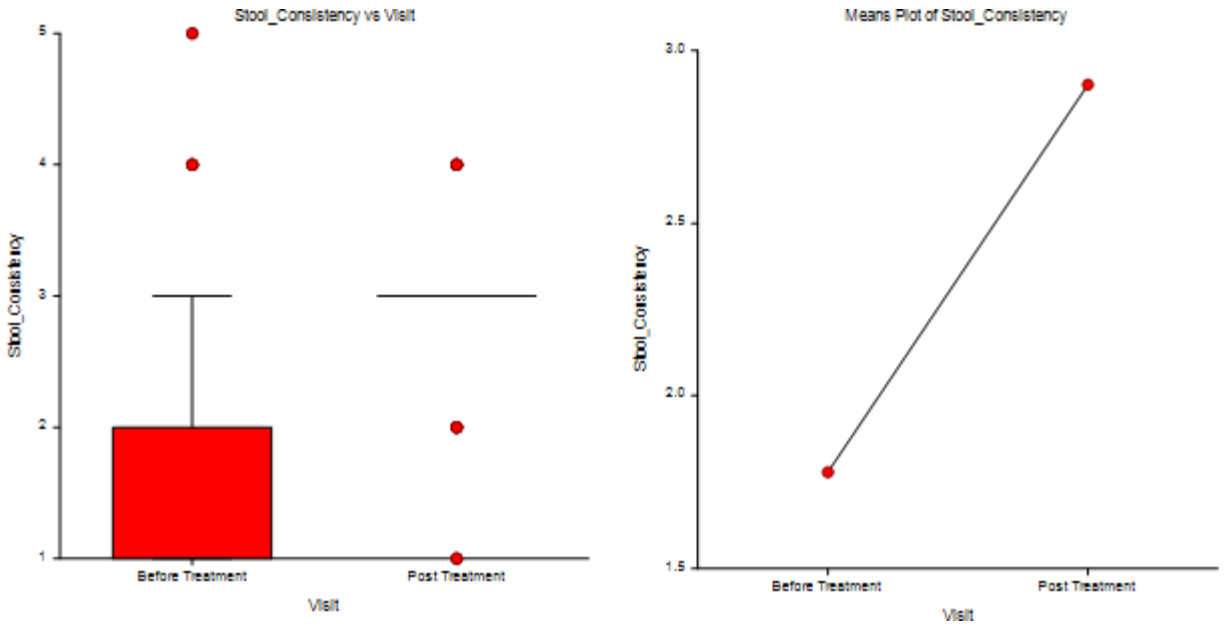


Figure 4: Mean Change in Stool consistency score

13. SAFETY EVALUATION

13.1. Extent of Exposure

In this study, a total of 100 patients were under treatment with Petshuddhi Churna, 1 tsp daily at bedtime, for 30 days.

The total duration was 30 days for the test product,

Total no. of patient exposed with Test Product: 100

13.2. Adverse Events

There was no treatment emergent adverse events were reported.

There was no laboratory change considered to be a serious adverse event or another significant adverse event.

13.3. Clinical Laboratory Evaluation

Clinical laboratory tests were recorded at Visit 1 and Visit 2 of study.

13.4. Safety Conclusions

No treatment emergent adverse events were reported. No death, serious or severe adverse events were reported during the conduct of the study.
There was no laboratory change considered to be a serious adverse event or another significant adverse event.

14. DISCUSSION AND OVERALL CONCLUSIONS

This clinical study report describes the methods and results of study MGCTSR6, a retrospective study to assess the effectiveness of Petshuddhi Churna in the treatment of Constipation.

The primary endpoint: The primary efficacy endpoint for the study was chosen as the change in the constipation symptoms measured as change in abdominal discomfort, stool consistency and feeling of incomplete defecation.

Overall, a total of One Hundred Fifteen (115) patient records were screened in the study of which hundred (100) patient records completed the study as per protocol. Fifteen (15) patient records were not considered as they were not incompliance with the inclusion & Exclusion Criteria.

Main analysis was performed within the PP population which was comprised of 100 patient records who received the test product Petshuddhi Churna. Analysis was performed using an ANOVA model with NCSS.

14.1. Discussion on Efficacy results:

1. Age of the cases in this study ranged from 20 to 65 years with average age 38.16 years among treatment group. 50% of the cases among the treatment group were male and 50% female.
2. Average BMI of the patients among treatment group was 22.93 Kg/m^2.
3. Complete Spontaneous Bowel Movement: 8% of the cases among the treatment group at baseline had complete spontaneous bowel movement. After 30 days of treatment 84% of the cases among treatment group complete spontaneous bowel movement. This indicates that Petshuddhi Churna helps in complete defecation.
4. Average abdominal discomfort score at baseline among the treatment group was 4.92 which was indicative of Medium abdominal discomfort. After 30 days of

treatment the abdominal discomfort score among the treatment group was 1.42 showing clinically significant improvement in the abdominal discomfort when compared to the baseline. This indicates that the abdominal discomfort reduces to a good level when used for 30 days regularly.

5. Average stool consistency score at baseline among the treatment group was 1.78 which was indicative of stool consistency like a sausage with cracks. After 30 days of treatment the mean stool consistency score among the treatment group was 2.90 which was indicative of stool consistency like a sausage but crumby and smooth on the surface which was significant from the baseline. This indicates that that stool consistency gets better when you use Petshuddhi Churna for 30 days.

14.2. Discussion on Safety Results:

The test and reference product were well tolerated by the patients.

No adverse event was reported during the study.

All the vital signs were found normal at baseline and the end visit.

Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

There were no protocol violations and deviations reported.

No death, serious or severe adverse events were reported during the conduct of the study.

14.3. Overall Conclusion:

Petshuddhi Churna was effective in maintaining and treating the constipation symptoms. In conclusion, there was significant change from the baseline till the end of the treatment among most of the efficacy parameters observed.

Petshuddhi Churna was effective in maintaining and treating the constipation symptoms, such as Complete spontaneous Bowel Movement, Abdominal Discomfort and Stool Consistency. No adverse events were reported by the patients after using Petshuddhi Churna indicating that it was well tolerated and thus safe to use.

15. REFERENCES

1. Dross man DA, Corazziari E, Delvaux N, Spiller R, Talley NJ, Thompson CA, et al. Rome III: The functional gastrointestinal disorders. 3 ed. McLean, VA: Degnon Associates; 2006.

2. Thompson WG. Constipation: pathogenesis and management. Lancet 1993 Jun 19; 341(8860):1569-72.

3. Lynn RB, Friedman LS. Constipation. N Engl J Med 1993 Dec 23; 329(26):1940-5.

4. Zighelboim J, Talley NJ. What are functional bowel disorders? Gastroenterology 1993 Apr; 104(4):1196-201.

Appendix:

Statistical Analysis

One-Way Analysis of Variance Report

Dataset Untitled
Response Abdominal_Discomfort

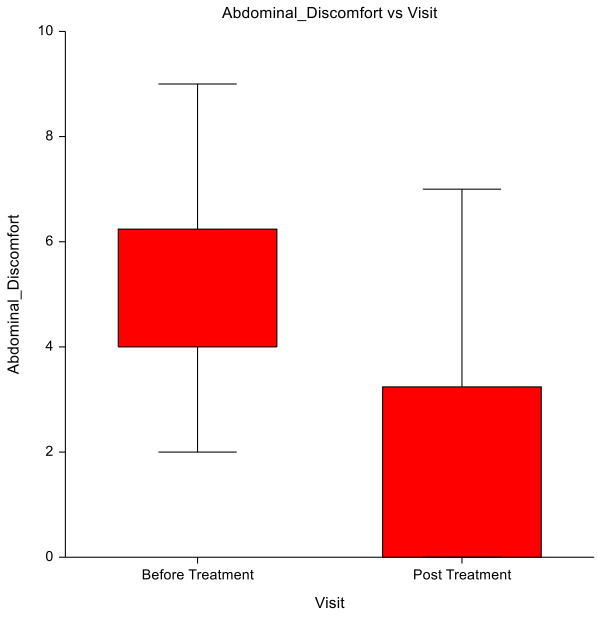
Tests of the Normality of Residuals Assumption

Normality Attributes	Test Value	Prob Level	Reject Normality? (α=0.20)
Skewness	3.9823	0.00007	Yes
Kurtosis	0.0843	0.93284	No
Skewness and Kurtosis (Omnibus)	15.8661	0.00036	Yes

Tests of the Equality of Group Variances Assumption

Test Name	Test Value	Prob Level	Reject Equal Variances? (α=0.20)
Brown-Forsythe (Data - Medians)	0.4693	0.49492	No
Levene (Data - Means)	4.1703	0.04382	Yes
Conover (Ranks of Deviations)	6.4002	0.01141	Yes
Bartlett (Likelihood Ratio)	3.1328	0.07673	Yes

Box Plot Section



One-Way Analysis of Variance Report

Dataset Untitled
Response Abdominal_Discomfort

Expected Mean Squares Table

Model Term	DF	Term Fixed?	Denominator Term	Expected Mean Square
A: Visit	1	Yes	σ^2	$\sigma^2 + sA$
Error	98	No		σ^2

Note: Expected Mean Squares are for the balanced cell-frequency case.

Analysis of Variance Table and F-Test

Model Term	DF	Sum of Squares	Mean Square	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)	Power (α=0.05)
Between (Visit)	1	306.25	306.25	79.4276	0.00000	Yes	1.00000
Within (Error)	98	377.86	3.855714				
Adjusted Total	99	684.11					
Total	100						

Welch's Test of Means Allowing for Unequal Variances

Model Term	Numerator DF	Denominator DF	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)
Between Groups	1	92.23	79.4276	0.00000	Yes

Kruskal-Wallis One-Way ANOVA on Ranks

Hypotheses
H0: All medians are equal.
H1: At least two medians are different.

Test Results

Method	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.05)
Not Corrected for Ties	1	36.5527	0.00000	Yes
Corrected for Ties	1	38.9268	0.00000	Yes

Number Sets of Ties	9
Multiplicity Factor	60984

Group Detail

Group	Count	Sum of Ranks	Mean Rank	Z-Value	Median
Before Treatment	100	3402.00	68.04	6.0459	4
Post Treatment	100	1648.00	32.96	-6.0459	0

One-Way Analysis of Variance Report

Dataset Untitled
Response Abdominal_Discomfort

Normal Scores Tests

Hypotheses
H0: All group data distributions are the same.
H1: At least one group has observations that tend to be greater than those of the other groups.

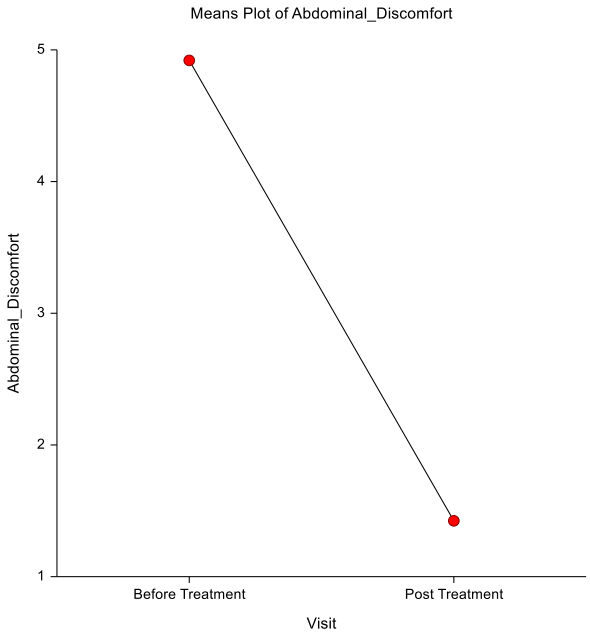
Results

Test	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.20)
Terry-Hoeffding - Expected Normal Scores	1	38.5699	0.00000	Yes
Van der Waerden - Normal Quantiles	1	38.6499	0.00000	Yes

Descriptive Statistics

Group	Count (ni)	Mean	Effect	Median	Standard Deviation	Standard Error √(MSE/ni)
All	200	3.17	3.17			
A: Visit						
Before Treatment	100	4.92	1.75	4	1.70042	0.2776946
Post Treatment	100	1.42	-1.75	0	2.19545	0.2776946

Plots of Means Section



One-Way Analysis of Variance Report

Dataset Untitled
Response Complete_Bowel_Movement

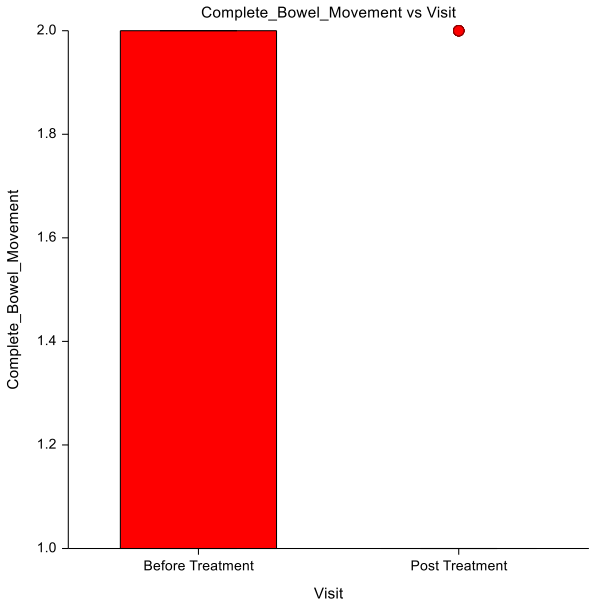
Tests of the Normality of Residuals Assumption

Normality Attributes	Test Value	Prob Level	Reject Normality? (α=0.20)
Skewness	-0.1297	0.89677	No
Kurtosis	0.3407	0.73335	No
Skewness and Kurtosis (Omnibus)	0.1329	0.93571	No

Tests of the Equality of Group Variances Assumption

Test Name	Test Value	Prob Level	Reject Equal Variances? (α=0.20)
Brown-Forsythe (Data - Medians)	5.0304	0.02716	Yes
Levene (Data - Means)	22.5835	0.00001	Yes
Conover (Ranks of Deviations)	32.8555	0.00000	Yes
Bartlett (Likelihood Ratio)	5.6213	0.01774	Yes

Box Plot Section



One-Way Analysis of Variance Report

Dataset Untitled
Response Complete_Bowel_Movement

Expected Mean Squares Table

Model Term	DF	Term Fixed?	Denominator Term	Expected Mean Square
A: Visit	1	Yes	σ^2	$\sigma^2 + sA$
Error	98	No		σ^2

Note: Expected Mean Squares are for the balanced cell-frequency case.

Analysis of Variance Table and F-Test

Model Term	DF	Sum of Squares	Mean Square	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)	Power (α=0.05)
Between (Visit)	1	8.41	8.41	52.2294	0.00000	Yes	1.00000
Within (Error)	98	15.78	0.1610204				
Adjusted Total	99	24.19					
Total	100						

Welch's Test of Means Allowing for Unequal Variances

Model Term	Numerator DF	Denominator DF	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)
Between Groups	1	88.33	52.2294	0.00000	Yes

Kruskal-Wallis One-Way ANOVA on Ranks

Hypotheses
H0: All medians are equal.
H1: At least two medians are different.

Test Results

Method	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.05)
Not Corrected for Ties	1	24.9802	0.00000	Yes
Corrected for Ties	1	34.4188	0.00000	Yes

Number Sets of Ties	2
Multiplicity Factor	274200

Group Detail

Group	Count	Sum of Ranks	Mean Rank	Z-Value	Median
Before Treatment	100	3250.00	65.00	4.9980	2
Post Treatment	100	1800.00	36.00	-4.9980	1

One-Way Analysis of Variance Report

Dataset Untitled
Response Complete_Bowel_Movement

Normal Scores Tests

Hypotheses
H0: All group data distributions are the same.
H1: At least one group has observations that tend to be greater than those of the other groups.

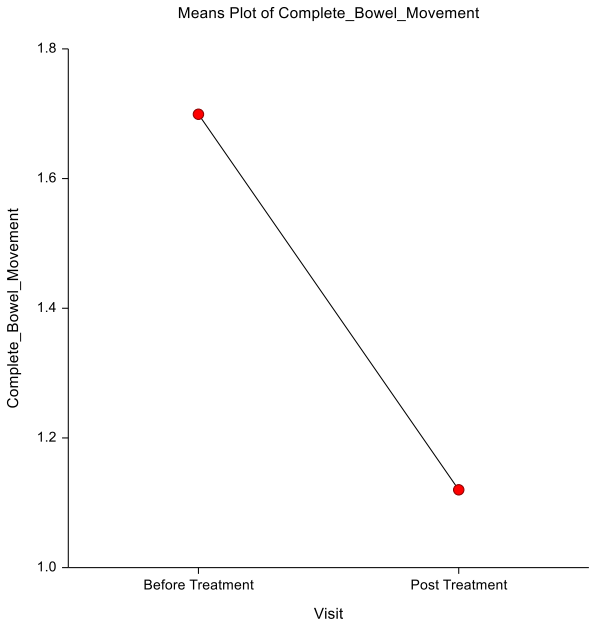
Results

Test	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.20)
Terry-Hoeffding - Expected Normal Scores	1	34.4188	0.00000	Yes
Van der Waerden - Normal Quantiles	1	34.4188	0.00000	Yes

Descriptive Statistics

Group	Count (ni)	Mean	Effect	Median	Standard Deviation	Standard Error √(MSE/ni)
All	200	1.41	1.41			
A: Visit						
Before Treatment	100	1.7	0.29	2	0.4629101	0.05674864
Post Treatment	100	1.12	-0.29	1	0.3282607	0.05674864

Plots of Means Section



One-Way Analysis of Variance Report

Dataset Untitled
Response Stool_Consistency

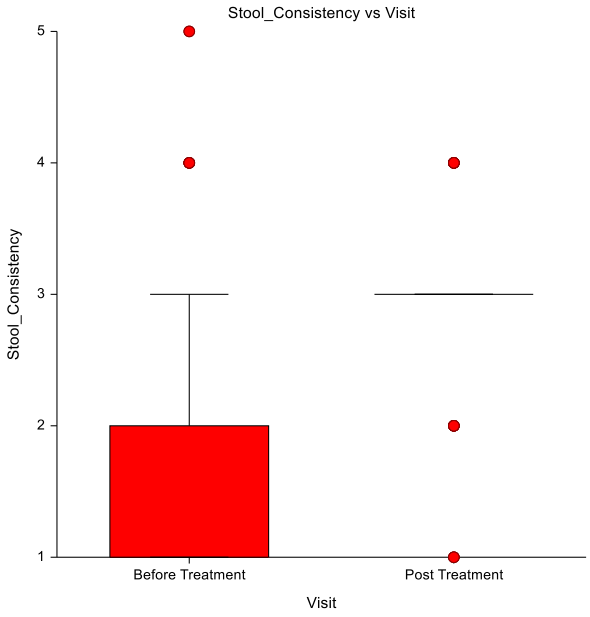
Tests of the Normality of Residuals Assumption

Normality Attributes	Test Value	Prob Level	Reject Normality? (α=0.20)
Skewness	3.9317	0.00008	Yes
Kurtosis	2.4578	0.01398	Yes
Skewness and Kurtosis (Omnibus)	21.4989	0.00002	Yes

Tests of the Equality of Group Variances Assumption

Test Name	Test Value	Prob Level	Reject Equal Variances? (α=0.20)
Brown-Forsythe (Data - Medians)	4.4364	0.03774	Yes
Levene (Data - Means)	17.4426	0.00006	Yes
Conover (Ranks of Deviations)	9.9313	0.00162	Yes
Bartlett (Likelihood Ratio)	12.9859	0.00031	Yes

Box Plot Section



One-Way Analysis of Variance Report

Dataset Untitled
Response Stool_Consistency

Expected Mean Squares Table

Model Term	DF	Term Fixed?	Denominator Term	Expected Mean Square
A: Visit	1	Yes	σ^2	$\sigma^2 + sA$
Error	98	No		σ^2

Note: Expected Mean Squares are for the balanced cell-frequency case.

Analysis of Variance Table and F-Test

Model Term	DF	Sum of Squares	Mean Square	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)	Power (α=0.05)
Between (Visit)	1	31.36	31.36	32.3231	0.00000	Yes	0.99988
Within (Error)	98	95.08	0.9702041				
Adjusted Total	99	126.44					
Total	100						

Welch's Test of Means Allowing for Unequal Variances

Model Term	Numerator DF	Denominator DF	F-Ratio	Prob Level	Reject Equal Means? (α=0.05)
Between Groups	1	79.36	32.3231	0.00000	Yes

Kruskal-Wallis One-Way ANOVA on Ranks

Hypotheses
H0: All medians are equal.
H1: At least two medians are different.

Test Results

Method	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.05)
Not Corrected for Ties	1	24.5684	0.00000	Yes
Corrected for Ties	1	27.2548	0.00000	Yes

Number Sets of Ties	5
Multiplicity Factor	98556

Group Detail

Group	Count	Sum of Ranks	Mean Rank	Z-Value	Median
Before Treatment	100	1806.00	36.12	-4.9567	1
Post Treatment	100	3244.00	64.88	4.9567	3

One-Way Analysis of Variance Report

Dataset Untitled
Response Stool_Consistency

Normal Scores Tests

Hypotheses
H0: All group data distributions are the same.
H1: At least one group has observations that tend to be greater than those of the other groups.

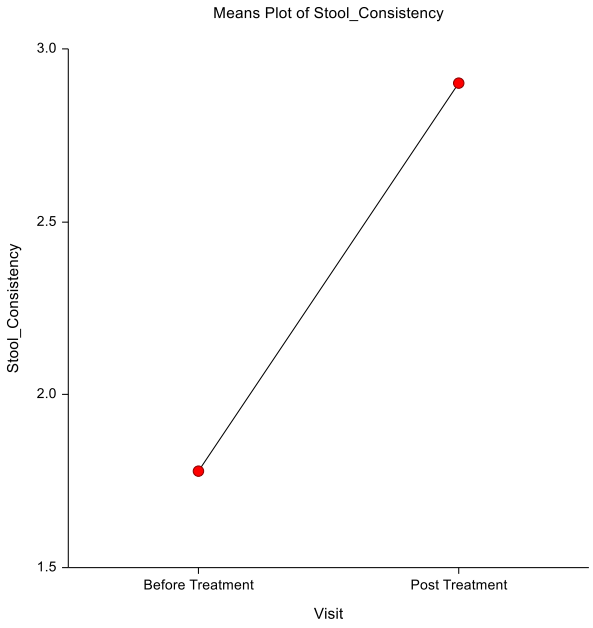
Results

Test	DF	Chi-Squared (H)	Prob Level	Reject H0? (α=0.20)
Terry-Hoeffding - Expected Normal Scores	1	21.3680	0.00000	Yes
Van der Waerden - Normal Quantiles	1	21.8530	0.00000	Yes

Descriptive Statistics

Group	Count (ni)	Mean	Effect	Median	Standard Deviation	Standard Error √(MSE/ni)
All	200	2.34	2.34			
A: Visit						
Before Treatment	100	1.78	-0.56	1	1.20017	0.1392985
Post Treatment	100	2.9	0.56	3	0.7071068	0.1392985

Plots of Means Section



SPONSOR
JEENA SIKHO LIFECARE LIMITED

CLINICAL RESEARCH ORGANIZATION
MITTAL GLOBAL CLINICAL TRIAL SERVICES (MGCTS)

MGCTS/25/737

Study Title: "An Open Label, Single Arm Clinical Study to Evaluate the safety and efficacy of Shuddhi Dr. B P Care tablets in patients with Hypertension."

Clinical Study Report

Title Page

Study Title: An Open Label, Single Arm Clinical Study to Evaluate the safety and efficacy of Shuddhi Dr. B P Care tablets in patients with Hypertension.

Protocol No.	MGCTS/25/737
Version Number and Date	1.0 DATED 12 March 2025
Investigational Product	Shuddhi Dr. B P Care tablets
Name & Address of Sponsor	Jeena Sikho Lifecare Limited
Name & Affiliation of the Investigator (s)	Name: Dr. Mansoor Riyaz Designation: Principal Investigator Affiliation: CCFT Laboratories
Date of First patient in the study	01 July 2025
Date of Last patient follow up	18 July 2025
No. of patients	60
Report Number	MGCTS/25/737
Date of the draft report	25 July 2025
Date of Final Report	27 July 2025

Confidential

The information in this document is confidential and is to be used only in connection with matters authorized by Jeena Sikho Lifecare Limited no part of it is to be disclosed to the others without prior written permission from Jeena Sikho Lifecare Limited This study was performed in accordance with ICH E6 R2, Schedule-Y (2017) and Ethical Principles as per the Declaration of Helsinki (2013) including archiving of all the essential documents.

INVESTIGATOR(S) SIGNATURE(S)

A Clinical study titled: "An Open Label, Single Arm Clinical Study to Evaluate the safety and efficacy of Shuddhi Dr. B P Care tablets in patients with Hypertension."

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name: Dr. Mansoor Riyaz **Designation:** Principle Investigator Site: CCFT Laboratories, Meerut	Mansoor 27 July 2025 SIGNATURE & DATE

STATEMENT OF COMPLAINCE

"An Open Label, Single Arm Clinical Study to Evaluate the safety and efficacy of Shuddhi Dr. B P Care tablets in patients with Hypertension."

This study was conducted in compliance with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

Name	**Designation & Address**	**Signature**	**Date (DD MM YYYY)**
PUNEET MITTAL	Director- Clinical Research, MGCTS, Mittal Building 121-B, Mansarovar Ind Estate, Panchli, Baghpat Road, Meerut-250002, India		27 July 2025

STATEMENT OF COMPLAINCE

(DATA SAFETY MONITORING BOARD)

A Clinical study titled: “An Open Label, Single Arm Clinical Study to Evaluate the safety and efficacy of Shuddhi Dr. B P Care tablets in patients with Hypertension.”

This study was verified and reviewed independently according with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

S. No	Name and Designation	Signature	Date (DD MM YYYY)
1	NIDHI DIXIT Study Director CCFT- Meerut		27 July 2025
2	Ms. Sheetal, Data Management Associate CCFT- Meerut		27 July 2025

REPORT SUMMARY:

Title of the Study	An Open Label, Single Arm Clinical Study to Evaluate the safety and efficacy of Shuddhi Dr. B P Care tablets in patients with Hypertension.
Name of Investigational product	Shuddhi Dr. B P Care tablets
Name of Sponsor	Jeena Sikho Lifecare Limited
SITE	CCFT LABORATORIES, MEERUT
Investigator (s)	Dr. Mansoor Riyaz
Study Objective	**Primary objective:** The primary objective is to study the efficacy and safety of Shuddhi Dr. B P Care Tablets with • Subject Global Assessment • Blood Pressure Measurement **Secondary Objective** The secondary objective is to evaluate the Heart Rate assessment with Shuddhi Dr. B P Care Tablets
Study Phase	NA
Study Design	An Open Label, Single arm clinical study. Each participant entering the trial will be assigned to a regimen of investigational product, and advised to take general precautions as needed. Patients will be assigned to investigational product for 6hrs, following up on T30min, T1hr, T2hr, T3hr, T4hr, 5hr, T6hr. On day 1, Blood pressure is monitored at T0min(Pre), and post T30min, T1hr, T2hr, T3hr, T4hr, 5hr, T6hr to check the instant action of the investigational Product. Subjects will be enrolled based on their Systolic and diastolic range, which corresponds to the following stages of Hypertension:

Category	Systolic, mm Hg		Diastolic, mm Hg
Optimal	<120	and	<80
Normal	<130	and	<85
High normal	130–139	or	85–89
Hypertension			
Stage 1 (mild)	140–159	or	90–99
Subgroup: borderline	140–149	or	90–94
Stage 2 (moderate)	160–179	or	100–109
Stage 3 (severe)	≥180	or	≥110
Isolated systolic hypertension	≥140	and	<90
Subgroup: borderline	140–149	and	<90

	During the screening process, blood pressure measurement will be taken prior to enrollment. Only individuals with a blood pressure reading below 149 or less than 90 will be eligible to participate. Additionally, a detailed medical history will be collected at the time of enrollment.
Sample Size	60 Subjects

Study Inclusion Criteria	**Inclusion Criteria** Subjects must meet all the following criteria to be eligible for participation in the trial: 1. Subject from 18-50 years of age. 2. Subject having BP range less than 180-120 or greater than 130-90 will be eligible for enrollment. 3. Subjects that are able to give written informed consent in a manner approved by the institutional ethics committee and comply with the requirements of the study. 4. Subject willing to avoid participation in any other interventional clinical trial for the duration of the study.
Study Exclusion Criteria	**Exclusive Criteria:** 1. Have used, are using, or are planning to use immunosuppressive or immunomodulatory medication (i.e., biologics), including oral or parenteral corticosteroids. 2. Subjects that have participated in any other interventional clinical trial in the previous 90 days. 3. Subjects with known sensitivity to any of the constituents of the investigational product. 4. Any clinically significant systemic or cutaneous disease, which may interfere with study treatment or procedures. 5. Chronic illness which may influence the outcome of the study. 6. Pregnant/nursing mothers
Test Product Study Product, Dose	**Test Product**: Shuddhi Dr. B P Care tablets **Dose:** 1 tablet **Route of Administration:** Oral
Clinical assessment and Laboratory Assessment	• SGA (Subject Global Assessment) • Blood Pressure • Heart Rate

Outcome Measures	**Primary Outcome Measures:** **<u>Efficacy</u>:** • Reduction in BP calculated as Change in the Systolic and Diastolic Blood pressure(Time Frame-0 min and 30 min, 1hr, 2hr, 3hr, 4hr, 5hr, 6hr) • Change in SGA (Subject Global Assessment) Score [0-3] such as Severe Headache, Chest pain, Difficulty breathing, Anxiety and Dizziness (Time Frame- 0 min and 6hr). • **<u>Safety</u>**: • Adverse Events Tolerability of Shuddhi Dr. B P Care tablets **Secondary Outcome Measures:** • Change in Heart rate (Time Frame- 0 min and 30 min, 1hr, 2hr, 3hr, 4hr, 5hr, 6hr)

SAFETY EVALUATION	Incidence of AE
Statistical Analysis	**Statistical Considerations** Data listings and summary tables will be provided. Listings will include all data captured on the case report form (CRF) unless specified otherwise. Calculated (derived) variables will be listed as appropriate. Summary tables will be provided for select variables as described in Section 5 through Section 8 of Statistical Analysis Plan. Analyses by visit will be performed on nominal visits regardless of actual visit day. The exception will be the case where a subject discontinued prior to Visit 1 yet data were mistakenly logged in the Visit 1 CRFs, as Visit 1 represents end of treatment. Here data will be analysed on the appropriate study visit day according to the visit window in which the actual study day falls; this will allow for correct implementation of the last observation carried forward method. **Quantitative Assessments** Quantitative assessments (continuous data) will be summarized by reporting the number of subjects (n), mean, standard deviation (SD), median, minimum value, and maximum. **Qualitative Assessments** Qualitative assessments (categorical data) will be summarized by reporting the frequency (count and percent) of subjects falling within thecategory. Unless specified otherwise for a particular assessment, the denominator for calculating a percentage will be the total number of subjects in the analysis population for the subgroup being analysed; for example, within study arm, the number of subjects within the study arm in the analysis population will be the denominator. For overall summaries, the total number of subjects in the analysis population will be used as the denominator. **Methods for Handling Missing Data** Missing efficacy data will be imputed using the last observation carried forward unless specified otherwise; unscheduled visit data will be included in the carry forward procedure. No imputations will be made for missing safety data.

Ethical Conduct of the study	The study was initiated after written approval from the hospital's Committee. The trial was conducted as per ICH E6 R2 Guidelines, Schedule Y (2017), Declaration of Helsinki (Brazil, 2013) and in accordance with other applicable guidelines.
Efficacy and Safety Results	Out of 66 subjects screened, none were found dropout, 6 screen failure due to out of range BP. 60 subjects who underwent the full trial period. The mean age of the subjects was 43.08 years in the study. The mean height of the subjects was 159.6 cm. The mean weight of the subjects was 68.25 kg. The BMI of the subjects were 26.83. Systolic blood pressure is the pressure in your arteries when your heart contracts and pumps blood out. It's the first, or top, number in a blood pressure reading. A healthy systolic blood pressure is generally considered to be below 120 mm Hg. Hypertension, or high blood pressure, is defined as a systolic blood pressure of 130 mm Hg or higher. Systolic pressure, the top number, represents the force of blood against artery walls when the heart beats. The assessment for Systolic Blood Pressure was done at timepoints T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour. The output was studied as change in the Mean systolic Blood Pressure with time. The Mean value of the Systolic Blood Pressure was 146.67, 138.78, 130.56, 122.78, 125.89, 127.56, 128.78 and 128.67 at T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour respectively. The results shows reduction in the Systolic Blood pressure from 30 mins, however the most reduction is observed in 2 hours. The reduced Systolic Heart rate was observed for the whole observation time, i.e. 6 hours. Diastolic blood pressure is the bottom number in a blood pressure reading, representing the pressure in the arteries when the heart is resting between beats. It indicates the force of blood against artery walls while the heart fills with blood. For Hypertension, the diastolic blood pressure is more than 80. The assessment for diastolic Blood Pressure was done at timepoints T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour. The output was studied as change in the Mean diastolic Blood Pressure with time. The Mean value of the diastolic Blood Pressure was 93.89, 86.67, 85.22, 82.78, 80.78, 81.67, 82.67 and 85.11 at T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour respectively. The results shows reduction in the

	diastolic Blood pressure from 30 mins, however the most reduction is observed in 3 hours. The reduced diastolic Heart rate was observed for the whole observation time, i.e. 6 hours. Heart rate, also known as pulse, is the number of times your heart beats per minute. It reflects how efficiently your heart is pumping blood to meet your body's needs. A normal resting heart rate for adults generally falls between 60 and 100 beats per minute. A lower resting heart rate within this range generally indicates better cardiovascular fitness. The assessment for Heart Rate was done at timepoints T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour. The output was studied as change in the Mean Heart rate with time. The Mean value of the Heart Rate was 87.78, 80.56, 77.56, 72.67, 73.67, 75.56, 72.56 and 74.67 at T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour respectively. The results shows reduction in the Heart Rate from 30 mins, however the most reduction is observed in 2 hours. The reduced diastolic Heart rate was observed for the whole observation time, i.e. 6 hours. Subject's Global Assessment was done for the Chest Pain, Difficulty in Breathing, Anxiety and Dizziness. The assessment was done on the 4 point scale of 0-3 where 0 means No Issue and 3 means severe issue. The output was studied as change in the mean Score. The Mean value of the chest pain has not changed in 6 hours. No change was observed in the chest pain. The mean value for Difficulty in breathing has reduced from 0.75 to 0.50 showing some improvement in the breathing difficulty. The mean value for the Anxiety has reduced from 1.17 to 0.92 showing that the test product reduces anxiety. The mean value of Dizziness has reduced from 0.83 to 0.58 in 6 hours, showing a dizziness reducing action. No adverse event was reported during the study. Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication. There were no protocol violations and deviations reported. There were none of the patient who lost to follow up. None of the patients withdrawn the consent.

Conclusion	In conclusion, Shuddhi Dr. B P Care tablets showed significant improvement Hypertension with significant reduction in the Blood Pressure and heart rate in 2-3 hours. The anti-hypertensive action of the tablets stays for the complete treatment period of 6 hours. Reduction in the Anxiety, Dizziness and breathing issues was also observed with no quick impact on the chest pain. No, adverse events were observed during the study.
Date of Report	27-July 2025

Contents

List of Abbreviations

Abbreviation	Definition
AE	Adverse event
ANOVA	Analysis of variance
AUC	Area under the curve
BOCF	Baseline observation carried forward
CI	Confidence interval
CRO	Contract Research Organisation
ECG	Electrocardiogram
CRF	Electronic case report form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
IP	Investigational product
IEC	Institutional Ethics Committee
ITT	Intent to treat
MI	Multiple imputation
MedDRA	Medical Dictionary for Regulatory Activities
OTC	Over the counter
PP	Per protocol
PRO	Patient-reported outcome
QOL	Quality of Life
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SD	Standard deviation
SGA	Subject's global assessment
SUSAR	Suspected unexpected serious adverse reaction
TC	Telephone call
UPT	Urine pregnancy test

Patient Information and Consent

All patients provided written informed consent to participate in the study prior to being screened. The patient information sheet detailed the procedures involved in the study (aims, methodology, potential risks and anticipated benefits) and the investigator explained these to each patient. The patient signed the consent form to indicate that the information had been explained and understood. The patients were allowed to take ample time to consider the information presented before signing and dating the informed consent form to indicate that they fully understood the information, and willingly volunteered to participate in the study. The patients were given a copy of the signed informed consent form for their information. The original informed consent documents were kept in a confidential file in the Investigators site record.

Investigators and Study Administrative Structure

Sponsor	Jeena Sikho Lifecare Limited
Principal Investigator (S)	Dr. Mansoor Riyaz
ETHICS COMMITTEE (S)	ARMHRC INSITUTIONAL ETHICS COMMITTEE
SITE(S) ADDRESS	CCFT LABORATORIES, MEERUT
NAME AND ADDRESS OF LABORATORY	SAME AS ABOVE

1. INTRODUCTION

1.1. Background

Hypertension (high blood pressure) is when the pressure in your blood vessels is too high (140/90 mmHg or higher). It is common but can be serious if not treated. People with high blood pressure may not feel symptoms. The only way to know is to get your blood pressure checked.

Things that increase the risk of having high blood pressure include:

- older age
- genetics
- being overweight or obese
- not being physically active
- high-salt diet
- drinking too much alcohol

Lifestyle changes like eating a healthier diet, quitting tobacco and being more active can help lower blood pressure. Some people may still need to take medicines.

Blood pressure is written as two numbers. The first (systolic) number represents the pressure in blood vessels when the heart contracts or beats. The second (diastolic) number represents the pressure in the vessels when the heart rests between beats.

Hypertension is diagnosed if, when it is measured on two different days, the systolic blood pressure readings on both days is ≥140 mmHg and/or the diastolic blood pressure readings on both days is ≥90 mmHg.

1.2. Rationale of the Trial

To determine the benefits from Shuddhi Dr. B P Care tablets with these following ingredients:

1. Convolvulus Pluricaulis
2. Asparagaceae
3. Withania Somnifera
4. Bacopa monnierl
5. Acorus calamus Linn
6. Rauvolfia serpentine
7. Cuminum cyminum
8. Tinospora cordifolia
9. Adhatoda Vasica
10. Nardostachys jatamansi Colour

11. Starch

1.3. Benefit-risk Assessment

The subject population will be composed of healthy volunteers.

The active ingredients in the investigational products are known to be effective for the control of high blood pressure. The safety and efficacy profiles for marketed products with these ingredients are well known. The acute toxicity study has already been done on this formulation.

It would be safe to assume that the risk factor in this clinical trial is minimal. However, the trial is designed to record any adverse event that may take place as well as handle any complication that may arise during the trial.

2. TRIAL OBJECTIVES AND PURPOSE

2.1. Primary objective

The primary objective is to study the efficacy and safety of Shuddhi Dr. B P Care Tablets with

- Blood Pressure Measurement
- Subject Global Assessment

2.2. Secondary objective

The secondary objective is to study the change in heart rate of the patients after the use of the investigational product.

3. TRIAL DESIGN

3.1. Overall Trial Design

An Open Label, Single arm clinical study.

Each participant entering the trial will be assigned to a regimen of investigational product, and advised to take general precautions as needed.

Patients will be assigned to investigational product for 6hrs, following up on T30min, T1hr, T2hr, T3hr, T4hr, 5hr, T6hr.

On day 1, Blood pressure is monitored at T0min(Pre), and post T30min, T1hr, T2hr, T3hr, T4hr, 5hr, T6hr to check the instant action of the investigational Product.

Subjects will be enrolled based on their Systolic and diastolic range, which corresponds to the following stages of Hypertension:

Category	Systolic, mm Hg		Diastolic, mm Hg
Optimal	<120	and	<80
Normal	<130	and	<85
High normal	130–139	or	85–89
Hypertension			
Stage 1 (mild)	140–159	or	90–99
Subgroup: borderline	140–149	or	90–94
Stage 2 (moderate)	160–179	or	100–109
Stage 3 (severe)	≥180	or	≥110
Isolated systolic hypertension	≥140	and	<90
Subgroup: borderline	140–149	and	<90

During the screening process, blood pressure measurement will be taken prior to enrollment. Only individuals with a blood pressure reading below 149 or less than 90 will be eligible to participate. Additionally, a detailed medical history will be collected at the time of enrollment.

3.2. Trial Endpoints

3.2.1. Endpoints

Efficacy:

Primary Outcome Measures:

Efficacy:

- Reduction in BP calculated as Change in the Systolic and Diastolic Blood pressure(Time Frame-0 min and 30 min, 1hr, 2hr, 3hr, 4hr, 5hr, 6hr)
- Change in SGA (Subject Global Assessment) Score [0-3] such as Severe Headache, Chest pain, Difficulty breathing, Anxiety and Dizziness (Time Frame- 0 min and 6hr).

Safety:

- Adverse Events
- Tolerability of Shuddhi Dr. B P Care tablets in treatment of Hypertension.

Secondary Outcome Measures:

- Change in Heart rate (Time Frame- 0 min and 30 min, 1hr, 2hr, 3hr, 4hr, 5hr, 6hr)

4. SELECTION OF TRIAL POPULATION

4.1. Subject Population

Subjects (60 in no.) were enrolled for the primary analysis. An individual subject was allowed to participate in the trial one time only.

Each potential subject signed and date an informed consent document before any trial-specified procedures was performed. Subjects were provided authorization for use of their personal data in accordance with the applicable regulations regarding privacy and data protection.

4.2. Inclusion Criteria

1. Subject from 18-50 years of age.

2. Subject having BP range systolic 180-120 or greater than 130-90 will be eligible for enrollment.

3. Subjects that are able to give written informed consent in a manner approved by the institutional ethics committee and comply with the requirements of the study.

4. Subject willing to avoid participation in any other interventional clinical trial for the duration of the study.

4.3. Exclusion Criteria

1. Have used, are using, or are planning to use immunosuppressive or immunomodulatory medication (i.e., biologics), including oral or parenteral corticosteroids.

2. Subjects that have participated in any other interventional clinical trial in the previous 90 days.

4. Subjects with known sensitivity to any of the constituents of the investigational product.

5. Any clinically significant systemic or cutaneous disease, which may interfere with study treatment or procedures.

6. Chronic illness which may influence the outcome of the study.

7. Pregnant/nursing mothers

4.4. Discontinuation of Treatment

In accordance with legal requirements and International Conference on Harmonization (ICH) – Good Clinical Practice (GCP) guidelines, every subject has the right to refuse Further participation in this trial at any time and without providing. A subject's participation is to be terminated immediately upon his/her request. The investigator should seek to obtain the reason and record this on the electronic case report form (eCRF) whenever possible.

If, at the time of refusal, a trial product has already been administered, the investigator should advise the subject on follow-up safety evaluations.

In the case of an SAE or development of a condition that would have met the trial safety-related exclusion criteria, the subject should be evaluated by the investigator. The investigator should use his/her discretion to determine whether the subject should continue treatment with the IP.

A subject may be withdrawn from the trial at any time at the discretion of the investigator. The reasons for early termination are to be fully documented on the CRF.

In addition, sponsor reserves the right to end or suspend the trial at any time.

If a subject withdraws from the trial, all efforts will be made to complete a final evaluation if possible. The withdrawal procedures for subjects who withdraw during the treatment period are the same as those for the End of Treatment visit. Subjects discontinued for an AE will be monitored until the AE is resolved, a reasonable explanation is provided for the event, or the subject is referred to his/her own primary medical doctor. The specific AE in question will be recorded on the appropriate CRF.

4.5. Replacement Policy

After trial enrolment has been completed, subjects who prematurely discontinue the trial after were not replaced.

5. TRIAL TREATMENTS

5.1. Investigational Product

Shuddhi Dr. B P Care tablets

Dosing Regimen

1 tablet

5.2. Dose Modification

Subjects classified as clear at on actual visits may stop the treatment at the investigator's discretion. They should remain in the trial and attend visits up to whole trial.

5.3. Packaging, Labeling, and Storage

Medication labels for the IPs will comply with the legal requirements of the country where the trial is performed and be printed in the local language.

The IPs will be supplied by the **Jeena Sikho Lifecare Limited** designated vendor and stored securely at the site under the control of the investigator. The temperature will be monitored and documented.

The cream was supplied to the clinical site. The product to be protected from sunlight, stored in a cool and dry place at a temperature of 25°C (below 77°F) at the site, and below 25°C (below 77°F) after dispensing to the subject however the product must not be refrigerated.

5.4. Prior, Concomitant, and Prohibited Therapy

All medications, including over-the-counter (OTC) drugs, taken within 30 days prior to the start of the trial were recorded at Screening. Thereafter, a record of all medications and supportive therapy taken during the course of the trial was made. Information regarding the total daily dose, route of administration, start and discontinuation dates, and indication were recorded on the subject's CRF.

5.4.1. Washout of Prohibited Medications Prior to Enrollment

A washout period of up to 2 weeks was completed if the subject has been treated with any medication as specified in the exclusion criteria.

5.4.2. Prohibited Medications during the Trial

Use of any medication that would exclude the subject from participation in the trial (as specified in Section 5.2 Exclusion Criteria) is also prohibited during the treatment which includes medications in the following categories:

Patients should not use any form of the topical interventions

5.4.3. Rescue Medication

In case the patient does not respond to the treatment, any other medication as judged by the Investigator would be better for the subject will be given to subjects. No other concomitant medicine will be allowed except study drug and rescue medication throughout study duration.

5.5. Treatment Compliance

Records of trial product used and dosages administered were kept during the trial. The trial monitor has noted product accountability during site visits and at the completion of the trial.

At all on-treatment visits, the subjects were asked if he/she has used the medication as prescribed. If this is not the case, the degree and nature of noncompliance was specified. In addition, subjects were asked to complete a dosing diary during the treatment period as a measure of treatment compliance.

Subjects who are consistently noncompliant were counseled.

Subjects were asked to return all used and unused bottles in the outer box at each visit. All returned bottles that had been dispensed to a subject were weighed to determine the amount of the IP used per treatment phase.

6. VISIT SCHEDULE AND ASSESSMENTS

Trial Procedures

The visit schedule and assessments are summarized in Table 1.

Visit	**Screening and Visit1(Baseline-Day0/1)**	**Screening and Visit1(Baseline-Day0/1) at (0 min and 30 min, 1hr, 2hr, 3hr, 4hr, 5hr, 6hr))**
Informed consent	X	
Inclusion/ exclusion criteria	X	
Demographics, medical history	X	
Concomitant medication	X	
Concurrent diagnoses	X	
Physical Exam	X	
Vital signs	X	
Pregnancy test	X	
SGA	X	X(6hr only)
Heart Rate	X	X
Blood pressure	X	X
Dispensing IP	X	
AE \ SAE Reporting		
Compliance	X	
Return of all trial Materials		

Table 1: Visit Schedule and Assessments

6.1 Trial Visits and Assessments

Visit 1/Baseline (Day 0):

Screening procedures should be completed no more than 1 days prior to Visit 1/ (Day 0).Visit 1/Screening and Visit 1/Baseline can occur on the same day if no washout of prohibited medications is required. The following screening procedures will be performed at the screening visit:

- Review trial information with subject and obtain written informed consent.
- Review inclusion and exclusion criteria with the subject to determine the subject'seligibility.
- Collect medical history;
    - other allergic history if the subject received concomitant medication for this condition
    - If subject participated in skin related study within last two months
- Review and record any current medical diagnoses.
- Perform the following assessments:

At baseline	Blood Pressure, Heart Rate, and SGA
After 30 min	Blood Pressure and Heart Rate
After 1 Hour	Blood Pressure and Heart Rate
After 2 Hour	Blood Pressure and Heart Rate
After 3 Hour	Blood Pressure and Heart Rate
After 4 Hour	Blood Pressure and Heart Rate
After 5 Hour	Blood Pressure and Heart Rate
After 6 Hour	Blood Pressure, Heart Rate, and SGA

Early Termination

If a subject withdraws from the trial prior to the 6 hours (End of Treatment), the subject is to return to the site for assessment of any post exposure AE.

Unscheduled Visit and Telephone Calls

An unscheduled visit may be performed at any time during the trial if judged necessary by the Investigator, such as for a severe reaction and clinically significant AE. Details of the event must be recorded in the subject's records.

Investigator Assessments

The investigator assessments are to be performed by a dermatologist, a dermatologist with at least 1 year of experience in dermatology. For dermatologist and dermatologist Assistants who do not fulfill the requirement regarding dermatologist experience and other state licensed professionals who have the ability to diagnose, treat and prescribe medications, the person must be preapproved by the sponsor. The assessments are to be performed as specified in the visit schedule (Table 1).

Assessment of Safety Adverse Events

Adverse Events Assessments

The investigator or designee was responsible for obtaining, assessing, and documenting all AEs during the study. Adverse Events information were collected from the time of the signature of the informed consent form until the end of the study. An AE is an untoward medical occurrence in any subject during the trial which does not necessarily have a causal relationship with the trial drug treatment.

All were will be documented in the CRF, including a description of each AE, AE relationship to trial product administration, start and stop dates, seriousness, severity, action taken and outcome.

Any AE that meets the serious criteria must be reported on the CRF and on a separate SAEs report form. SAEs must be reported to the Ethics Committee within 24 hours of awareness.

Throughout the trial, the occurrence of AEs should be sought by nondirective questioning of the subject at each visit during the trial. Information on AEs can also be obtained from signs and symptoms detected during examination, observations made by the trial site personnel, or spontaneous reports from subjects. Pre-existing conditions that worsen during the trial should also be recorded as AEs.

AEs requiring therapy must be treated with recognized standards of medical care to protect the health and well-being of the subject. Treatment due to an AE will be recorded in the subject's records and on the appropriate CRF.

Any AE that is considered related to the trial product must be followed by the investigator until it is resolved or until the medical condition of the subject is stable; all relevant follow-up information will be reported to the Sponsor/CRO or

designee.

The outcome of an AE was classified as recovered, recovered with squeal, recovering/resolving, ongoing, or death.

No AE were observed in the study in either of the arms.

Timing

AEs were collected/assessed from the time of the signature of the informed consent form by the subject and first trial-related activity performed.

Severity of Adverse Events

The investigator is to classify the severity (intensity) of an AE according to the following definitions:

- Mild – The subject was aware of the signs and symptoms but the signs and symptoms were easily tolerated and does not interfere with daily activity.
- Moderate – The signs and symptoms were sufficient to restrict, but did not prevent, usual daily activity for the subject. The subject is still able to function.
- Severe – The subject was unable to perform usual daily activity.

The maximum intensity of an AE (mild, moderate, or severe) will be assessed taking into account the possible range of intensity of the symptom(s).

Relationship of an Adverse Event to Trial Treatment

The investigator is responsible to assess the relationship of an AE to the IP using good clinical judgment and the following definitions:

Not Related	The AE is clearly explained by another cause not related to the trial product administration; the temporal relationship of the AE to IP administration makes a causal relationship unlikely, or, concomitant medication, therapeutics interventions, or underlying condition providea sufficient explanation for the observed AE
Possibly Related	The AE and administration of trial product are temporally related, but the AE can be explained equally well by causes other than the trial product administration

Probably Related	The AE and use of trial product are temporally related, and the AE is more likely explained by trial product administration than by other causes
Definitely Related	The AE and trial product administration are related in time, and a direct association can be demonstrated. Concomitant medication, therapeutics interventions, or underlying conditions do not provide a sufficient explanation for the observed AE

Unexpected Adverse Events

Any AE assessed as related to the IP will be assessed for expectedness by the sponsor or designee. An AE is considered ―unexpected‖ if its nature or severity is not consistent with information in the Investigator's Brochure.

―Unexpected as used in this definition, also refers to AEs that are mentioned in the Investigator's Brochure or product prescribing information as occurring with a class of drugs or as anticipated from the pharmacological properties of the drug, but are not specifically mentioned as occurring with the particular drug under investigation.

Trial Medication Overdose

An overdose of the IP, i.e., a dose that is higher than the highest dose under clinical investigation or the known therapeutic dose, will be fully documented even if no toxic effects were observed and will be considered as an AE.

Serious Adverse Event

An SAE is any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect, or is an important medical event?
- Other serious or important medical event

The death of a subject enrolled in a trial is per se not an event, but an outcome. Any event resulting in a fatal outcome must be fully documented and reported, regardless of the causalityrelationship to the IP.

Any medical important events that may not result in death, be life-threatening, or

require hospitalization may be considered an SAE when, based on appropriate medical judgment, jeopardize the subject, or the subject may require medical or surgical intervention to prevent one of the outcomes listed in the above definitions.

Any pre-planned hospitalizations that are known at the time of signing the ICF will not be recorded as SAEs, however they will be recorded as AEs only.

Any SAE, whether or not deemed drug-related or expected, must be reported immediately tothe Sponsor or designee as soon as it becomes known to the investigator and not later than within 24 hours of his/her knowledge of the occurrence of an SAE). The investigator will document such events in the best possible detail on the SAE Report Form.

A suspected unexpected serious adverse reaction (SUSAR) is an SAE that is both unexpected(not consistent with the current Investigator's Brochure) and for which there is evidence to suggest a causal relationship between the drug and the SAE. The Institutional Ethics Committee (IEC) will be informed of SUSARS according to local requirements. All investigators participating in the trial will also be notified of unexpected SAEs. The sponsor or designee will report SAEs and other events requiring expedited reporting to regulatory authorities as required.

Investigator instructions for reporting SAEs.

Vital Signs

At all the visits, the investigator or designee will take measurements of vital signs, including blood pressure and heart rate (pulse) with the subject in the sitting position with approximately5 minutes rest prior to measurement. The same arm is to be used for all measurements.

Physical Examination

At Visit 1/Baseline the investigator or designee will complete a general physical examination including measurements of height (at screening only) and weight (with indoor clothing and without shoes) and on visit 2, the investigator also takes all the vitals and examine any delayed erythema response on the site.

During the trial, any new clinically significant findings of signs/symptoms that could indicate systemic safety will be reported as AEs.

Appropriateness of Measurements

The assessments to be used in this trial are the standardized and most widely accepted methods for acne testing as per guidelines.

7. Statistical Methods and Analytical Plans

Prior to the analysis of the final study data, a detailed Statistical Analysis Plan (SAP) was written describing all analyses that will be performed. Data was analyzed using a combination of NCSS & R software version 2.15.0 (R Development core team, R Foundation for statistical computing, Vienna, Austria) with appropriate statistical test. The SAP may contain any modifications to the analysis plan described below.

7.1. Data Sets Analyzed

All eligible patients who are included into the study and receive single dose on same day of the study

7.2. Demographic and Baseline Characteristics

The following demographic variables at screening were summarized by dose level: race, gender, age, height and weight.

7.3. Analysis of Endpoints

All data will be expressed as percentage of subjects with improvement in the condition, with no statistical Safety and tolerability data was summarized by treatment group.

Adverse event rates were coded by body system and MedDra classification term. Adverse events were tabulated by treatment group and include the number of patients for whom the event occurred, the rate of occurrence, and the severity and relationship to study drug.

7.4. Sample Size

Sample size for this protocol is 60. The eligible patients will be assigned to study drug and there is no need of randomization in it.

8. CHANGES IN THE PLANNED TRIAL

8.1. Protocol Amendments

Except for administrative changes, any changes or additions to this clinical trial protocol require a written protocol amendment that must be approved by the IEC before implementation.

These requirements for approval should in no way prevent any immediate action from being taken by the investigator or SPONSOR/CRO in the interests of preserving the safety of all subjects included in the trial. If an immediate change to the protocol is felt to be necessary by the investigator and is implemented for safety reasons, SPONSOR/CRO or designee should be notified and the IEC should be informed according to their reporting requirements.

8.2. Termination or Suspension of the Trial

SPONSOR/CRO reserves the right to terminate or suspend the trial at any time. In case of premature termination or suspension of the trial, the contract research organization (CRO) project manager has to promptly inform the investigators, regulatory authorities, and s about the premature termination or suspension, including the reason for it. In terminating the trial, SPONSOR/CRO and the investigator should ensure that adequate consideration is given to the protection of the subjects' interests.

9. DATA HANDLING AND RECORD KEEPING

9.1. Recording of Data

9.1.1. Source Documents

Source data are all the information in original records and copies of original records of clinical findings, observations, or other activities in the trial, which are necessary for the reconstruction and evaluation of the trial. The identification of any data to be recorded directly on the CRFs is to be considered source data.

Trial data collection procedures must ensure that each data element can be traced with a high level of confidence from its originator or recorder to its representation in the trial database and then to its place in the analysis and report of trial results. Once recorded, the trial data must be protected from unauthorized modification or deletion, and all authorized modifications and deletions must be securely linked in the permanent record with their author, time of change, and reason for change (i.e., the audit trail must be maintained).

The investigator should permit trial-related monitoring, audit(s), IEC review(s) and regulatory inspection(s), with direct access to all the required source records.

The principal investigator should certify the data to be accurate and complete and release the data for transmittal to SPONSOR/CRO or designee.

Source records need to be preserved for the maximum period of time permitted by local requirements. For each subject enrolled, the investigator will indicate in the source record(s) that the subject participated in the trial.

9.1.2. Case Report Forms

The primary data collection tool for the trial is a CRF designed specifically for the trial. For each subject enrolled in the trial, a CRF was completed by the trial coordinator and signed by the investigator or his/her designate.

The investigator was responsible for ensuring the accuracy of all data entered in the CRFs. All CRFs are to be completed in a timely manner.

Errors occurring in the CRFs were queried. Queries raised by data reviewers must be addressed by site personnel.

On request, the investigator should provide the SPONSOR/CRO with additional data relating to the trial, or copies of relevant source records, duly anonymized (i.e., subject's name is redacted).

9.2. Retention of Documents

The investigator should take responsibility for maintaining adequate and accurate source documents of all observations and data generated during this trial, including any data clarification forms received from the SPONSOR/CRO or designee. Such documentation is subject to inspection by the sponsor or its agents, the FDA and/or other regulatory agencies. The investigator is responsible for retention of essential documents including the Investigator Trial File until SPONSOR/CRO informs the investigator that the documents are no longer to be retained or longer if required by local regulations.

10. QUALITY CONTROL AND QUALITY ASSURANCE

10.1. Direct Access to Source Documents

As specified in the investigator's agreement, the investigator agrees to allow trial-related monitoring, audit(s), IEC review(s) and regulatory inspection(s), with direct access to all the required source records, and to allocate his/her time and the time of his/her staff to the auditor/inspector to discuss findings and any issues.

10.2. Monitoring Procedures

The Clinical Trial Monitor will contact and/or visit the investigator site periodically to verify the adherence to the protocol, the maintenance of trial-related source records, and the completeness and accuracy of all CRF entries compared to source data. The investigator will cooperate with the trial monitor to ensure that any discrepancies that may be identified are resolved.

10.3. Audit and Inspection

The investigator has made all the trial-related source data and records available to a quality assurance auditor mandated by the sponsor, or to domestic or foreign regulatory inspectors, after reasonable notice. The main purposes of an audit or inspection are to confirm that the rights and well-being of the subjects have been adequately protected, and that all data relevant for the evaluation of the IP have been processed and reported in compliance with GCP/ICH and applicable regulatory requirements.

The investigator has to notify the SPONSOR/CRO or designee immediately of any inspection by regulatory authorities.

11. ETHICS

11.1. Ethical Conduct of the Trial

This trial must be carried out in compliance with the protocol and the applicable laws and regulatory requirements of the appropriate regulatory agency. The trial must be conducted in accordance with the ethical principles originating from the Declaration of Helsinki and amendments and the ICH-GCP guidelines.

11.2. Institutional Ethics Committee (IEC)

This protocol, the proposed informed consent form, and other information for subjects must be reviewed and approved by an IEC, before the start of the trial, in compliance with local regulations. This committee must also approve any amendments to the protocol, other than administrative ones, before initiation of the amendment procedures. This protocol was approved dated 20 March 2025 by ARMHRC Institutional Ethics Committee.

11.3. Subject Information and Consent

Before participation in the trial, each subject or guardian is required to provide written consent to participate in the trial. No trial-specific procedures should be performed before a subject's informed consent is obtained.

11.4. Disclosure and Confidentiality

11.4.1. Confidentiality of Trial Documentation

By signing the protocol, the investigator agrees to keep all information provided by the sponsor in strict confidence and to request similar confidentiality from his/her staff and the or IEC. Trial documents provided by the trial sponsor (i.e., protocols, Investigators' Brochures, CRFs and other material) should be stored appropriately to ensure their confidentiality. The information provided by the sponsor to the investigator may not be disclosed to others without direct written authorization from the sponsor, except to the extent necessary to obtain informed consent from subjects who wish to participate in the trial.

11.4.2. Privacy of Individual Health Information

The investigator should undertake to protect the privacy of all individually identifiable health information except as specifically authorized by each individual subject through the written informed consent. The Informed Consent document should include a request of the subject's consent to release the collected data for research purposes in such a way that the individual's identity remains masked. While all data records should be identified by the corresponding subject number, the identity of the subject will be held in confidential source documents at the trial site. All trial personnel with access to this information are legally bound not to disclose such information.

11.5. Reporting of Serious Adverse Events and Pregnancies

11.5.1. Contact Person(s) and Number(s)

SAEs and pregnancies must be reported immediately (i.e., not later than 24 hours after first knowledge). The SAE or pregnancy report should be e-mailed or texted to IEC and Sponsor using the following e-mail or fax-number:

Email: info@mittalayurved.com

Name: Nitin Jharsi

11.5.2. Reporting Procedures

Serious Adverse Events

For each SAE, the investigator should complete a Serious Adverse Event Report Form and assess the relationship of each SAE to trial treatment. The completed form(s) should be sent electronically to the UBC using the SAE Reporting fax number within 24 hours of first knowledge of the SAE.

Follow-up reports regarding the status of the SAE and the subject's subsequent course should be submitted until the SAE has subsided, the condition stabilized (in the case of persistent impairment), the subject receives alternative therapy, or the subject dies. The form and fax confirmation should be retained. Contacts for reporting SAEs, pregnancies and other safety concerns are provided to each site.

12. INSURANCE

SPONSOR/CRO has taken out appropriate insurance policies covering the subjects in the clinical trial in accordance with applicable laws and regulations.

13. PUBLICATION POLICY

The clinical trial information should be posted on www.ctri.nic.in or www.clinical trial.gov and in accordance with applicable regulations.

All publications (e.g., manuscripts, abstracts, oral/slide presentations, book chapters) based on this trial must be submitted to SPONSOR/CRO for review, as specified in the Clinical TrialAgreement between the institution, investigator, and SPONSOR/CRO or its designee.

14. Results

14.1. Subject disposition:

Out of 66 subjects screened, none were found dropout, 6 screen failure due to out of range BP. 60 subjects who underwent the full trial period.

S. No	Variable	Number of subjects
1.	No. of subjects screened for study	66
2.	No. of subject's screen failure	6
3.	No. of subjects enrolled in the study	60
4.	Number of subjects completed the Study	60
5.	Dropout	0

Table 2: Patient disposition details

S. No	Schedule	Dates
1.	First subject ICF date	01 July 2025
2.	Last subject ICF date	18 July 2025
3.	First subject screening date	01 July 2025
4.	Last subject screening start date	18 July 2025
5.	Date of first subject completed study	01 July 2025
6.	Date of Last subject completed study	18 July 2025

Table 3: Study dates/schedules:

Subjects disposition chart

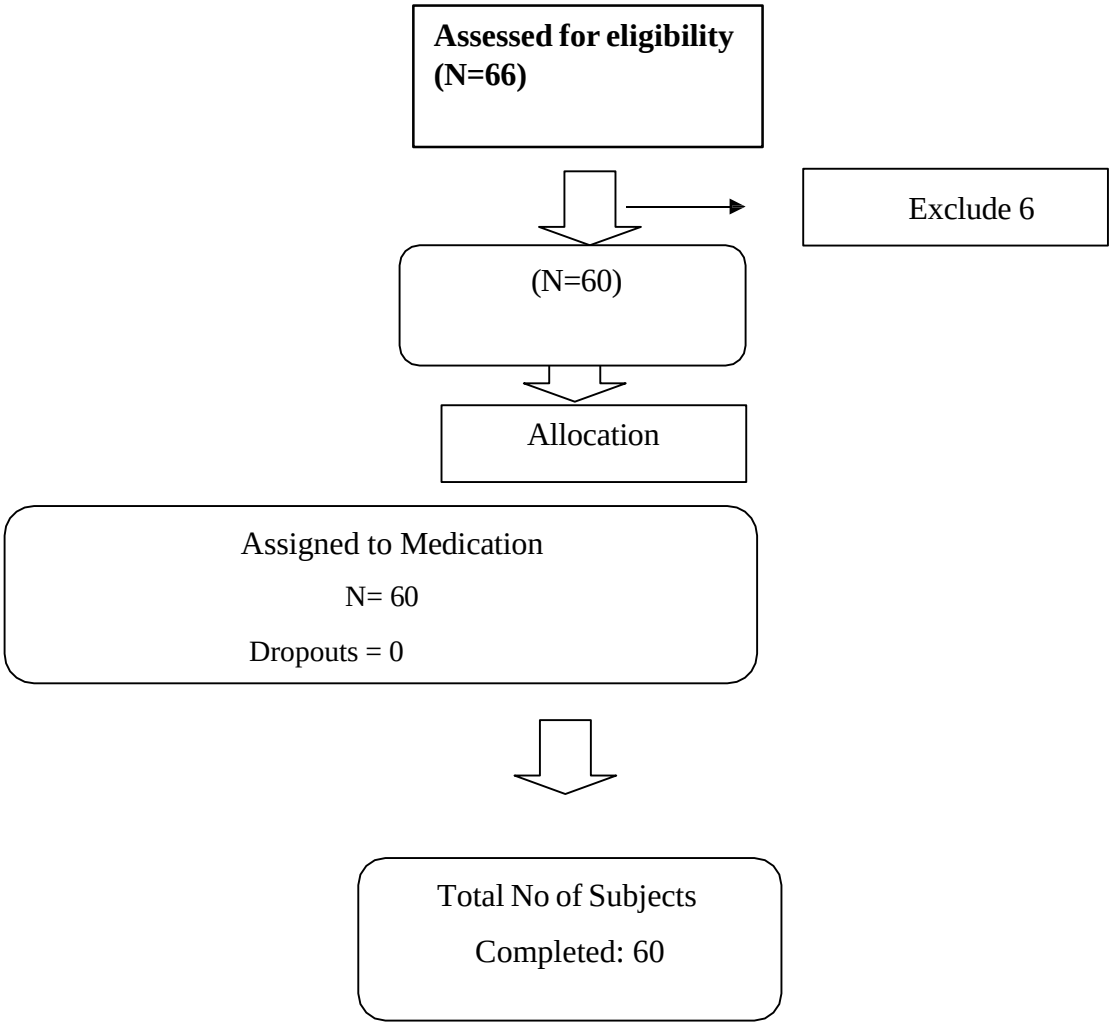


Figure 1: Subject disposition chart details

14.2. Demographic and Other Baseline Characteristics

The mean age of the subjects was 43.08 years in the study. The mean height of the subjects was 159.6 cm. The mean weight of the subjects was 68.25 kg. The BMI of the subjects were 26.83.

14.3. Efficacy Evaluations

Data sets Analyzed. Data from 60 patients who completed the study were analyzed.

Treatments	Test Product(s)
Total screened	66
Enrolled	60
No. of patients completed	60

Table 4: Data sets analyzed

Efficacy Results and Tabulations of Individual Patient Data

14.3.1. Systolic Blood Pressure:

Systolic blood pressure is the pressure in your arteries when your heart contracts and pumps blood out. It's the first, or top, number in a blood pressure reading. A healthy systolic blood pressure is generally considered to be below 120 mm Hg. Hypertension, or high blood pressure, is defined as a systolic blood pressure of 130 mm Hg or higher. Systolic pressure, the top number, represents the force of blood against artery walls when the heart beats.

The assessment for Systolic Blood Pressure was done at timepoints T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour. The output was studied as change in the Mean systolic Blood Pressure with time.

The Mean value of the Systolic Blood Pressure was 146.67, 138.78, 130.56, 122.78, 125.89, 127.56, 128.78 and 128.67 at T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour respectively.

The results shows reduction in the Systolic Blood pressure from 30 mins, however the most reduction is observed in 2 hours. The reduced Systolic Heart rate was

observed for the whole observation time, i.e. 6 hours.

Timepoint	Systolic Blood Pressure
T0min	146.67
T30min	138.78
T1hour	130.56
T2hour	122.78
T3hour	125.89
T4hour	127.56
T5hour	128.78
T6hour	128.67

Table 5: Change in Systolic Blood Pressure

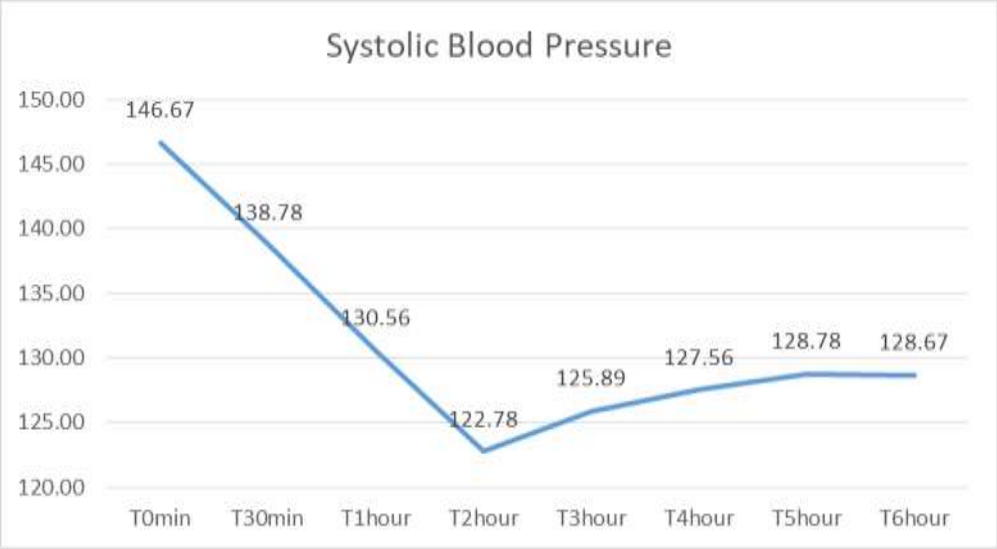


Figure 2: Change in Systolic Blood Pressure

14.3.2. Diastolic Blood Pressure:

Diastolic blood pressure is the bottom number in a blood pressure reading, representing the pressure in the arteries when the heart is resting between beats. It indicates the force of blood against artery walls while the heart fills with blood. For Hypertension, the diastolic blood pressure is more than 80.

The assessment for diastolic Blood Pressure was done at timepoints T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour. The output was studied as change in the Mean diastolic Blood Pressure with time.

The Mean value of the diastolic Blood Pressure was 93.89 , 86.67, 85.22, 82.78, 80.78, 81.67, 82.67 and 85.11 at T0min, T30min, T1hour, T2hour, T3hour,

T4hour, T5hour and T6hour respectively.

The results shows reduction in the diastolic Blood pressure from 30 mins, however the most reduction is observed in 3 hours. The reduced diastolic Heart rate was observed for the whole observation time, i.e. 6 hours.

Timepoint	diastolic Blood Pressure
T0min	93.89
T30min	86.67
T1hour	85.22
T2hour	82.78
T3hour	80.78
T4hour	81.67
T5hour	82.67
T6hour	85.11

Table 6: Change in Diastolic Blood Pressure

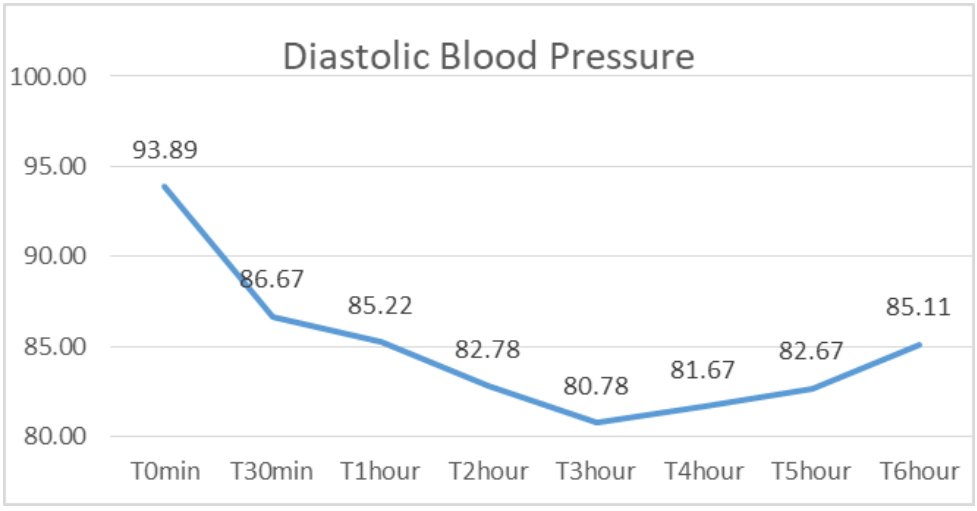


Figure 3: Change in Diastolic Blood Pressure

14.3.3. Heart Rate:

Heart rate, also known as pulse, is the number of times your heart beats per minute. It reflects how efficiently your heart is pumping blood to meet your body's needs. A normal resting heart rate for adults generally falls between 60 and 100 beats per minute. A lower resting heart rate within this range generally indicates better cardiovascular fitness.

The assessment for Heart Rate was done at timepoints T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour. The output was studied as change in

the Mean Heart rate with time.

The Mean value of the Heart Rate was 87.78, 80.56, 77.56, 72.67, 73.67, 75.56, 72.56 and 74.67 at T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour respectively.

The results shows reduction in the Heart Rate from 30 mins, however the most reduction is observed in 2 hours. The reduced diastolic Heart rate was observed for the whole observation time, i.e. 6 hours.

Timepoints	Heart Rate
T0min	87.78
T30min	80.56
T1hour	77.56
T2hour	72.67
T3hour	73.67
T4hour	75.56
T5hour	72.56
T6hour	74.67

Table 6: Change in Heart Rate

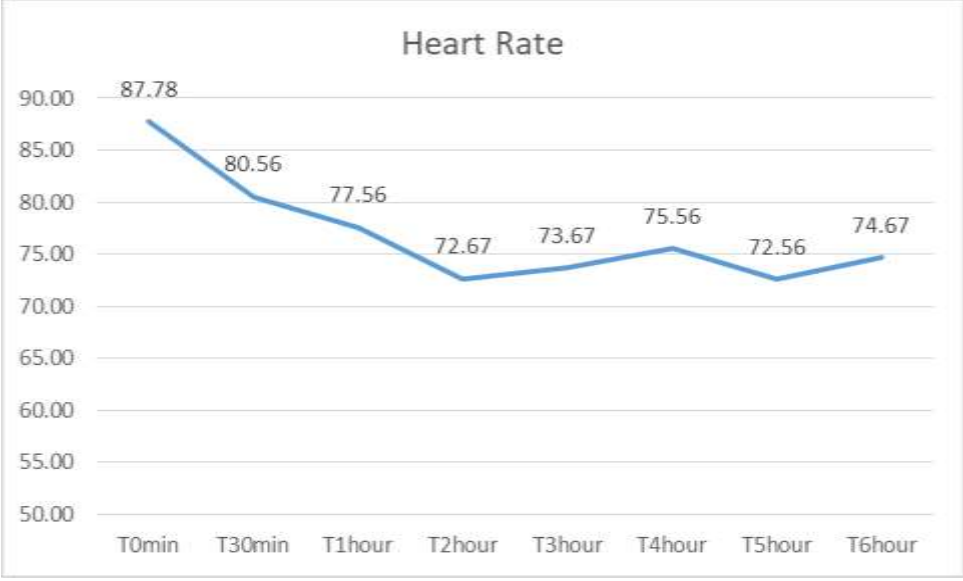


Figure 3: Change in Heart Rate

14.3.4. SGA- Subject's Global Assessment:

Subject's Global Assessment was done for the Chest Pain, Difficulty in Breathing, Anxiety and Dizziness. The assessment was done on the 4 point scale of 0-3 where 0 means No Issue and 3 means severe issue. The output was studied as change in

the mean Score.

The Mean value of the chest pain has not changed in 6 hours. No change was observed in the chest pain. The mean value for Difficulty in breathing has reduced from 0.75 to 0.50 showing some improvement in the breathing difficulty. The mean value for the Anxiety has reduced from 1.17 to 0.92 showing that the test product reduces anxiety. The mean value of Dizziness has reduced from 0.83 to 0.58 in 6 hours, showing a dizziness reducing action.

Parameter	T0min	T6hour
Chest Pain	0.33	0.33
Difficulty in Breathing	0.75	0.50
Anxiety	1.17	0.92
Dizziness	0.83	0.58

Table 7: Change in SGA

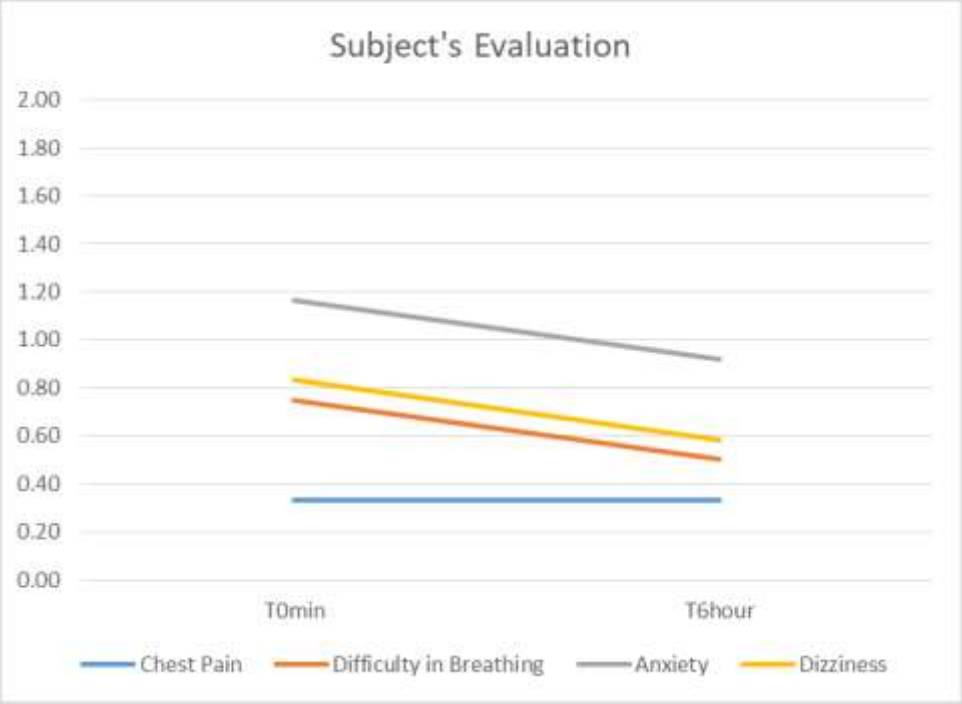


Figure 4: Change in SGA

14.3.12. Other concomitant medications:

All standard treatments were given to the subjects as deemed necessary by the Investigator. Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones

subjects take as their routine prior medication.

15. Discussion:

Out of 66 subjects screened, none were found dropout, 6 screen failure due to out of range BP. 60 subjects who underwent the full trial period.

The mean age of the subjects was 43.08 years in the study. The mean height of the subjects was 159.6 cm. The mean weight of the subjects was 68.25 kg. The BMI of the subjects were 26.83.

Systolic blood pressure is the pressure in your arteries when your heart contracts and pumps blood out. It's the first, or top, number in a blood pressure reading. A healthy systolic blood pressure is generally considered to be below 120 mm Hg. Hypertension, or high blood pressure, is defined as a systolic blood pressure of 130 mm Hg or higher. Systolic pressure, the top number, represents the force of blood against artery walls when the heart beats. The assessment for Systolic Blood Pressure was done at timepoints T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour. The output was studied as change in the Mean systolic Blood Pressure with time. The Mean value of the Systolic Blood Pressure was 146.67, 138.78, 130.56, 122.78, 125.89, 127.56, 128.78 and 128.67 at T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour respectively. The results shows reduction in the Systolic Blood pressure from 30 mins, however the most reduction is observed in 2 hours. The reduced Systolic Heart rate was observed for the whole observation time, i.e. 6 hours.

Diastolic blood pressure is the bottom number in a blood pressure reading, representing the pressure in the arteries when the heart is resting between beats. It indicates the force of blood against artery walls while the heart fills with blood. For Hypertension, the diastolic blood pressure is more than 80. The assessment for diastolic Blood Pressure was done at timepoints T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour. The output was studied as change in the Mean diastolic Blood Pressure with time.

The Mean value of the diastolic Blood Pressure was 93.89 , 86.67, 85.22, 82.78, 80.78, 81.67, 82.67 and 85.11 at T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour respectively. The results shows reduction in the

diastolic Blood pressure from 30 mins, however the most reduction is observed in 3 hours. The reduced diastolic Heart rate was observed for the whole observation time, i.e. 6 hours.

Heart rate, also known as pulse, is the number of times your heart beats per minute. It reflects how efficiently your heart is pumping blood to meet your body's needs. A normal resting heart rate for adults generally falls between 60 and 100 beats per minute. A lower resting heart rate within this range generally indicates better cardiovascular fitness. The assessment for Heart Rate was done at timepoints T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour. The output was studied as change in the Mean Heart rate with time. The Mean value of the Heart Rate was 87.78, 80.56, 77.56, 72.67, 73.67, 75.56, 72.56 and 74.67 at T0min, T30min, T1hour, T2hour, T3hour, T4hour, T5hour and T6hour respectively. The results shows reduction in the Heart Rate from 30 mins, however the most reduction is observed in 2 hours. The reduced diastolic Heart rate was observed for the whole observation time, i.e. 6 hours.

Subject's Global Assessment was done for the Chest Pain, Difficulty in Breathing, Anxiety and Dizziness. The assessment was done on the 4 point scale of 0-3 where 0 means No Issue and 3 means severe issue. The output was studied as change in the mean Score. The Mean value of the chest pain has not changed in 6 hours. No change was observed in the chest pain. The mean value for Difficulty in breathing has reduced from 0.75 to 0.50 showing some improvement in the breathing difficulty. The mean value for the Anxiety has reduced from 1.17 to 0.92 showing that the test product reduces anxiety. The mean value of Dizziness has reduced from 0.83 to 0.58 in 6 hours, showing a dizziness reducing action.

No adverse event was reported during the study.

Concomitant medications were allowed only for Fever or any physical injury during the study treatment period on SOS basis apart from the ones subjects take as their routine prior medication.

There were no protocol violations and deviations reported. There were none of the patients who lost to follow up.

None of the patients withdrawn the consent.

16. Conclusion:

In conclusion, Shuddhi Dr. B P Care tablets showed significant improvement Hypertension with significant reduction in the Blood Pressure and heart rate in 2-3 hours. The anti-hypertensive action of the tablets stays for the complete treatment period of 6 hours. Reduction in the Anxiety, Dizziness and breathing issues was also observed with no quick impact on the chest pain. No, adverse events were observed during the study.

17. Reference List

1. https://www.who.int/news-room/fact-sheets/detail/hypertension