



indoco remedies limited

INDOCO HOUSE, 166 C. S. T. ROAD, SANTACRUZ (EAST), MUMBAI - 400 098 (INDIA) • Website : www.indoco.com
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February 04, 2014

To
The Listing Department
National Stock Exchange of India Limited
Exchange Plaza,
Bandra – Kurla Complex
Bandra (East)
Mumbai – 400 051

To
The Listing Department
Bombay Stock Exchange Limited
Floor 25, P. J. Towers,
Dalal Street,
Mumbai – 400 001

Dear Sirs,

Sub: Certificate of Good Manufacturing Practice (GMP) Compliance of a Manufacturer

Indoco Remedies has received from State Institute for Drug Control (SUKL), Czech Republic, Certificate of Good Manufacturing Practice (GMP) Compliance for their Goa Plant II located at L-32,33,34 Verna Industrial Estate, Goa 403722. The Certificate pertains to manufacture of Sterile Ophthalmic Formulations.

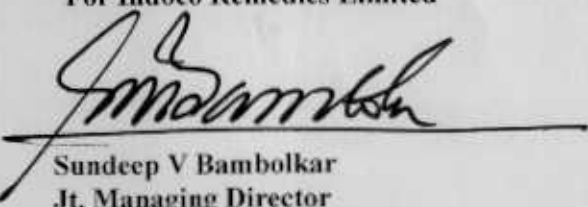
The Plant has been inspected in connection with marketing authorization(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of the Directive 2001/83/EC transposed in the following national legislation: Section 101 paragraph 3 of the Act No. 378/2007 Coll., on Pharmaceuticals and on Amendment to Some Related Acts (the Act of Pharmaceuticals) as amended. From the knowledge gained during inspection of Plant II, the latest which was conducted on 09/11/2013 it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

Directive 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 6th November 2001 relates to control of medicinal products for human use in the European Union.

The GMP certificate confirms that the Plant fulfills the GMP recommendation of World Health Organization (WHO)

A copy of the said certificate is enclosed herewith.

Yours faithfully,
For Indoco Remedies Limited



Sundeep V Bambolkar
Jt. Managing Director

☒ Část 2
Humánní léčivé přípravky

1 VÝROBNÍ OPERACE

1.1 Sterilní přípravky

1.1.1 Asepticky připravované (výrobní operace pro následující
lékové formy)

1.1.1.6 Ostatní asepticky připravované – oční
přípravky

1.5 Balení

1.5.2 Sekundární balení

1.6 Kontrola jakosti

1.6.1 Mikrobiologické: zkouška na sterilitu

1.6.2 Mikrobiologické: mikrobiologická nezávadnost

1.6.3 Chemické/Fyzikální

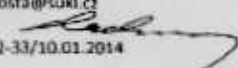
Jakákoli omezení nebo vysvětlení vztahující se k rozsahu
certifikátu:

Datum: 28.01.2014

Jméno a podpis oprávněné osoby příslušného orgánu České
republiky

František Chuchma
vedoucí inspekčního odboru

Státní ústav pro kontrolu léčiv
Šrobárova 48
100 41 Praha 10
Česká republika
e-mail: posta@sukl.cz
telefon: +420 272 185 832
fax: +420 271 732 377

Certifikát SVP sp.zn.: sukl146686/2013
Datum: 28.01.2014
Strana 2 z 2
Jméno: František Chuchma
e-mail: posta@sukl.cz
Podpis: 
F-INS-002-33/10.01.2014

☒ Part 2
Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.1 Sterile Products

1.1.1 Aseptically prepared (processing operations for the
following dosage forms)

1.1.1.6 Other aseptically prepared products -
Ophthalmic formulations

1.5 Packaging

1.5.2 Secondary packing

1.6 Quality control testing

1.6.1 Microbiological: sterility

1.6.2 Microbiological: non-sterility

1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of
this certificate:

Date: 28.01.2014

name and signature of the authorised person of the
competent authority of the Czech Republic

František Chuchma
Head of the Inspection section

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100 41 Prague 10
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phone: +420 272 185 832
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GMP Certificate Ref.No.: sukl146686/2013
Date: 28.01.2014
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Name
Phone number: +420 272 185 832
Signature of the authorised person of the competent authority