

December 08, 2025

BSE Limited

Department of Corporate Relationship
1st Floor, New Trade Ring, Rotunda Building
Phiroze Jeejeebhoy Towers
Dalal Street, Mumbai- 400001
Scrip Code: 524742

National Stock Exchange of India Ltd

Department of Corporate Services
Exchange Plaza, 5th Floor,
C-1, Block G, Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
Scrip Code: CAPLIPOINT.

Dear Sir/Madam,

Sub: Press Release – Receipt of USFDA Approval

Attaching herewith a Press Release regarding receipt of final approval by our Subsidiary, Caplin Steriles Limited, from the United States Food and Drug Administration (USFDA) for the Abbreviated New Drug Application (ANDA) Acetaminophen Injection, 1000 mg/100 mL (10 mg/mL) Single-dose Infusion Bags, a generic therapeutic equivalent version of the Reference Listed Drug (RLD) from Mallinckrodt Pharmaceuticals Ireland Limited.

Request you to take the same on record.

Thanking You,

Sincerely Yours

For Caplin Point Laboratories Limited

Venkatram G

General Counsel & Company Secretary
Membership No. A23989

Encl: A/a

CAPLIN STERILES GETS USFDA APPROVAL FOR ACETAMINOPHEN INJECTION, INFUSION BAGS

Chennai, Dec 08th, 2025: Caplin Steriles Limited (Caplin), a Subsidiary Company of Caplin Point Laboratories Limited (BSE: CAPPL (524742), NSE: CAPLIPOINT), has been granted **final approval** from the United States Food and Drug Administration (**USFDA**) for its Abbreviated New Drug Application (ANDA) **Acetaminophen Injection, 1000 mg/100 mL (10 mg/mL) Single-dose Infusion Bags**, a generic therapeutic equivalent version of the Reference Listed Drug (RLD) from Mallinckrodt Pharmaceuticals Ireland Limited.

Acetaminophen Injection is indicated for the management of mild to moderate pain in adult and pediatric patients 2 years and older; the management of moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years and older; and the reduction of fever in adult and pediatric patients. According to IQVIA™ (IMS Health), Acetaminophen Injection had US sales of approximately \$86 million for the 12-month period ending October 2025.

About Caplin Steriles Limited

Caplin Steriles Limited, a Subsidiary of Caplin Point Laboratories Limited, is a fast growing sterile product manufacturing company that is approved by several regulatory agencies such as US FDA, EU-GMP, ANVISA and INVIMA. Caplin Steriles Limited has developed and filed **53 ANDAs** in USA on its own and with partners (including four ANDAs acquired from third parties), with **43 approvals** so far.

The Company is also working on a portfolio of **40+ simple and complex Injectable and Ophthalmic products** that it intends to file over the next 4 years. The company also has multiple products filed with several approvals in non-US markets such as Australia, Canada, Mexico, Chile, UAE, Hong Kong, Malaysia, Saudi Arabia etc.

About Caplin Point Laboratories Limited

Caplin Point Laboratories Limited is a fast-growing pharmaceutical company with a unique business model catering predominantly to emerging markets of Latin America and Africa. The Company has state of the art manufacturing facilities that cater to a complete range of finished dosage forms. Caplin Point is one of the few companies to show consistent high-quality growth in cash flows, Profitability and Revenues over the last 15 years.

Caplin Point has appeared on **Forbes “Asia’s 200 Best Under a Billion”** list for an unprecedented **7th time in the last 10 years**, and was awarded **“The Emerging Company of 2018”** and **“Business Excellence Award for 2019”** by Economic Times.

CAUTIONARY STATEMENT:

This press release contains certain forward-looking statements. Any forward-looking statement applies only on the date of this press release. By their nature, forward-looking statements are subject to a number of known and unknown risks and uncertainties that may or may not occur in the future and as a result of which the actual results and performance may differ substantially from the expected future results or performance expressed or implied in the forward-looking statements. No warranties or representations are made as to the accuracy, achievement or reasonableness of such statements, estimates or projections, and Caplin Point has no obligation to update any such information or to correct any inaccuracies herein or omission here from which may become apparent.

For details, please contact:

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