

**February 24, 2026**

**BSE Limited**

Department of Corporate Relationship  
1<sup>st</sup> 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, 5<sup>th</sup> 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 for Sodium Phosphates Injection**

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) Sodium Phosphates Injection USP, 15mM P/5mL, 45mM P/15mL and 150mM P/50mL (3mM P/mL) Single-Dose Vials, a generic therapeutic equivalent version of the Reference Listed Drug (RLD) from Hospira, Inc., USA (NDA 018892).

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 SODIUM PHOSPHATES INJECTION**

**Chennai, February 24<sup>th</sup>, 2026:** 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) **Sodium Phosphates Injection USP, 15mM P/5mL, 45mM P/15mL and 150mM P/50mL (3mM P/mL) Single-Dose Vials**, a generic therapeutic equivalent version of the Reference Listed Drug (RLD) from Hospira, Inc., USA (NDA 018892).

**Sodium Phosphates Injection** is indicated as a source of phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific parenteral fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions. According to IQVIA<sup>TM</sup> (IMS Health), Sodium Phosphates Injection USP, 15mM P/5mL, 45mM P/15mL and 150mM P/50mL (3mM P/mL) Single-Dose Vials had total US sales of approximately \$67 million for the 12-month period ending December 2025.

### **About Caplin:**

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 7<sup>th</sup> time in the last 10 years, and was awarded "The Emerging Company of 2018" and "Business Excellence Award for 2019" by Economic Times.

Caplin Steriles Limited (CSL), 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. CSL has developed and filed 54 ANDAs in USA on its own and with partners, with 51 approvals (including acquired ANDA's) so far. CSL is also working on a portfolio of 55+ simple and complex Injectable and Ophthalmic products that it intends to file over the next 4 years. CSL also has multiple products filed with several approvals in non-US markets such as Australia, Canada, Mexico, Chile, UAE, Hong Kong, Malaysia, South Africa, Saudi Arabia etc. Caplin One Labs Limited (COL), a Subsidiary of Caplin Point Laboratories Limited, is into the second year of its operations at its oncology unit in Kakkalur, with various ongoing projects in different stages of completion for generic and specialty products for both regulated and other markets. COL holds 5 approved ANDAs for Injectable and Ophthalmic products.

**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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