



Bharat Parenterals Limited

Registered Office & Works:
Survey No.: 144-A, Jarod-Samlaya Road, Vill. Haripura,
Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Mobile : 99099 28332
E-mail: info@bplindia.in, Web.: www.bplindia.in
CIN NO: L24231GJ1992PLC018237
(WHO-GMP CERTIFIED ★ STAR EXPORT HOUSE)

Date: April 21, 2026

**To,
BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort,
Mumbai - 400 001**

Scrip Code: 541096

Dear Sir/Madam,

**Sub: Outcome of U.S FDA inspection at Innoxel Lifesciences Pvt. Ltd,
Subsidiary Company of Bharat Parenterals Limited.**

Pursuant to Regulation 30 of the SEBI (Listing Obligations & Disclosure Requirements) Regulations, 2015, this is to inform that the United States Food and Drug Administration (U.S FDA) has conducted a surprise / unannounced inspection at our Subsidiary Company Namely Innoxel Lifesciences Pvt. Ltd. at its finished dosage manufacturing facility in Vadodara, Gujarat. The inspection was conducted from April 13, 2026 to April 17, 2026 and April 20, 2026.

Please find the enclosed Company statement titled “**Outcome of U.S. FDA Inspection at Innoxel Lifesciences Private Limited**”

The Company is committed to maintain the highest quality standards and compliance at all times.

We request you to kindly take the same on record.

Thanking You,

For, **Bharat Parenterals Limited**

Sharmin Soni
Company Secretary & Compliance Officer
ICSI M. No: A75694



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PRESS RELEASE

Bharat Parenterals Limited

Vadodara, April 21, 2026

Outcome of U.S. FDA Inspection at Innoxel Lifesciences Private Limited

Bharat Parenterals Limited (BSE: 541096) hereby informs that its subsidiary, Innoxel Lifesciences Private Limited, was subject to a surprise / unannounced inspection by the United States Food and Drug Administration (U.S. FDA) at its finished dosage manufacturing facility in Vadodara, Gujarat.

The inspection of the **General Injectables Block** was conducted from **April 13, 2026 to April 17, 2026 and April 20, 2026**.

At the conclusion of the inspection, the U.S. FDA has issued five (5) observations under a Voluntary Action Indicated (VAI) classification. The Company's subsidiary will submit its response within the prescribed timelines. The final Establishment Inspection Report (EIR) is awaited.

The General Injectables Block is a key manufacturing facility supporting the supply of sterile injectable formulations to regulated markets, including the United States and the European Union.

For reference, the regulatory track record of the facility is as follows:

- **U.S. FDA inspection (April-May 2025):** EIR received on July 30, 2025
- **EU GMP inspection by Belgium's Federal Agency for Medicines and Health Products (FAMHP) (November 24-28, 2025):** Zero critical and zero major observations. EUGMP Certificate for all 4 lines issued on March 06, 2026.
- **U.S. FDA inspection (April 13-17, 20, 2026):** Five observations issued under VAI classification

Commenting on the development, the management stated:

A surprise U.S. FDA inspection of a sterile injectables block, concluding with few procedural observations under a VAI classification, reflects the consistency of the quality and compliance systems at Innoxel. The Company continues to focus on strengthening its manufacturing and regulatory capabilities.

About Bharat Parenterals Limited

Bharat Parenterals Limited is a BSE-listed pharmaceutical manufacturer with over three decades of formulation expertise, exporting to 40+ countries. Through its subsidiaries, **Innoxel Lifesciences Private Limited** (complex dosage forms, U.S. FDA and EU-focused) and Varenyam Healthcare (domestic branded generics), the Group operates an integrated platform across sterile injectables, oral solids, and specialty formulations.
