

## February 19, 2025

National Stock Exchange of India Limited, Exchange Plaza, Bandra Kurla Complex, Bandra (E), Mumbai-400051 BSE Limited Phiroze Jeejeebhoy Towers, Dalal Street, Fort, Mumbai-400001

Symbol: ORCHPHARMA

Scrip Code: **524372** 

## Subject: Press Release - Orchid Pharma Limited ("the Company")

Dear Sir/Madam,

In accordance to Regulation 30 read with Schedule III of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015, as amended, kindly find enclosed the Press Release titled **"Orchid Pharma's Alathur API facility successfully completes USFDA inspection, maintaining its position as India's only USFDA approved facility for Sterile Cephalosporins"**.

You are requested to take the above information on record.

Thanking You, For **Orchid Pharma Limited** 

Kapil Dayya Company Secretary & Compliance Officer Mem. No.- F10698

Encl. As above



## Orchid Pharma's Alathur API facility successfully completes USFDA inspection, maintaining its position as India's only USFDA approved facility for Sterile Cephalosporins

Orchid's Alathur facility also secures EU GMP certificate renewal for Cephalosporin API manufacturing

**New Delhi, 19 February 2025:** Orchid Pharma Ltd., a vertically integrated pharmaceutical company spanning the entire pharmaceutical value chain from discovery to delivery, today announced the successful completion of a surprise U.S. Food and Drug Administration (USFDA) inspection at its Active Pharmaceutical Ingredient (API) manufacturing facility in Alathur, Tamil Nadu. The inspection, which commenced on 10 February 2025 and concluded on 18 February 2025, resulted in seven minor observations, none of which pertain to the data integrity of the facility. This successful inspection maintains Orchid Pharma's distinguished position as India's only USFDA-approved facility for Sterile Cephalosporins. It reaffirms Orchid Pharma's compliance with USFDA regulatory standards, reinforcing the company's commitment to quality and excellence in pharmaceutical manufacturing.

The Alathur facility specializes in the production of Cephalosporin antibiotics, a critical class of life-saving drugs. Orchid Pharma remains committed to maintaining the highest standards in pharmaceutical manufacturing to ensure continuous supply to the U.S. and global markets.

Additionally, the Alathur API facility has also secured the renewal of its EU Good Manufacturing Practice (GMP) certificate following a successful inspection. This further validates the facility's compliance with European regulatory requirements and its capability to serve global markets.

Speaking on the achievement, **Mr. Manish Dhanuka, Managing Director, Orchid Pharma**, said: "The successful completion of the USFDA inspection underscores our unwavering commitment to quality, compliance, and global regulatory standards. Our teams have consistently worked towards upholding the highest manufacturing practices, ensuring the continued supply of worldclass antibiotics. As India's only USFDA approved facility for Sterile Cephalosporins, we take immense pride in maintaining this exclusive status that sets us apart in the global pharmaceutical landscape. The renewal of the EU GMP certificate further strengthens our position as a trusted pharmaceutical manufacturer for global markets."

With these regulatory milestones, Orchid Pharma continues to reinforce its reputation as a global leader in antibiotic manufacturing, supplying high-quality APIs to key international markets.



## About Orchid Pharma Limited:

Established in 1992 as an export-oriented unit (EOU), Orchid Pharma Ltd. (Orchid) is a vertically integrated Company spanning the entire pharmaceutical value chain with established credentials in research, manufacturing, and marketing.

Orchid, is the only Indian Pharmaceutical Company, to ever have invented a New Chemical Entity (NCE, also colloquially called New Drug). The molecule is out licensed (on Royalty model) and now approved in US and Europe.

Orchid is a pioneer in Production of Quality Cephalosporins especially the Sterile Products, for which it is the one out of the only three USFDA approved facilities in the world, and the only one from India. Besides this, the facility has other approvals like EU GMP, ANVISA and PMDA.