



CERTIFICATE OF COMFORMITY

2025

Facility Registration

This certifies that:

Establishment : ITRACE PHARMACEUTICAL SOLUTIONS PRIVATE LIMITED

Address : Unit No. F-7, D-Wing, Udyog Bhavan 2, Plot No. K-2 Additional Ambernath
MIDC, Ambernath East, Thane, 421506, India (IND)

Manufacturer: ITRACE PHARMACEUTICAL SOLUTIONS PRIVATE LIMITED

UEI Number: 854208771

Is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as of the date stated hereof.

U.S. FDA Establishment (FEI) Registration Number.: **3018238790**

This certificate is issued by American Business Association Rating Inc, California affirms that the above stated facility is registered with the Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as effective by ITRACE PHARMACEUTICAL SOLUTIONS PRIVATE LIMITED as of the date hereof, and ITRACE PHARMACEUTICAL SOLUTIONS PRIVATE LIMITED will confirm that such registration remains effective upon request and presentation of this certificate until December 31, 2025, unless such registration has been terminated after issuance of this certificate.

Registration information can also be found on the FDA website, it can be found by entering the company name.

The website is <https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>