



# Lake Chemicals Pvt. Ltd.

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## CERTIFICATE OF ANALYSIS

**PRODUCT NAME** : LORAZEPAM **PHARMACOPOEIA** : Ph.Eur.  
**BATCH No.** : 814025003A **A.R No** : FPR/25/146  
**MFG. DATE** : MAY - 2025 **EXPIRY DATE** : APRIL - 2030  
**DATE OF ANALYSIS** : 27/05/2025 **CONTROL No** : C/25/146/04  
**MANUFACTURED BY** : M/s LAKE CHEMICALS PVT. LTD, BANGALORE, INDIA

| TESTS                                        | LIMITS                                                                                                                                       | RESULT                                                             |
|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| APPEARANCE                                   | A white or almost white, crystalline powder. It shows polymorphism.                                                                          | White crystalline powder, It shows polymorphism.                   |
| SOLUBILITY                                   | Practically insoluble in water, sparingly soluble in ethanol (96%), sparingly soluble or slightly soluble in methylene chloride.             | Complies                                                           |
| IDENTIFICATION (BY IR)                       | The IR absorption spectrum of sample should be concordant with the IR absorption spectrum of Lorazepam working standard                      | Complies                                                           |
| RELATED SUBSTANCES<br>(BY HPLC)              | a) Lorazepam Impurity B NMT 0.10%<br>b) Lorazepam Impurity D NMT 0.10%<br>c) Unspecified impurity NMT 0.10%<br>d) Total impurities NMT 0.20% | Below Disregard Limit<br>Not detected<br>0.05%<br>0.06%            |
| LOSS ON DRYING                               | NMT 0.50%                                                                                                                                    | 0.20%                                                              |
| SULPHATED ASH                                | NMT 0.10%                                                                                                                                    | 0.05%                                                              |
| ASSAY( By Potentiometry)<br>(ON DRIED BASIS) | 98.5% to 102.0%                                                                                                                              | 99.1%                                                              |
| **RESIDUAL SOLVENTS<br>(BY GC)               | Methanol NMT 3000 ppm<br>Toluene NMT 890 ppm<br>Ethyl acetate NMT 5000 ppm<br>n-Propyl Alcohol NMT 5000 ppm<br>Acetone NMT 5000 ppm          | Not detected<br>Not detected<br>32 ppm<br>Not detected<br>2684 ppm |
| *PARTICLE SIZE                               | 90 % less than 20 microns                                                                                                                    | 8.2microns                                                         |

\*\*Additional In-House test

\*Additional tests and limits as per party's requirements.

**CONCLUSION:** THE PRODUCT COMPLIES WITH THE ABOVE SPECIFICATIONS.

PREPARED BY :   
(OFFICER - QC)  
DATE : 27/05/2025  
LC/QC/F/022/R3

CHECKED BY :   
(HEAD -QC)  
DATE : 27/05/2025

APPROVED BY :   
(HEAD -QA)  
DATE : 27/05/2025  
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Visit Us at : [www.lakechemicals.com](http://www.lakechemicals.com)

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GST NO : 29AAACL3683K1Z3

