



Lake Chemicals Pvt. Ltd.

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : DIAZEPAM **PHARMACOPOEIA** : Ph. Eur.
BATCH No. : 875025002A **REFERENCE**
MFG. DATE : MAY - 2025 **A.R No** : FPR/25/154
EXPIRY DATE : APRIL - 2030
DATE OF ANALYSIS : 29/05/2025 **CONTROL NO.** : C/25/154/01
MANUFACTURED BY : M/s LAKE CHEMICALS PVT. LTD, BANGALORE, INDIA

TESTS	SPECIFICATION	RESULT
APPEARANCE	A white or almost white, crystalline powder	White crystalline Powder
SOLUBILITY	Very slightly soluble in water, soluble in ethanol (96%)	Complies
IDENTIFICATION A. BY IR	A. The IR absorption spectrum of sample should be concordant with the IR absorption spectrum of Diazepam working standard.	Complies
RELATED SUBSTANCES (By HPLC)	i) Impurity - A NMT 0.10% ii) Impurity - B NMT 0.10% iii) Impurity -E NMT 0.10% iv) Any Unspecified Impurities NMT0.10% v) Total Impurities NMT 0.20%	Below disregard limit Not detected Below disregard limit Below disregard limit 0.05%
LOSS ON DRYING	NMT 0.50%	0.22%
SULPHATED ASH	NMT 0.10%	0.05%
ASSAY (By Potentiometry) (On dried basis)	99.0% w/w to 101.0% w/w	100.5%
**RESIDUAL SOLVENTS (By GC)	Methanol NMT 3000 ppm Ethyl Acetate NMT 5000 ppm Toluene NMT 890 ppm Isopropyl Alcohol NMT 5000 ppm Ethanol NMT 5000 ppm	69 ppm Not detected Not detected 36 ppm Not detected
*PARTICLE SIZE	90% Less than 20 microns	7.1microns

**Additional In-house Test

*Additional tests and limits as per party's requirement.

CONCLUSION: THE PRODUCT COMPLIES WITH THE ABOVE SPECIFICATION.

PREPARED BY : *AA* CHECKED BY : *me* APPROVED BY : *G. V. R.*
(OFFICER - QC) : 29/05/2025 (HEAD - QC) : 29/05/2025 (HEAD - QA) : 29/05/2025
DATE : DATE : DATE :
LC/QC/F/022/R3 Page: 1 of 1

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GST NO : 29AAACL3683K1Z3

