



Lake Chemicals Pvt. Ltd.

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : LORAZEPAM PHARMACOPOEIA : Ph.Eur.9.0
INJECTABLE GRADE REFERENCE
BATCH No. : 81400620006 A.R No : FPR/20/147
MFG. DATE : JUNE-2020 EXPIRY DATE : MAY-2025
DATE OF ANALYSIS : 27/10/2023 CONTROL No : C/20/147/03
MANUFACTURED BY : M/s LAKE CHEMICALS PVT. LTD, BANGALORE, INDIA

TESTS	LIMITS	RESULT
APPEARANCE	A white or almost white, crystalline powder.	A white crystalline powder.
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 (BY HPLC)	a) Lorazepam Impurity B NMT 0.10% b) Lorazepam Impurity D NMT 0.10% c) Unspecified impurity NMT 0.10% d) Total impurities NMT 0.20%	0.06% 0.06% Below Disregard Limit 0.12%
LOSS ON DRYING	NMT 0.50%	0.33%
SULPHATED ASH	NMT 0.10%	0.05%
ASSAY(By Potentiometry) (ON DRIED BASIS)	98.5% to 102.0%	99.8%
**RESIDUAL SOLVENTS (BY GC)	Methanol NMT 3000 ppm Toluene NMT 890 ppm Ethyl acetate NMT 5000 ppm n-Propyl Alcohol NMT 5000 ppm Acetone NMT 5000 ppm	Not detected 42 ppm Not detected Not detected 240 ppm
*PARTICLE SIZE	90% less than 20 microns	6.922 microns
*TEST FOR ENDOTOXINS	NMT 100.0EU/mg	<100.0EU/mg
* MICROBIOLOGY TEST	(i) Total aerobic microbial count NMT 1000 CfU/gm (ii) Total combined yeast & mould count NMT 100Cfu/gm (iii) E.Coli Should be absent/gm (iv) Salmonella Should be absent/10gm (v) Staphylococcus aureus Should be absent/gm (vi) Pseudomonas aeruginosa Should be absent/gm	< 10 CfU/gm < 10 CfU/gm Absent Absent Absent Absent

**Additional In-House test

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

CONCLUSION: THE PRODUCT COMPLIES WITH THE ABOVE SPECIFICATIONS.

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

CHECKED BY :
(HEAD -QC)
DATE :

APPROVED BY :
(HEAD -QA)
DATE :

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