

1804000384



Lake Chemicals Pvt. Ltd.

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : CLOBAZAM PHARMACOPOEIA : EP.9
BATCH No. : 80400218002 REFERENCE :
MFG. DATE : FEBRUARY-2018 A.R No : FPR/18/037
DATE OF ANALYSIS : 12/02/2018 EXPIRY DATE : JANUARY -2023
MANUFACTURED BY : M/s LAKE CHEMICALS PVT. LTD, BANGALORE, INDIA. CONTROL No : C/18037/01

TESTS	SPECIFICATION	RESULT
APPEARANCE	White or almost white, crystalline powder	Almost White crystalline powder.
SOLUBILITY	Slightly soluble in water, freely soluble in methylene chloride, sparingly soluble in alcohol.	Complies
IDENTIFICATION (By IR)	The IR absorption spectrum of sample should be concordant with IR absorption spectrum of Clobazam working standard	Complies
RELATED SUBSTANCES (By HPLC)	a) Impurity A NMT 0.50% b) Any other impurity NMT 0.20% c) Total other impurities NMT 1.0%	0.21% 0.08% 0.08%
LOSS ON DRYING	NMT 0.50 %	0.20%
SULPHATED ASH	NMT 0.10%	0.05%
ASSAY (By UV) (ON DRIED BASIS)	97.5% to 103.0% w/w	99.2%
**RESIDUAL SOLVENTS (BY GC-MS)	A) Methanol NMT 3000 ppm Ethyl acetate NMT 5000 ppm Hexane NMT 290 ppm Diethylformamide NMT 880 ppm B) Ethylene dichloride NMT 5 ppm	Not detected 710 ppm Not detected Not detected Not detected
*PARTICLE SIZE	90 % Should be less than 15 microns 10% Should be between 15 to 20 microns	Complies

** Additional In-house Test.

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

CONCLUSION: THE PRODUCT COMPLIES WITH THE ABOVE SPECIFICATION.

PREPARED BY : *[Signature]*
(OFFICER - QC)

CHECKED BY : *[Signature]*
(HEAD - QC)

APPROVED BY : *[Signature]*
(HEAD - QA)

DATE : 12/02/2018

DATE

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LC/QC/F/022/R2

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