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Lake Chemicals Pvt. Ltd.

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : CLOBAZAM PHARMACOPOEIA REFERENCE : Ph.Eur 7.0
BATCH No. : 80400215004 A.R No : FPR/15/045
MFG. DATE : FEBRUARY-2015 RETEST DATE : JANUARY-2020
DATE OF ANALYSIS : 24/02/2015 CONTROL No : C/15/045/03
MANUFACTURED BY : M/s LAKE CHEMICALS PVT. LTD, BANGALORE, INDIA

TESTS	SPECIFICATION	RESULT
APPEARANCE	White or almost white, crystalline powder	white powder
SOLUBILITY	Freely soluble in methylene chloride, sparingly soluble in Ethanol (95%).	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%	0.12% 0.06% 0.06%
LOSS ON DRYING	NMT 0.50 %	0.23%
SULPHATED ASH	NMT 0.10%	0.04%
ASSAY (By UV) (ON DRIED BASIS)	97.0% to 103.0% w/w	100.3%
**RESIDUAL SOLVENTS (BY GC)	A)Methanol NMT 3000 ppm Ethyl acetate NMT 5000 ppm Hexane NMT 290 ppm Dimethylformamide NMT 880 ppm B)Ethylene dichloride NMT 5 ppm	Not detected Not detected Not detected Not detected Not detected
*PARTICLE SIZE	90% Less than 10 microns 10% between 15 – 20 microns	Complies Complies

** Additional In-house Test

* Additional tests and limits as per party's requirement

CONCLUSION: THE PRODUCT COMPLIES WITH THE ABOVE SPECIFICATION.

PREPARED BY : *G. real* CHECKED BY

APPROVED BY

(OFFICER - QC)

DATE

09/07/2015

(HEAD - QC)

DATE

K. Shw
09/07/2015

(HEAD - QA)

DATE

M. K. ...

09/07/2015

LC/QC/F/022/R2

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