

## Lake Chemicals Pvt. Ltd.

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PRODUCT NAME

CLONAZEPAM

PHARMACOPOEIA REFERENCE

: USP-37

BATCH No.

80700215006

A.R No

FPR/15/052

MFG. DATE

FEBRUARY-2015

RETEST/EXPIRY DATE

JANUARY-2020

DATE OF ANALYSIS

28/02/2014

CONTROL No

: C/15/052/01

MANUFACTUREDBY

M/s LAKE CHEMICALS PVT. LTD, BANGALORE, INDIA

TESTS	SPECIFICATION	)N	1 ****
DESCRIPTION	A light yellow powder, having a faint odor.		RESULT A light yellow powde having a faint odor
SOLUBILITY	Insoluble in water; Sparingly soluble in acetone and in Chloroform; slightly soluble in alcohol and in ether.		Complies
IDENTIFICATION	By IR Spectrophotometry: The IR absorption spectrum of sample Should be concordant with the IR absorption spectrum of Clonazepam working standard		Complies
MELTING RANGE	Between 237°C and 240°C		239°C to 240°C
LOSS ON DRYING	NMT 0.50%		A 4790 -
RESIDUE ON IGNITION	NMT 0.10%		0.17%
HEAVY METALS	NMT 0.002%		0.04%
LIMIT OF CLONAZEPAM RELATED COMPOUND 'C' (By TLC)		NMT 0.20%	<0.20% <0.20%
RELATED COMPOUNDS By HPLC	a) Clonazepam related compound A b) Clonazepam related compound B c) Any other impurity d) Total other impurities	NMT 0.10% NMT 0.10% NMT 0.20% NMT 0.30%	Not detected Not detected 0.06% 0.12%
ASSAY BY HPLC (ON DRIED BASIS)		98.0% to 102.0%	99.9%
**RESIDUAL SOLVENTS By GC)	Methanol Acetone Toluene Iso propyl alcohol	NMT 3000 ppm NMT 5000 ppm NMT 890 ppm NMT 5000 ppm	Not detected 100 ppm Not detected Not detected
PARTICLE SIZE	98% Less than 10 microns 90% Less than 5 microns		Complies Complies

<sup>\*\*</sup> Additional In-house test

CONCLUSION: THE PRODUCT COMPLIES WITH THE ABOVE SPECIFICATIONS.

PREPARED BY

Gricli CHECKED BY

APPROVED BY

(OFFICER - QC)

DATE

(HEAD-QC)

2.8 102-12015 (HEAD-QA) DATE

LC/QC/F/022/R2

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<sup>\*</sup> Additional tests and limits as per party's requirement