



Lake Chemicals Pvt. Ltd.

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CERTIFICATE OF ANALYSIS

PRODUCT NAME : ZOLPIDEM TARTRATE PHARMACOPOEIA : Ph.Eur-9.0
BATCH No. : 82800420007 REFERENCE : FPR/20/099
MFG. DATE : APRIL-2020 A.R No : MARCH-2025
DATE OF ANALYSIS : 22/04/2020 EXPIRY DATE : C/20/099/01
MANUFACTURED BY : M/s LAKE CHEMICALS PVT. LTD, BANGALORE, INDIA.

TEST	SPECIFICATIONS	RESULTS
DESCRIPTION	A White or almost white, hygroscopic, crystalline powder.	A white hygroscopic crystalline powder
SOLUBILITY	Slightly soluble in water, sparingly soluble in methanol, practically insoluble in methylene chloride.	Complies
IDENTIFICATION A) BY IR	A. The IR absorption spectrum of sample should be concordant with the IR absorption spectrum of Zolpidem tartrate working standard.	Complies
B) BY TLC	B. The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution(a).	Complies
C) Reaction (b) for Tartrates	C. Should comply	Complies
APPEARANCE OF SOLUTION	The solution is clear and not more intensely coloured than YS6 or BYS6	Complies
RELATED SUBSTANCES (BY HPLC)	Impurity-B NMT 0.15% Any individual impurity NMT 0.10% Total Impurities NMT 0.20%	Not detected 0.07% 0.13%
SULPHATED ASH		0.05%
WATER CONTENT (BY KF)		0.90%
ASSAY (BY POTENTIOMETRY) (ON ANHYDROUS BASIS)	98.5 % to 101.0 % w/w	99.6%
**RESIDUAL SOLVENTS (BY GC)	Methanol NMT 3000 ppm Acetone NMT 5000 ppm Isopropyl alcohol NMT 5000 ppm Dichloromethane NMT 600 ppm Hexane NMT 290 ppm	312 ppm Not detected Not detected Not detected Not detected

**Additional In-house Test.

CONCLUSION: THE PRODUCT COMPLIES WITH THE ABOVE SPECIFICATION.

PREPARED BY : *CP*
(OFFICER - QC)

DATE : 21/08/2020

CHECKED BY : *Gamm*

(HEAD QC)

DATE : 21/08/2020

APPROVED BY : *KR*

(HEAD -QA)

DATE : 21/08/2020

LC/QC/F/022/R2

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