



ELIKEM
Pharmaceuticals Private Limited

ELIKEM PHARMACEUTICALS PRIVATE LIMITED

PLOT NO : 816/1, RAKANPUR IND. AREA, RAKANPUR
TA : KALOL, DIST : GANDHINAGAR - 382721, GUJARAT, INDIA

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : ZOPIFRESH 7.5 TABLETS	A.R. No. : FP-22982
Packing : 10 Tab	Rel. Dt. : 15-02-2025
Generic Name : ZOPICLONE TABLETS I.P. 7.5 MG	T.R. Slip No. : REPAP01813
Product Code : 8ZOPI06	T.R. Slip Dt. : 14-02-2025
Batch No. : 19169	Analysis Date :
Actual Batch Size : 1,92,000 Tab	Mfg. Lic. No. : G/25/1210
Mfg. Dt. : 06-FEB-2025	Sample Size : 50,000 Tab
Exp. Dt. : 31-JAN-2028	Released Qty. : 1,91,010 Tab
Test As per : IP	Location : RAKANPUR
	Company : ELIKEM

Sr.	Test	Result	Specification
1.00	DESCRIPTION	BLUE COLOUR ROUND SHAPED FILM-COATED TABLET, BOTH SIDES PLAIN.	BLUE COLOUR ROUND SHAPED FILM-COATED TABLET, BOTH SIDES PLAIN.
2.00	AVG. WEIGHT OF TABLETS	0.2100 GM	0.1850 GM TO 0.2150 GM
3.00	UNIFORMITY OF WEIGHT	COMPLIES	COMPLIES AS PER IP
4.00	DISINTEGRATION TIME	02 MINT	NMT 30 MINT
5.00	THICKNESS	3.20 MM	TO COMPLY
6.00	HARDNESS	9.0 KG/CM2	TO COMPLY
7.00	IDENTIFICATION	COMPLIES	COMPLIES AS PER IP
8.00	DISSOLUTION	93.36% TO 97.45%	NLT 75%
9.00	RELATED SUBSTANCE	COMPLIES	COMPLIES AS PER IP
10.00	UNIFORMITY OF DOSAGE UNITS [CONTENT UNIFORMITY]	93.22% TO 102.47%	85% TO 115%
11.00	ASSAY-EACH FILM-COATED TABLET CONTS	7.4894 MG	ZOPICLONE I.P.....7.5 MG

Conclusion : The above sample complies as per IP

Prepared By
MUNAFHUSAIN
Q.C. CHEMIST
15-Feb-2025 15:24

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