

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. : EPF-0035
Packing : 10 Tab	Rel. Dt. : 16-11-2025
Generic Name : ZOPICLONE TABLETS I.P. 7.5 MG	T.R. Slip No. : REPAP01041
Product Code : 8ZOPI06	T.R. Slip Dt. : 15-11-2025
Batch No. : EPT1127	Analysis Date :
Actual Batch Size: 2,02,000.000 Tab	Mfg. Lic. No. : G/25/1210
Mfg. Dt. : 13-NOV-2025	Sample Size : 50.000 Tab
Exp. Dt. : 31-OCT-2028	Released Qty. : 2,01,520.000 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	0.2114 GM	0.1979 GM TO 0.2300 GM
3.00	UNIFORMITY OF WEIGHT	COMPLIES	COMPLIES AS PER IP
4.00	DISINTEGRATION TIME	05 MINT	NMT 30 MINT
5.00	THICKNESS	3.17 MM	TO COMPLY
6.00	HARDNESS	8.6 KG/CM2	TO COMPLY
7.00	IDENTIFICATION	COMPLIES	COMPLIES AS PER IP
8.00	DISSOLUTION	92.01% TO 97.63%	NLT 75%
9.00	RELATED SUBSTANCE	COMPLIES	COMPLIES AS PER IP
10.00	UNIFORMITY OF DOSAGE UNITS [CONTENT UNIFORMITY]	93.69% TO 104.09%	85% TO 115%
11.00	ASSAY-EACH FILM-COATED TABLET CONTS	7.3222 MG	ZOPICLONE I.P.....7.5 MG

Conclusion : The above sample complies as per IP

Prepared By
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