

CERTIFICATE No.: FP242486	ACME LIFE TECH-LLP
Quality Control Department.	Plot No.103,104,105-EPIP Phase-1,Jharmajri Baddi Tehsil Nalagarh,Dist.Solan.(H.P)

CERTIFICATE OF ANALYSIS

PRODUCT NAME : DAPASMART-5 mg TABLET	
GENERIC NAME : DAPAGLIFLOZIN TABLETS 5 mg	
BATCH No. : ALT240721	BATCH SIZE : 3.00 LACS
MFG. DATE : OCT.2024	EXP DATE : JUL.2026
DATE OF SAMPLING : 25/10/2024	SAMPLE QTY : 140 TABLETS
DATE OF ANALYSIS : 25/10/2024	DATE OF RELEASE : 13/11/2024
REFERENCE SPECIFICATION No.: IHS	

SR.No.	TEST	RESULT	SPECIFICATION
1	Description	Yellow coloured, round shaped biconvex tablets with plain on both sides.Packed in alu-alu packing.	Yellow coloured, round shaped biconvex tablets with plain on both sides.Packed in alu-alu packing.
2	Identification.	Complies	The retention time of the major peaks in the chromatogram of the sample preparation corresponds to that of the standard preparation obtained as directed in the assay.
3	Average weight	0.1316 gm	0.1300 gm $\pm$ 5% (0.1235 gm to 0.1365 gm)
4	Uniformity of weight	0.1271 gm to 0.1338 gm	$\pm$ 7.5 % of Avg. weight.
5	Uniformity of Diameter	6.94 mm to 6.97 mm	Bet. 6.90 mm & 7.50 mm
6	Uniformity of Thickness	3.26 mm to 3.31 mm	Bet. 3.20 mm & 3.80 mm
7	Disintegration Time	1 Minute 20 Seconds.	NMT 30 Minutes.
8	Uniformity of Content	Min.:98.60 % Max.: 101.24%	85.00% to 115.00% of Average Value
9	Dissolution	Min.: 99.46 % , Max.:103.80%	Q. NLT 70%
10	Related Substances	Not detected	Any individual unknown impurity: NMT 0.2%
		Not detected	Total impurity: NMT 1.0%
11	Assay : Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate Equivalent to Dapagliflozin---5 mg	5.33 mg/tab i.e. 106.60%	90.0 % to 110.0%

Remarks : In the opinion of the undersigned the sample referred above complies / ~~Does not~~ complies as per finished product specification.

Shiv Kumar
Analyzed By

Shashi Kumar
Checked By

Sushil Kumar
Approved By

Format No: SOP/QC/017/F05-00