

CERTIFICATE No.: FP241093	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. : ALT240302	BATCH SIZE : 2.00 LACS
MFG. DATE : MAY 2024	EXP DATE : APR.2026
DATE OF SAMPLING : 14/05/2024	SAMPLE QTY : 140 TABLETS
DATE OF ANALYSIS : 14/05/2024	DATE OF RELEASE : 21/05/2024
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	0.1325 gm	0.1300 gm± 5% (0.1235 gm to 0.1365 gm)
4	Uniformity of weight	0.1281 gm to 0.1353 gm	± 7.5 % of Avg. weight.
5	Uniformity of Diameter	7.19 mm to 7.22 mm	Bet. 6.90 mm & 7.50 mm
6	Uniformity of Thickness	3.41 mm to 3.56 mm	Bet. 3.20 mm & 3.80 mm
7	Disintegration Time	28 Seconds.	NMT 30 Minutes.
8	Uniformity of Content	Min.:98.74 % Max.: 101.08%	85.00% to 115.00% of Average Value
9	Dissolution	Min.: 86.51 % , Max.:101.31%	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	4.931 mg/tab i.e. 98.62%	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.

8/21/05/2024
Analyzed By

Checked By 8/21/05/2024

8/21/05/2024
Approved By

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