

CERTIFICATE No.: FP241137	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-10mg TABLET			
GENERIC NAME : DAPAGLIFLOZIN TABLETS 10mg			
BATCH No.	: ALT240282	BATCH SIZE	: 8.00 LACS
MFG. DATE	:MAY 2024	EXP DATE	: APR.2026
DATE OF SAMPLING	: 11/05/2024	SAMPLE QTY	: 140 TABLETS
DATE OF ANALYSIS	: 11/05/2024	DATE OF RELEASE	: 24/05/2024
REFERENCE SPECIFICATION No.: IHS			
SR.No.	TEST	RESULT	SPECIFICATION
1	Description	Yellow coloured, diamond shaped biconvex film coated tablets with plain on both sides.Packed in alu-alu packing.	Yellow coloured, diamond shaped biconvex film coated 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	0.2639 gm	0.2600 gm± 5% (0.2470 gm to 0.2730 gm)
4	Uniformity of weight	0.2603 gm to 0.2682 gm	± 7.5 % of Avg. weight.
5	Uniformity of Length	11.31 mm to 11.37 mm	Bet. 10.90 mm & 11.50 mm
6	Uniformity of Breadth	8.01 mm to 8.20 mm	Bet. 7.80 mm & 8.40 mm
7	Uniformity of Thickness	4.69 mm to 4.84 mm	Bet. 4.50 mm & 4.90 mm
8	Disintegration Time	33 Seconds.	NMT 30 Minutes.
9	Uniformity of Content	Min.:98.94 % Max.: 101.64%	85.00% to 115.00% of Average Value
10	Dissolution	Min.: 86.56 % , Max.:98.66%	Q .NLT 70%
11	Related Substances	0.014%	Any individual unknown impurity: NMT 0.2%
		0.014%	Total impurity: NMT 1.0%
12	Assay : Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate Equivalent to Dapagliflozin---10 mg	10.077 mg/tab i.e. 100.77%	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.

824/05/2024
Analyzed By

11/05/2024
Checked By

24/05/2024
Approved By

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