

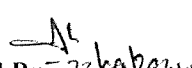
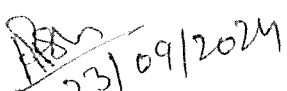
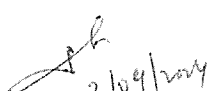
CERTIFICATE No.: FP242056	ACME LIFE TECH-LLP Plot No.103,104,105-EPiP Phase-1,Jharmajri Baddi Tehsil Nalagarh,Dist.Solan.(H.P)
Quality Control Department.	

CERTIFICATE OF ANALYSIS

PRODUCT NAME : DAPASmart M 10/500 TABLET	
GENERIC NAME : DAPAGLIFLOZIN & METFORMIN EXTENDED RELEASE TABLETS	
BATCH No. : ALT240572B	BATCH SIZE : 2.00 LACS
MFG. DATE : AUG.2024	EXP DATE : JUL.2026
DATE OF SAMPLING : 07/09/2024	SAMPLE QTY : 140 TABLETS
DATE OF ANALYSIS : 07/09/2024	DATE OF RELEASE : 23/09/2024
REFERENCE SPECIFICATION No.: IHS	

SR. No.	TEST	RESULT	SPECIFICATION
1	Description	Yellow coloured, Capsule shaped biconvex film coated bilayered tablets with plain on one side and break line on the other sides.Packed in alu-alu packing.	Yellow coloured, Capsule shaped biconvex film coated bilayered tablets with plain on one side and break line on the other 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	0.9619 gm	0.9650 gm± 3% (0.8924 gm to 0.9476 gm)
4	Uniformity of Weight	0.9530gm to 0.9685gm	± 5 % of Avg. weight.
5	Uniformity of Length	16.80 mm to 16.89 mm	Bet.16.50 mm & 17.10 mm
6	Uniformity of Thickness	6.36 mm to 6.44 mm	Bet. 6.20 mm & 6.80 mm
7	Uniformity of Breadth	8.54 mm to 8.60 mm	Bet. 8.20 mm & 8.80 mm
8	Dissolution for Metformin Hydrochloride (Sustained Released)	After 1 Hour: 28.96% to 29.88%	25.0% to 45.0%
		After 3 Hour: 61.58% to 67.51%	45.0% to 80.0%
		After 10 Hour: 95.10% to 99.89%	NLT 80.0%
9	Uniformity of Content	Min.:100.37% Max.: 104.27%	85.00% to 115.00%
10	Dissolution For Dapagliflozin	Min.: 78.68 % , Max.:111.46%	Q. NLT 70 %
11	Related Substances For Dapagliflozin	Not detected	Ind.impurity: NMT 1.0%
		Not detected	Total impurity NMT 2.0%
	Related Substances For Metformin	Not detected	Ind.impurity: NMT 1.0%
		Not detected	Total impurity NMT 2.0%
12	Assay: Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate Equivalent to Dapagliflozin---10 mg Metformin Hydrochloride IP -500 mg(As Sustained Release form)	9.93 mg/tab i.e. 99.30%	90.0 % to 110.0%
		492.328 mg/tab i.e. 98.47%	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.

 Analyzed By - 23/09/2024	 Checked By - 23/09/2024	 Approved By - 23/09/2024
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