

CERTIFICATE No.: FP241154

Quality Control Department.

ACME LIFE TECH-LLP

Plot No.103,104,105-EPIP Phase-I,Jharmajri
Baddi Tehsil Nalagarh,Dist.Solan.(H.P)

CERTIFICATE OF ANALYSIS

PRODUCT NAME : DAPASMA RT M 10/500 TABLET

GENERIC NAME : DAPAGLIFLOZIN & METFORMIN EXTENDED RELEASE TABLETS

BATCH No. : ALT240267

BATCH SIZE : 2.00 LACS

MFG. DATE : APR.2024

EXP DATE : MAR.2026

DATE OF SAMPLING : 15/05/2024

SAMPLE QTY : 140 TABLETS

DATE OF ANALYSIS : 15/05/2024

DATE OF RELEASE : 03/06/2024

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	0.9571 gm	0.9650 gm $\pm$ 3% (0.8924 gm to 0.9476 gm)
4	Uniformity of Weight	0.9410gm to 0.9658gm	$\pm$ 5 % of Avg. weight.
5	Uniformity of Length	16.91 mm to 16.98 mm	Bet.16.50 mm & 17.10 mm
6	Uniformity of Thickness	6.49 mm to 6.68 mm	Bet. 6.20 mm & 6.80 mm
7	Uniformity of Breadth	8.57 mm to 8.67 mm	Bet. 8.20 mm & 8.80 mm
8	Dissolution for Metformin Hydrochloride (Sustained Released)	After 1 Hour: 30.68% to 35.07%	25.0% to 45.0%
		After 3 Hour: 51.07% to 59.55%	45.0% to 80.0%
		After 10 Hour: 90.99% to 100.65%	NLT 80.0%
9	Uniformity of Content	Min.:100.30% Max.: 105.32%	85.00% to 115.00%
10	Dissolution For Dapagliflozin	Min.: 88.47 % , Max.:95.16%	Q. NLT 70 %
11	Related Substances For Dapagliflozin	0.139%	Ind.impurity: NMT 1.0%
		0.142%	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	10.01 mg/tab i.e. 100.10%	90.0 % to 110.0%
	Metformin Hydrochloride IP -500 mg(As Sustained Release form)	500.207 mg/tab i.e. 100.04%	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

AFey
03/06/2024

Checked By

03/06/2024

Approved By

03/06/2024

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