

1 CERTIFICATE No.: FP241449	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 : DAPAFOX M 500
GENERIC NAME : DAPAGLIFLOZIN & METFORMIN EXTENDED RELEASE TABLETS

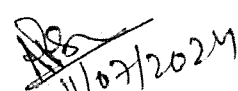
BATCH No. : ALT240378	BATCH SIZE : 2.00 LACS
MFG. DATE : JUN.2024	EXP DATE : MAY 2026
DATE OF SAMPLING : 29/06/2024	SAMPLE QTY : 140 TABLETS
DATE OF ANALYSIS : 29/06/2024	DATE OF RELEASE : 11/07/2024

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	0.9589 gm	0.9650 gm± 3% (0.8924 gm to 0.9476 gm)
4	Uniformity of Weight	0.9509 gm to 0.9671gm	± 5 % of Avg. weight.
5	Uniformity of Length	16.84 mm to 16.92 mm	Bet.16.50 mm & 17.10 mm
6	Uniformity of Thickness	6.51 mm to 6.69 mm	Bet. 6.20 mm & 6.80 mm
7	Uniformity of Breadth	8.57 mm to 8.62 mm	Bet. 8.20 mm & 8.80 mm
8	Dissolution for Metformin Hydrochloride (Sustained Released)	After 1 Hour: 32.28% to 32.57%	25.0% to 45.0%
		After 3 Hour: 61.53% to 62.02%	45.0% to 80.0%
		After 10 Hour: 92.05% to 92.83%	NLT 80.0%
9	Uniformity of Content	Min.: 96.39% Max.: 98.10%	85.00% to 115.00%
10	Dissolution For Dapagliflozin	Min.: 79.90 % , Max.:82.49%	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)	9.935 mg/tab i.e. 99.35%	90.0 % to 110.0%
		481.407 mg/tab i.e. 96.28%	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  11/07/2024


11/07/2024
Checked By


11/07/2024
Approved By