CERTIFICATE No.: FP241656	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 1000
GENERIC NAME : DAPAGLIFLOZIN & METFORMIN EXTENDED RELEASE TABLETS

BATCH No.	: ALT240368A	BATCH SIZE	: 2.00 LACS
MFG. DATE	: JUN.2024	EXP DATE	: MAY 2026
DATE OF SAMPLING	: 14/06/2024	SAMPLE QTY	: 140 TABLETS
DATE OF ANALYSIS	: 14/06/2024	DATE OF RELEASE:	02/08/2024

REFERENCE SPECIFICATION No.: IHS

SR. No.	TEST	RESULT	SPECIFICATION
1	Description	Yellow coloured, Capsule shaped biconvex film coated bilayered tablets with plain on both sides. sides.Packed in alu-alu packing.	Yellow coloured, Capsule shaped biconvex film coated bilayered tablets with plain on both sides. 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	1.4527gm	1.4700 gm± 3% (1.4259 gm to 1.5141 gm)
4	Uniformity of Weight	1.4326 gm to 1.4721 gm	± 5 % of Avg. weight.
5	Dissolution for Metformin Hydrochloride (Sustained Released)	After 1 Hour: 30.45% to 30.94%	25.0% to 45.0%
		After 3 Hour: 59.45% to 59.84%	45.0% to 80.0%
		After 10 Hour: 89.49% to 89.78%	NLT 80.0%
6	Uniformity of Content	Min.: 99.63 % Max.: 101.07%	NLT 85.0% & NMT 115.0 % of Average Value
7	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%
8	Dissolution For Dapagliflozin	Min.: 81.25 % , Max.:96.59%	Q. NLT70.0%
9	Assay: Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate Equivalent to Dapagliflozin---10 mg	10.318 mg/tab i.e. 103.18%	90.0 % to 110.0%
	Metformin Hydrochloride IP -1000 mg(As Extended Release form)	980.340 mg/tab i.e. 98.03%	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 02/08/2024 Checked By 02/08/2024 Approved By 02/08/2024

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