BIOALTUS PHARMACEUTICALS PVT.LTD.

19-20 Industrial Area, Baddi -173205 Distt. Solan
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name	**Empagliflozin 12.5mg and Metformin Hydrochloride 500 mg Tablets (Empafox MET 12.5/500)**	**A.R. No.**	BRDII/03/25/BD/2174TF
Master/FG B. No.	BD250481/BD250481C	**Master/FG B. Size**	5.0 Lac/2.0 Lac
Mfd. By	Self	**Sample Qty.**	70Tablets
MFD.	FEB.2025	**Date of Receipt**	24/03/2025
EXP.	JAN.2027	**Date of Release**	24/03/2025

RESULTS OF ANALYSIS

Reference to Protocol : IHS

S.No.	Test	Results	Specification
01.	**Description**	Light purple coloured elongated biconvex oval shaped film coated tablets plain on both sides.	Light purple coloured elongated biconvex oval shaped film coated tablets plain on both sides.
02.	**Identification (By HPLC)** **For Empagliflozin** **For Metformin Hydrochloride**	Complies Complies	To Comply To Comply
03.	**Average weight**	0.66783 gm	0.6690 gm ± 3.0%
04.	**Uniformity of weight**	Min. 0.6616gm, Max. 0.6827gm	±5.0% of average weight
05.	**Dissolution** **For Empagliflozin(By HPLC)** **For Metformin Hydrochloride (By UV)**	Min. 103.87 %, Max. 105.59 % Mean 104.72% Min. 97.4%, Max.98.8% Mean 98.1 %	Q.NLT 70% Q.NLT 70%
06.	**Assay (By HPLC)** **Each film coated tablet contains:** **Empagliflozin 12.5 mg** **Metformin Hydrochloride IP 500mg**	12.47 mg (99.8%) 493.50 mg (98.7 %)	NLT 11.25 mg & NMT 13.75mg (NLT 90.0 % & NMT 110.0 %) NLT 450.0 mg & NMT 550.0mg (NLT 90.0% & NMT 110.0 %)

Remark: In the opinion of the undersigned, the sample referred to above is of **standard quality**/is ~~not of standard quality~~ as defined in the Act and the Rules made there under for the reasons given below:
Complies as per **IHS (BRD II/QC/FPS/445F1)**

	Prepared By	Checked By	Approved By
Name	**Mohd Fazil**	**Priyanka**	**Suresh Chand**
Designation	**QC Officer**	**Reviewer**	**QC Manager**
Sign/Date	Fazil 24/03/2025	24/03/2025	24/03/2025