

**BIOALTUS PHARMACEUTICALS PVT.LTD.**  
19-20 Industrial Area, Baddi -173205 Distt. Solan  
**QUALITY CONTROL DEPARTMENT**

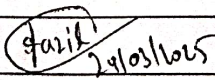
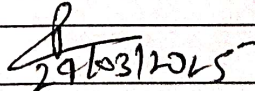
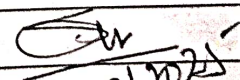
**CERTIFICATE OF ANALYSIS**

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 $\pm$ 3.0%
04.	Uniformity of weight	Min. 0.6616gm, Max. 0.6827gm	$\pm$ 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	 24/03/2025	 24/03/2025	 24/03/2025