BIOALTUS PHARMACEUTICALS PVT.LTD.

19-20 Industrial Area, Baddi -173205 Distt. Solan

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name	**Sitagliptin 50 mg & Metformin HCl 500 mg Tablets (SITAFOX M 50/500)**	**A.R. No.**	BRDII/10/24/BD/1192TF
Master/FG B. No.	BD241845/BD241845C	**Master/FG B. Size**	4.93851 Lac/1.95 Lac
Mfg. Date	SEP.2024	**Sample Qty.**	75Tablets
Exp. Date	AUG.2026	**Test As Per**	In House Specification
Date of Receipt	26/11/2024	**Date of Release**	26/11/2024

RESULTS OF ANALYSIS

Reference to Protocol : In House Specification

S.No.	Test	Result	Specification
1.	Description	Light orange colored elongated shaped biconvex film coated tablet, central breakline on one side & plain on other side.	Light orange colored elongated shaped biconvex film coated tablet, central breakline on one side & plain on other side.
2.	Identification (By HPLC)	Complies	To Comply
3.	Average weight	0.77792 gm	0.7800 gm ± 5.0 %
4.	Uniformity of weight	Min.0.7588 gm, Max.0.7960 gm	± 5.0% of average weight
5.	Dissolution (By HPLC) Sitagliptin 50mg Metformin HCl 500mg	 Min. 93.87%, Max. 98.31 % Mean 96.29 % Min. 97.31%, Max.103.02 % Mean 99.38 %	 NLT 75.0 % NLT 75.0 %
6.	Uniformity of content (By HPLC) (For Sitagliptin)	Min. 99.48 %, Max. 101.16 % average content 49.67mg	NLT 85% & NMT 115% of the average content
7.	Assay (By HPLC) Each film coated tablet Contains: Sitagliptin Phosphate monohydrate IP equivalent to Sitagliptin 50 mg Metformin Hydrochloride IP 500mg	 49.13 mg (98.3 %) 492.35 mg (98.5 %)	 NLT 45.0 mg & NMT 55.0 mg (NLT 90.0 % & NMT110.0 %) NLT450.0 mg & NMT550.0 mg (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:

In House Specification No. BRDII/QC/FPS/389 F1

	Prepared By	Checked By	Approved By
Name	Komal	Priyanka	Harpreet Kaur
Designation	QC Officer	Reviewer	Manager QC
Sign/Date	26/11/2024	26/11/2024	26/11/2024

B.Pharma

Reg No. 48650