

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

CERTIFICATE OF ANALYSIS

Product Name	Sitagliptin Phosphate Tablets IP 50 mg (Sitafox 50)	A.R. No.	BRDII/09/24/BD/1090TF
Master/FG B. No.	BD241863/BD241863E	Master/FG B.Size	6.30 Lac/2.10 Lac
Mfd. By	Self	Sample Qty.	70Tablets
MFD.	SEP.2024	Date of Receipt	29/10/2024
EXP.	AUG.2026	Date of Release	29/10/2024

RESULTS OF ANALYSIS

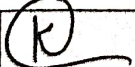
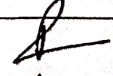
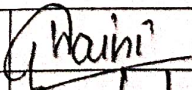
Reference to Protocol : IP

S.No.	Test	Result	Specification
1.	Description	Light orange coloured round shaped biconvex film coated tablet, central breakline on one side & plain on other side.	Light orange coloured round shaped biconvex film coated tablet, central breakline on one side & plain on other side.
2.	Identification(By HPLC)	Complies	To Comply
3.	Average weight	0.18888gm	0.1860gm \pm 3.0 %
4.	Uniformity of weight	Min. 0.1852gm,Max.0.1913gm	\pm 7.5 % of average weight
5.	Disintegration	Min. 01 minutes, 41seconds Max.02 minutes, 26seconds	NMT 30 minutes
6.	Dissolution (By HPLC)	Min. 89.66 %, Max. 98.93 % Mean 94.33%	Q.NLT 70.0 %
7.	#Related Substances (By HPLC) I) The area of any secondary peak	Not Detected	NMT 0.2 %
	II)The sum of areas of all secondary peaks	Not Detected	NMT 0.5 %
8.	Assay(By HPLC) Each film coated tablet contains: Sitagliptin phosphate monohydrate IP eq. to Sitagliptin50 mg	52.45mg (104.9%)	NLT47.5mg&NMT 52.5 mg (NLT 95.0% & NMT 105.0%)

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 IP (BRDII/QC/FPS/319F2)

#Test refers to Vorick Lab Report No.VAF240920242

Prepared By		Checked By		Approved By	
Date	29/10/2024	Date	29/10/2024	Date	29/10/2024