



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

CERTIFICATE OF ANALYSIS

Product Name	Sitagliptin Phosphate Tablets IP 100 mg (Sitafox 100)	A.R. No.	BRDII/09/24/BD/1094TF
Master/FG B. No.	BD241859/BD241859C	Master/FG B. Size	3.50 Lac/2.0 Lac
Mfd. By	Self	Sample Qty.	70Tablets
MFD.	SEP.2024	Date of Receipt	07/11/2024
EXP.	AUG.2026	Date of Release	07/11/2024

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	0.30481gm	0.3000gm ± 3.0 %
4.	Uniformity of weight	Min. 0.3011gm,Max. 0.3079gm	± 5.0 % of average weight
5.	Disintegration	Min. 01 minutes, 52seconds Max. 02 minutes,37 seconds	NMT 30 minutes
6.	Dissolution (By HPLC)	Min. 95.89 %, Max. 100.06 % Mean 97.67 %	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 Sitagliptin100 mg	104.67 mg (104.7 %)	NLT 95.0mg& NMT 105.0 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/320F1)

#Test refers to Vorick Lab Report No. VAF240921233

	Prepared By	Checked By	Approved By
Name	Komal	Priyanka	Harpreet Kaur
Designation	QC officer	Reviewer	Manager QC
Sign / Date	 07/11/2024	 07/11/2024	 07/11/2024