BIOALTUS PHARMACEUTICALS PVT.LTD.

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name	**Teneligliptin Tablets IP 20 mg (Tenlifine 20)**	**A.R. No.**	BRDII/08/24/BD/0889TF
Master/FG B. No.	BD241599/BD241599	**Master/FG B. Size**	2.0 Lac/2.0 Lac
Mfd. By	Self	**Sample Qty.**	80 Tablets
MFD.	AUG.2024	**Date of Receipt**	13/09/2024
EXP.	JUL.2026	**Date of Release**	13/09/2024

RESULTS OF ANALYSIS

Reference to Protocol : IP

S.No.	Test	Results	Specification
01.	Description	Yellow colored round shaped biconvex, film coated tablets plain on both sides.	Yellow colored round shaped biconvex, film coated tablets plain on both sides.
02.	Identification(By HPLC)	Complies	To Comply
03.	Average weight	0.13480 gm	0.1330 gm ± 3.0 %
04.	Uniformity of weight	Min. 0.1317 gm Max. 0.1365 gm	± 7.5% of average weight
05.	Dissolution(By HPLC)	Min.96.74 % Max.105.31 %, Mean 101.24%	Q.NLT 70 %
06.	Disintegration Time	Min. 04 minutes, 08 seconds Max.04 minutes, 53 seconds	NMT 30 minutes
07.	Diameter	Min.7.2 mm, Max. 7.3 mm	7.20 mm ± 0.3 mm
08.	Thickness	Min. 3.1 mm, Max 3.2 mm	3.10 mm ± 0.3 mm
09.	Uniformity of content(By HPLC)	Min.87.18%, Max. 107.86 %, average content.20.03 mg	NLT 85% & NMT 115% of the average content
10.	#Related Substances (By HPLC) I.Teneligliptin Impurity A II.Any other Individual Impurity III.Total Impurities	 Not Detected Not Detected Not Detected	 NMT 1.0 % NMT 0.5 % NMT 2.0 %
11.	Assay(By HPLC) Each film coated tablet contains Teneligliptin Hydrobromide Hydrate IP Eq.to Teneligliptin 20 mg	 19.64 mg (98.2%)	 NLT18.0 mg &NMT 22.0 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:

Complies as per **IP (BRD II/QC/FPS/148F1)**

#Test refer to Vorick Lab report No. VAF240905217

Prepared By		**Checked By**		**Approved By**	
Date	13/09/2024	**Date**	13/09/2024	**Date**	13/09/2024