

**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/11/24/BD/1458TF
Master/FG B. No.	BD242317/BD242317B	Master/FG B. Size	3.50 Lac/2.0 Lac
Mfd. By	Self	Sample Qty.	80 Tablets
MFD.	NOV.2024	Date of Receipt	03/12/2024
EXP.	OCT.2026	Date of Release	03/12/2024

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	0.13507 gm	0.1330 gm $\pm$ 3.0 %
04.	Uniformity of weight	Min. 0.1335gm Max. 0.1362 gm	$\pm$ 7.5% of average weight
05.	Dissolution(By HPLC)	Min.96.26 % Max.103.01%, Mean 99.76 %	Q.NLT 70 %
06.	Disintegration Time	Min. 04 minutes, 27seconds Max.05 minutes, 10 seconds	NMT 30 minutes
07.	Diameter	Min.7.18 mm, Max. 7.21 mm	7.20 mm $\pm$ 0.3 mm
08.	Thickness	Min. 3.08 mm, Max 3.11 mm	3.10 mm $\pm$ 0.3 mm
09.	Uniformity of content(By HPLC)	Min.98.75 %, Max. 106.27%, average content.20.01 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	19.59 mg (98.0 %)	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. VAF241125246

	Prepared By	Checked By	Approved By
Name	Ikmal	Priyanka	Harpreet Kaur
Designation	QC officer	Reviewer	Manager QC
Sign/Date	 03/12/2024	 03/12/2024	 03/12/2024

B. Pharma
Reg No. 48650