

**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/04/24/BD/0035TF
Master/FG B. No.	BD240580/ BD240580	Master/FG B. Size.	2.0 Lac/2.0 Lac
Mfd. By	Self	Sample Qty.	80 Tablets
MFD.	APR. 2024	Date of Receipt	27/05/2024
EXP.	MAR. 2026	Date of Release	27/05/2024

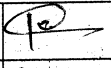
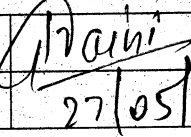
RESULTS OF ANALYSIS**Reference to Protocol : IP**

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	0.13219 gm	0.1330 gm $\pm$ 3.0 %
04.	Uniformity of weight	Min. 0.1291 gm (- 2.34 %) Max. 0.1341 gm (+ 1.45 %)	$\pm$ 7.5% of average weight
05.	Dissolution(By HPLC)	Min.90.78 % Max.96.38 %, Mean 93.50 %	Q.NLT 70 %
06.	Disintegration Time	Min. 7 minutes,55 seconds Max.8 minutes, 38 seconds	NMT 30 minutes
07.	Diameter	Min.6.95 mm, Max. 7.02 mm	7.20 mm $\pm$ 0.3 mm
08.	Thickness	Min. 2.98 mm, Max 3.12 mm	3.10 mm $\pm$ 0.3 mm
09.	Uniformity of content(By HPLC)	Min.95.83 %, Max. 102.50%, average content. 20.14 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	19.61 mg (98.1 %)	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/148F2)

#Test refer to SKAS Lab report No. SGF-120424062

Prepared By		Checked By	Ravi	Approved By	
Date	27/05/2024	Date	27/05/2024	Date	27/05/2024