



UNITED BIOCEUTICALS PVT. LTD.

Plot No. 33C, Industrial Park-IV, Begumpur, Haridwar-249402,(Uttarakhand)

CERTIFICATE OF ANALYSIS

Product Name: TENLIFINE M 1000		Test SPC No.: UB/QC/STP1820
Generic Name: Teneligliptin Hydrobromide Hydrate & Metformin Hydrochloride Sustained Release tablets		
Marketed by: Healing Pharma		
Mfg. Lic No.: 94/UA/2017		Batch No.: T240265
Batch Size: 92,000 Tabs	Pack Size : 5 x 3 x 10's	A. R. No.: FPT24250438
Sample Quantity: 60 Tabs	Mfg. Date: 04/2024	Expiry Date: 03/2026
Shelf Life: 24 Months	Sampling Date: 25.05.2024	Report Date: 26.05.2024

Test	Specification	Results
Description	Yellow, off white coloured, elongated, biconvex, uncoated bilayered tablet, break line on one side.	Yellow, off white coloured, elongated, biconvex, uncoated bilayered tablet, break line on one side.
Identification: Teneligliptin Metformin Hydrochloride	By HPLC By UV	Complies Complies
Average Weight	1400.0 mg $\pm$ 3.0% (1358.0 to 1442.0 mg)	1403.1 mg
Uniformity of Weight	Not more than two tablets deviate from $\pm$ 5% and none deviates from $\pm$ 10% of average weight	Complies
Dissolution Test: Metformin HCl (SR form) Release in 1 hrs Release in 3 hrs Release in 8 hrs	20.0% to 50.0% 40.0% to 70.0% NLT 75.0%	35.24% to 44.61% 52.18% to 64.34% 90.20% to 94.66%
Friability Test	NMT 1.0%	0.20%
Assay: Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20 mg Metformin Hydrochloride IP 1000 mg (As Sustained Release)	18.00 mg to 22.00 mg 90.00% to 110.00% 900.00 mg to 1100.00 mg 90.00% to 110.00%	19.980 mg 99.90% 998.12 mg 99.81%

OPINION: The sample **Complies/Does not Complies** as per Standard specification.

Analysed by:
Date:

26/05/2024

Checked by:
Date:

26/05/2024

Approved by:
Date:

26/05/2024