ORISON PHARMA INTERNATIONAL,
Vill, Khari, kala Amb (H.P)

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Name of Product	TENLIFINE – M	A.R. No.	OPI-FGT4821/23
Generic Name	Teneligliptin & Metformin Hydrochloride (Sustained Release)Tablet IP	Received date	27/12/2023
Batch No.	231 – T2129	Analysis Completion /Release Date	28/12/2023
Mfg. Date	12/2023	Batch Size	2.0 Lac Tablets
Best Before /Expiry	11/2026	Mfg. Lic. No.	MNB/07/644 & MB/07/645

Sr. No.	Test	Specifications	Results
1.	Description	White & yellow colour elongated shape biconvex both side plain bilayered uncoated Extended Release tablet.	White & yellow colour elongated shape biconvex both side plain bilayered uncoated Extended Release tablet.
2.	**Identification**		
2.1	**By UV** (Metformin)	In the assay for Metformin Hydrochloride the absorbance maxima obtained with the test solution corresponds to the absorbance maxima at same wavelength obtained with the reference solution.	Complies
2.2	**By HPLC** (Teneligliptin)	In the assay of Teneligliptin the principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with the reference solution.	Complies
3.	Average wt. of tablet	820.0 mg ± 5% (779.0 mg to 861.0 mg)	794.7 mg
4.	Uniformity of wt.	Average weight. ± 5%	Max +3.18% Min -3.86%
5.	**Dissolution**		
5.1	Teneligliptin	NLT 75% of the stated amount	Min - 90.30% Max +101.33%
5.2	Metformin HCL: (Extended Release) 1- For 1st hour 2- For 3rd hour 3- For 10th hour	 1- Between (25% to 50%) 2- Between (45% to 75%) 3- (NLT 80% of the stated amount)	 Min - 28.92% to Max +45.80% Min – 59.57% to Max +65.12% Min - 85.445% to Max +89.52%
6.	Friability	NMT 1.0%	0.15%
7.	Related Substances	Should be comply as per IP	Complies
8.	Uniformity of Content (For Teneligliptin)	Between 85.0% to 115.0%	Complies
9.	**ASSAY :-** (Each uncoated Extended Release tablets contains)		
9.1	Teneligliptin Hydrobromide Hydrate **IP** Eq to Teneligliptin **20 mg**	18.0 mg to 22.0 mg & 90% to 110%	19.15 mg & 95.75%
9.2	Metformin Hydrochloride **IP 500 mg** (As Extended Release)	450.0 mg to 550.0 mg & 90% to 110%	503.16 mg & 100.63%

Remark : - In the opinion of the undersigned the sample referred to above is standard quality as complies as per IP/~~BP/USP/JH~~ Specification.

Signatories	Prepared By (QC)	Checked By (QC)	Approved By (QC)
Name	Bhawna	Sunil Maurya	
Designation	Chemist	Asstt. Manager-Q.C	
Signature & Date:	28/12/2023	28/12/2023	28/12/2023

ORISON PHARMA INTERNATIONAL Distt. Sirmour (H.P.)