



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

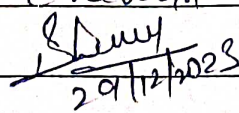
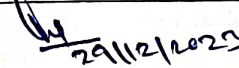
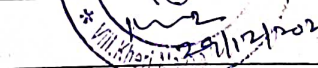
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QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Name of Product	SITASMART – 100	A.R. No.	OPI-FGT4794/23
Generic Name	Sitagliptin Phosphate Tablets IP 100 mg	Received date	26/12/2023
/Batch No.	23H – T1818	Analysis Completion /Release Date	29/12/2023
Mfg. Date	11/2023	Batch Size	3.0 Lac Tablets
Best Before /Expiry	10/2025	Mfg. Lic. No.	MNB/07/644 & MB/07/645

Sr. No.	Test	Specifications	Results
1.	Description	Light orange colour round shape biconvex both side plain film coated tablet.	Light orange colour round shape biconvex both side plain film coated tablet.
2.	Identification		
2.1	By HPLC	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution.	Complies
3.	Average wt. of tablet	330 mg $\pm$ 5% (313.5 mg to 346.5 mg)	327.4 mg
4.	Uniformity of wt.	Average weight. $\pm$ 5%	Max +3.23% Min – 3.17%
5.	Disintegration Time	NMT 15 Minutes	05 minute 40 Second
6.	Related Substances	Should be comply as per IP	Complies
7.	ASSAY :- (Each film coated tablets contains)		
7.1	Sitagliptin Phosphate Monohydrate IP Eq to Sitagliptin 100 mg	95.0 mg to 105.0 mg & 95% to 105%	95.474 mg & 95.47%

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

Signatories	Prepared By (QC)	Checked By (QC)	Approved By (QC)
Name	Shawn	Sunil maurya	M. K. Singh
Designation	Chemist	Asst. manager - Q.C	Dist. Simla (H.P.)
Signature & Date:	 29/12/2023	 29/12/2023	 29/12/2023