

CERTIFICATE OF ANALYSIS

Product : Sitasmart-M 50/1000
(Sitagliptin Phosphate 50mg and Metformin Hydrochloride 1000mg Tablets)

Analytical Report No. : FFPOSD0951-23

Batch/Lot No. : IFSIL302

Mfg. Date : 12/23

Ref. Specification No. : ISL/SPC/FPR/724-00

Exp. Date : 11/25

Batch Size : 3.0 Lac Tablets

Sampled Quantity : 105 Tablets

Date of Analysis : 02.01.2024

Date of Completion : 04.01.2024

Sr.No.	Parameters	Limits	Results
1	Description	Reddish coloured, biconvex, capsule shaped film coated tablet with both side plain.	Reddish coloured, biconvex, capsule shaped film coated tablet with both side plain.
2	Length	20.2 ± 0.2 mm	20.19 mm
3	Width	9.7 ± 0.2 mm	9.72 mm
4	Thickness	6.8 ± 0.2 mm	6.76 mm
5	Average weight	1254 mg ± 5.0%	1252.16 mg
6	Weight variation	± 5.0 % of the average weight of	-0.58 % to + 1.29 %
7	Disintegration	Not more than 30 min	13 minutes 39 Seconds
8	Identification (by HPLC)		
	Sitagliptin	Retention time of the principal peak of test corresponds to that of Sitagliptin W.S.	Complies
	Metformin HCl	Retention time of the principal peak of test corresponds to that of Metformin HCl W.S.	Complies
9	Dissolution: (By HPLC) Metformin HCl	Not less than 80 % of label claim	Avg. 99.7 % Min. 99.3% Max. 99.9 %
10	Related Substances (by HPLC)		
	unknown impurity	Not more than 1.0%	Not Detected
	Total impurities	Not more than 2.0%	Not Detected
11	Assay: (by HPLC) Each film coated tablet contains:		
	Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin - 50 mg	45 mg – 55 mg per tablet of average weight. (90% - 110 % of the label claim)	49.84 mg per tablet of average mass. (99.67 % of the label claim)
	Metformin HCl IP - 1000 mg	900 mg – 1100 mg per tablet of average weight. (90% - 110 % of the label claim)	992.81 mg per tablet of average mass. (99.28 % of the label claim)
12	Microbial Purity		
	Total aerobic count	Not more than 1000 cfu /g	Not Applicable
	Yeast and moulds count	Not more than 100 cfu /g	
	Escherichia coli	Shall be Absent/g	

Remarks : The sample complies / does not comply as per above specification.
Parent B.No. : 23SL0740
Reported Date : 04.01.2024

Prepared By
Sign/Date

Darshan Kumar
04.01.2024

Checked By
Sign/Date

Amit
04.01.2024

Approved By
Sign/Date

Ratan
04.01.2024