

Certificate of Analysis

Product Name: Sitasmart-50

Generic Name	Sitagliptin Tablets IP / USP	Packing Code	G1780005
Batch Log No	32415761	Packing Batch No	G1784002
Bulk Batch No	G1784002	Batch Size	1.0 Lac
Packing Type	5*3*10 Tabs	Date of Analysis	13/04/2024
A.R. No.	2003FP324001820	Reference	IP/USP
Mfg. Date	04/2024	Exp. Date	03/2026
Specification No	FPS-G178-01	Date of Release	06/05/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Beige colored, round shaped, biconvex film coated tablet plain on both side.	Beige colored, round shaped, biconvex film coated tablet plain on both side.
2	Identification		
2.1	By UV Spectrophotometer	The UV spectrum of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	The UV spectrum of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay
2.2	By High Performance Liquid Chromatography	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.
3	Average weight	205.0mg $\pm$ 7.5%	205.59 mg
4	Uniformity of weight	$\pm$ 7.5% of avg. wt.	%Maximum +ve deviation : 2.0 % %Maximum -ve deviation:-2.0 %
5	Disintegration time	Not more than 5 minutes	Disintegration time:0.40 Minutes
6	Uniformity of Dosage Units (By weight variation)	Acceptance Value $\leq$ 15.0	Acceptance value:3.91 NA
7	Dissolution	Not less than 75% (Q) of the stated amount of Sitagliptin dissolve in 45 minutes.	Min: : 98.8 % Max: : 106.3 % Average::103.6 %
8	Assay Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP/USP equivalent to sitagliptin.....50mg	47.50mg to 52.50mg (95.0% to 105.0% of Labeled Claim)	Assay % of Label Claim: : 101.8 % Assay:mg/Tab:50.88 mg/tab
9	Organics impurities		
9.1	Sitagliptin acid	Not more than 0.2%	Not Detected
9.2	Fumarate adduct (if present)	Not more than 0.2%	Not Detected
9.3	Sitagliptin triazecine analog	Not more than 0.2%	Not detected
9.4	Sitagliptin styrylacetyl analog	Not more than 0.2%	Not Detected
9.5	Sitagliptin phenylcrotonyl analog	Not more than 0.2%	Not Detected

Remarks: APPROVED (Sample conforms to above Specification)

Prepared By		Reviewed By	Approved By
satyendra.p(Chemist)		omprakash.sharma(Manager)	Mahendra.Bisht(Manager)
06/05/2024 16:02		06/05/2024 16:35	06/05/2024 16:38
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JHARMAJRI, BADDI (HP) INDIA

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S. No.	TEST	SPECIFICATION	RESULT
9.6	Any other individual impurity	Not more than 0.2%	Below Disregard Limit
9.7	Total impurities	Not more than 0.6%	Below Disregard Limit
10	Additional Tests		
10.1	Hardness	Not less than 30.0 Newton	Max : 69.0 N Min:43.9 N
10.2	Water Content (by KF)	Not more than 6.0% w/w	3.61 %

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Prepared By satyendra.p(Chemist) 06/05/2024 16:02	Reviewed By omprakash.sharma(Manager) 06/05/2024 16:35	Approved By Mahendra.Bisht(Manager) 06/05/2024 16:38
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