



INNOVA CAPTAB LTD
1281/1, HILLTOP INDUSTRIAL ESTATE, NEAR EPIP PHASE-I,
JHARMAJRI, BADDI (HP) INDIA

Certificate of Analysis

Product Name: Sitasmart-50

Generic Name	Sitagliptin Tablets IP / USP	Packing Code	G1780005
Batch Log No	32415751	Packing Batch No	G1784001
Bulk Batch No	G1784001	Batch Size	2.0 Lac
Packing Type	5*3*10 Tabs	Date of Analysis	06/04/2024
A.R. No.	2003FP324002201	Reference	IP/USP
Mfg. Date	04/2024	Exp. Date	03/2026
Specification No	FPS-G178-01	Date of Release	11/05/2024

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	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
3	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.
4	Average weight	205.0mg $\pm$ 7.5%	207.30 mg
5	Uniformity of weight	$\pm$ 7.5% of avg. wt.	%Maximum +ve deviation : 2.8 % %Maximum -ve deviation:-2.7 %
6	Disintegration time	Not more than 5 minutes	Disintegration time:0.43 Minutes
7	Uniformity of Dosage Units (By weight variation)	Acceptance Value $\leq$ 15.0	Acceptance value:4.82 NA
8	Dissolution	Not less than 75% (Q) of the stated amount of Sitagliptin dissolve in 45 minutes.	Min: : 99.0 % Max: : 107.1 % Average::101.5 %
9	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: : 102.6 % Assay:mg/Tab:51.29 mg/tab
10	Organics impurities		
10.1	Sitagliptin acid	Not more than 0.2%	Not Detected
10.2	Fumarate adduct (if present)	Not more than 0.2%	Not Detected
10.3	Sitagliptin triazecine analog	Not more than 0.2%	Not detected
10.4	Sitagliptin styrylacetyl analog	Not more than 0.2%	Not Detected

Remarks: APPROVED (Sample conforms to above Specification)

Comments: --

Prepared By	Reviewed By	Approved By
ranjit.nayak(Analyst)	omprakash.sharma(Manager)	Mahendra.Bisht(Manager)
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S. No.	TEST	SPECIFICATION	RESULT
10.5	Sitagliptin phenylcrotonyl analog	Not more than 0.2%	Not Detected
10.6	Any other individual impurity	Not more than 0.2%	Below Disregard Limit
10.7	Total impurities	Not more than 0.6%	Below Disregard Limit
11	Hardness	Not less than 30.0 Newton	Max : 68.7 N Min:44.2 N
12	Water Content (by KF)	Not more than 6.0% w/w	3.32 %
13	Microbial Limits		
13.1	Total aerobic microbial count	Not more than 10^3 CFU/gm	10 CFU/gm
13.2	Total molds & yeasts count	Not more than 10^2 CFU/gm	<10 CFU/gm
13.3	E.coli	Absent /gm	Absent /gm

Remarks: APPROVED (Sample conforms to above Specification)

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