



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

Certificate of Analysis

Product Name: Sitasmart-100

Generic Name	Sitagliptin Tablets IP / USP	Packing Code	G1790006
Batch Log No	32415781	Packing Batch No	G1794002
Bulk Batch No	G1794002	Batch Size	1.0 Lac
Packing Type	5*3*10 Tabs	Date of Analysis	16/04/2024
A.R. No.	2003FP324001851	Reference	IP/USP
Mfg. Date	04/2024	Exp. Date	03/2026
Specification No	FPS-G179-01	Date of Release	07/05/2024

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	410.0mg $\pm$ 7.5%	411.73 mg
4	Uniformity of weight	$\pm$ 7.5% of avg. wt.	%Maximum +ve deviation : 1.6 % %Maximum -ve deviation:-3.0 %
5	Disintegration time	Not more than 5 minutes	Disintegration time:1.17 Minutes
6	Uniformity of Dosage Units (By weight variation)	Acceptance Value $\leq$ 15.0	Acceptance value:1.45 NA
7	Dissolution	Not less than 75% (Q) of the stated amount of Sitagliptin dissolve in 45 minutes.	Min : 98.2 % Max : 109.0 % Average::103.6 %
8	Assay Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP/USP equivalent to sitagliptin.....100mg	95.00mg to 105.00mg (95.0% to 105.0% of Labeled Claim)	Assay % of Label Claim: : 101.0 % Assay: mg/Tab:100.96 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)
07/05/2024 14:22	07/05/2024 15:05	07/05/2024 15:57
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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 60.0 Newton	Max: : 222.7 N Min.:180.4 N
10.2	Water Content (by KF)	Not more than 6.0% w/w	3.17 %

Remarks: APPROVED (Sample conforms to above Specification)

Prepared By

satyendra.p(Chemist)

07/05/2024 14:22

Reviewed By

omprakash.sharma(Manager)

07/05/2024 15:05

Approved By

Mahendra.Bisht(Manager)

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