



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	32458440	Packing Batch No	G1794010
Bulk Batch No	G1794010	Batch Size	4.0 Lac
Packing Type	5*3*10 Tabs	Date of Analysis	10/01/2025
A.R. No.	2003FP325000192	Reference	IP/USP
Mfg. Date	12/2024	Exp. Date	11/2026
Specification No	FPS-G179-01	Date of Release	16/01/2025

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%	411.14 mg
4	Uniformity of weight	$\pm$ 7.5% of avg. wt.	%Maximum +ve deviation : 2.4 % %Maximum -ve deviation:-1.1 %
5	Disintegration time	Not more than 5 minutes	Disintegration time:0.38 Minutes
6	Uniformity of Dosage Units (By weight variation)	Acceptance Value $\leq$ 15.0	Acceptance value:2.16 NA
7	Dissolution	Not less than 75% (Q) of the stated amount of Sitagliptin dissolve in 45 minutes.	Min: : 99.4 % Max: : 101.9 % Average::101.1 %
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: : 102.3 % Assay: mg/Tab:102.31 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

Remarks: APPROVED (Sample conforms to above Specification)

Comments: --

Prepared By		Reviewed By		Approved By	
Mansi.Pareek(Analyst)		omprakash.sharma(Manager)		Mahendra.Bisht(Manager)	
16/01/2025 14:20		16/01/2025 14:54		16/01/2025 16:31	
Printed By: omprakash.sharma			Printed On: 17/01/2025 09:52		
Copy No.: 1			Page No.: 1 of 2		
Note: This document has been generated electronically with E-Signature.					
CNo.: M25000048					
Format No.: SOP/GQC/027/F/02-02					



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	32458440	Packing Batch No	G1794010
Bulk Batch No	G1794010	Batch Size	4.0 Lac
Packing Type	5*3*10 Tabs	Date of Analysis	10/01/2025
A.R. No.	2003FP325000192	Reference	IP/USP
Mfg. Date	12/2024	Exp. Date	11/2026
Specification No	FPS-G179-01	Date of Release	16/01/2025

S. No.	TEST	SPECIFICATION	RESULT
9.4	Sitagliptin styrylacetyl analog	Not more than 0.2%	Not Detected
9.5	Sitagliptin phenylcrotonyl analog	Not more than 0.2%	Not Detected
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: : 143.3 N Min::119.6 N
10.2	Water Content (by KF)	Not more than 6.0% w/w	0.13 %
11	Microbial Limits		
11.1	Total aerobic microbial count	Not more than 10^3 CFU/gm	10 CFU/gm
11.2	Total molds & yeasts count	Not more than 10^2 CFU/gm	<10 CFU/gm
11.3	E.coli	Absent /gm	Absent /gm

Remarks: APPROVED (Sample conforms to above Specification)

Comments: --

Prepared By	Reviewed By	Approved By
Mansi.Pareek(Analyst)	omprakash.sharma(Manager)	Mahendra.Bisht(Manager)
16/01/2025 14:20	16/01/2025 14:54	16/01/2025 16:31

Printed By: omprakash.sharma

Printed On: 17/01/2025 09:52

Copy No.: 1

Page No.: 2 of 2

Note: This document has been generated electronically with E-Signature.

CNo.: M25000048

Format No.: SOP/GQC/027/F/02-02