



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

Certificate of Analysis

Product Name: Sitasart-50

Generic Name	Sitagliptin Tablets IP / USP	Packing Code	G1780005
Batch Log No	32426011	Packing Batch No	G1784004
Bulk Batch No	G1784004	Batch Size	2.0 Lac
Packing Type	5*3*10 Tabs	Date of Analysis	22/06/2024
A.R. No.	2003FP324003091	Reference	IP
Mfg. Date	06/2024	Exp. Date	05/2026
Specification No	FPS-G178-01	Date of Release	06/07/2024

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%	201.90 mg
4	Uniformity of weight	$\pm$ 7.5% of avg. wt.	%Maximum +ve deviation : 3.0 % %Maximum -ve deviation:-2.0 %
5	Disintegration time	Not more than 5 minutes	Disintegration time:0.55 Minutes
6	Uniformity of Dosage Units (By weight variation)	Acceptance Value $\leq$ 15.0	Acceptance value:3.64 NA
7	Dissolution	Not less than 75% (Q) of the stated amount of Sitagliptin dissolve in 45 minutes.	Min: : 94.4 % Max: : 96.5 % Average::95.4 %
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: : 99.0 % Assay:mg/Tab:49.51 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

Remarks: APPROVED (Sample conforms to above Specification)

Prepared By

ranjit.nayak(Analyst)

06/07/2024 13:07

Reviewed By

omprakash.sharma(Manager)

06/07/2024 14:05

Approved By

Mahendra.Bisht(Manager)

06/07/2024 15:00

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Printed On: 06/07/2024 15:33

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CNo.: C240003572

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



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S. No.	TEST	SPECIFICATION	RESULT
9.5	Sitagliptin phenylcrotonyl analog	Not more than 0.2%	Not Detected
9.6	Any other individual impurity	Not more than 0.2%	Not Detected
9.7	Total impurities	Not more than 0.6%	Not Detected
10	Additional Tests		
10.1	Hardness	Not less than 30.0 Newton	Max : 68.7 N Min:44.6 N
10.2	Water Content (by KF)	Not more than 6.0% w/w	3.53 %

Remarks: APPROVED (Sample conforms to above Specification)

Prepared By		Reviewed By		Approved By	
ranjit.nayak(Analyst)		omprakash.sharma(Manager)		Mahendra.Bisht(Manager)	
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