



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

Certificate of Analysis

Product Name: Sitasmart-M 50/1000

Generic Name	Sitagliptin & Metformin Hydrochloride Tablets	Packing Code	G7700005
Batch Log No	32418812	Packing Batch No	G7704002
Bulk Batch No	G7704002	Batch Size	3.0 Lac
Packing Type	(10*2*15) Tabs	Date of Analysis	17/05/2024
A.R. No.	2003FP324002419	Reference	In house
Mfg. Date	05/2024	Exp. Date	04/2026
Specification No	FPS-G770-00	Date of Release	25/05/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Brown colour biconvex, oval shaped, film coated tablet having plain on both side.	Brown colour biconvex, oval shaped, film coated tablet having plain on both side.
2	Identification (By HPLC) For Sitagliptin & Metformin HCl	The retention times of the peaks of sample solution should correspond to those of the standard solution, as obtained in the Assay.	The retention times of the peaks of sample solution should correspond to those of the standard solution, as obtained in the Assay.
3	Average weight	1380.0mg $\pm$ 5.0%	1372.36 mg
4	Uniformity of weight	$\pm$ 5.0% of average weight	%Maximum +ve deviation : 1.1 % %Maximum -ve deviation:-1.0 %
5	Disintegration time	Not more than 30 minutes	Disintegration time:14.12 Minutes
6	Dissolution For Sitagliptin (By HPLC)	Not less than 70% (Q) of the labeled amount of Sitagliptin should be dissolved in 30 minutes.	Min: : 89.0 % Max: : 94.7 % Average::92.7 %
7	Dissolution For Metformin Hydrochloride (By UV)	Not less than 70% (Q) of the labeled amount of Metformin Hydrochloride should be dissolved in 30 minutes.	Min: : 86.3 % Max: : 88.4 % Average::87.2 %
8	Related Substances		
8.1	For Metformin Hydrochloride		
8.1.1	Dicyandiamide	Not more than 0.02% w/w	Not detected
8.1.2	Any other secondary peak	Not more than 0.1%	0.03 %
8.2	For Sitagliptin		
8.2.1	Single maximum impurity	Not more than 0.2%	Not detected
8.2.2	Total impurities	Not more than 0.5%	Not detected
9	Assay-Each Film Coated tablet contains:		
9.1	Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin.....50mg	47.50mg to 52.50mg (95.0% to 105.0% of Labeled claim)	Assay % of Label Claim: : 100.4 % Assay:mg/Tab:50.22 mg/tab
9.2	Metformin Hydrochloride IP..... 1000mg	950.00mg to 1050.00mg (95.0% to 105.0% of Labeled claim)	Assay (i) % : 100.4 %

Remarks: APPROVED (Sample conforms to above Specification)

Prepared By		Reviewed By	Approved By
satyendra.p(Chemist)		omprakash.sharma(Manager)	Mahendra.Bisht(Manager)
25/05/2024 14:17		25/05/2024 16:40	25/05/2024 16:46
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S. No.	TEST	SPECIFICATION	RESULT
			Assay:mg/Tab:1003.74 mg/tab

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