



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

Certificate of Analysis

Product Name: Sitasmart-M 50/500

Generic Name	Sitagliptin & Metformin Hydrochloride Tablets	Packing Code	G7680006
Batch Log No	32418791	Packing Batch No	G7684001
Bulk Batch No	G7684001	Batch Size	5.0 Lac
Packing Type	(10*2*15)Tabs	Date of Analysis	10/05/2024
A.R. No.	2003FP324002297	Reference	IH
Mfg. Date	05/2024	Exp. Date	04/2026
Specification No	FPS-G768-00	Date of Release	17/05/2024

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Pink colour biconvex, capsule shaped, film coated tablet having break line on one side & plain on other side.	Pink colour biconvex, capsule shaped, film coated tablet having break line on one side & plain on other 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 correspond to those of the standard solution, as obtained in the Assay.
3	Average weight	720.0mg $\pm$ 5.0%	716.95 mg
4	Uniformity of weight	$\pm$ 5.0% of average weight	%Maximum +ve deviation : 1.4 % %Maximum -ve deviation:-2.1 %
5	Disintegration time	Not more than 30 minutes	Disintegration time:4.18 Minutes
6	Dissolution		
6.1	For Sitagliptin	Not less than 70% (Q) of the labeled amount of Sitagliptin should be dissolved in 30 minutes.	Min: : 98.4 % Max: : 101.7 % Average::100.2 %
6.2	For Metformin Hydrochloride	Not less than 70% (Q) of the labeled amount of Metformin Hydrochloride should be dissolved in 30 minutes.	Min: : 90.4 % Max: : 92.4 % Average::91.4 %
7	Related Substances (By HPLC) For Metformin Hydrochloride		
7.1	Dicyandiamide	Not more than 0.02% w/w	Not detected
7.2	Any other secondary peak	Not more than 0.1%	Not detected
8	Related Substances (By HPLC) For Sitagliptin		
8.1	Single maximum impurity	Not more than 0.2%	Not detected
8.2	Total impurities	Not more than 0.5%	Not detected

Remarks: APPROVED (Sample conforms to above Specification)

Comments: --

Prepared By	Reviewed By	Approved By
satyendra.p(Chemist)	omprakash.sharma(Manager)	Mahendra.Bisht(Manager)
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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: : 97.7 % Assay:mg/Tab:48.85 mg/tab
9.2	Metformin Hydrochloride IP..... 500m	475.00mg to 525.00mg (95.0% to 105.0% of Labeled claim)	Assay % of Label Claim: : 99.2 % Assay:mg/Tab:495.88 mg/tab
10	Microbial Limits		
10.1	Total aerobic microbial count	Not more than 10^3 CFU/gm	10 CFU/gm
10.2	Total molds & yeasts count	Not more than 10^2 CFU/gm	<10 CFU/gm
10.3	E.coli	Absent /gm	Absent /gm

Remarks: APPROVED (Sample conforms to above Specification)

Comments: --

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