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

Certificate of Analysis

Product Name: Sitasmart-Dapa 100/10			
Generic Name	Dapagliflozin & Sitagliptin Tablets	**Packing Code**	GG490003
Batch Log No	32422761	**Packing Batch No**	GG494002
Bulk Batch No	GG494002	**Batch Size**	2.0 Lac
Packing Type	10*10 Tablets	**Date of Analysis**	15/06/2024
A.R. No.	2003FP324002949	**Reference**	IH
Mfg. Date	06/2024	**Exp. Date**	05/2026
Specification No	FPS-GG49-00	**Date of Release**	06/07/2024

S. No.	TEST	SPECIFICATION	RESULT
1	**Description**	Red colored, round shaped, biconvex, film coated tablet having plain on both side	Red colored, round shaped, biconvex, film coated tablet having plain on both side
2	**Identification**		
2.1	**For Dapagliflozin (By HPLC)**	In the Assay, the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with dapagliflozin propanediol monohydrate standard solution	In the Assay, the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with dapagliflozin propanediol monohydrate standard solution
2.2	**For Sitagliptin (By HPLC)**	In the Assay, the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with sitagliptin phosphate monohydrate standard solution	In the Assay, the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with sitagliptin phosphate monohydrate standard solution
3	**Average weight**	410.0mg ± 5%	408.85 mg
4	**Uniformity of weight**	± 5% of average weight	%Maximum +ve deviation : 2.3 % %Maximum –ve deviation:-1.0 %
5	**Disintegration time**	Not more than 30 minutes	Disintegration time:1.15 Minutes
6	**Uniformity of dosage units**		
6.1	**Content Uniformity for Dapagliflozin Propanediol Monohydrate (By HPLC)**	Between 85.0% and 115.0% of average content	Max : 101.0 % Min:98.4 %
6.2	**Content Uniformity for Sitagliptin (By weight variation)**	The acceptance value (L1) is less than or equal to 15.0	Acceptance value:2.4 NA
7	**Dissolution**		
7.1	**For Dapagliflozin (By HPLC) (Apparatus-Paddle, 100rpm,**	Not less than 75% (Q) of the stated amount of Dapagliflozin is dissolved in 45 minutes	Min : 87.4 %

Remarks: APPROVED (Sample conforms to above Specification)

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Prepared By	**Reviewed By**	**Approved By**
yogesh.singh(Analyst)	ramujagir.yadav(Chemist)	Mahendra.Bisht(Manager)
06/07/2024 15:38	06/07/2024 15:39	06/07/2024 16:23

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S. No.	TEST	SPECIFICATION	RESULT
	1000ml of Phosphate buffer pH 7.8 at 45 minutes)		Max : 91.3 % Average:89.1 %
7.2	For Sitagliptin (By HPLC) (Apparatus-Paddle, 75rpm, 900ml of 0.025M sodium chloride at 45 minutes)	Not less than 70% (Q) of the stated amount of Sitagliptin is dissolved in 45 minutes	Min : 90.4 % Max : 98.7 % Average:94.8 %
8	Assay-Each Film Coated tablet contains:		
8.1	Dapagliflozin Propanediol Monohydrate USP Equivalent to Dapagliflozin.....10mg	9.00mg to 11.00g (90.0% to 110.0% of Labeled claim)	Assay % of Label Claim : 98.7 % Assay:mg/Tab:9.87 mg/tab
8.2	Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin.....100mg	95.00mg to 105.00mg (95.0% to 105.0% of Labeled claim)	Assay % of Label Claim : 101.4 % Assay:mg/Tab:101.42 mg/tab
9	Related Substances		
9.1	For Dapagliflozin		
9.1.1	Unknown single impurity	Not more than 0.5%	0.02 %
9.1.2	Total impurities	Not more than 2.0%	0.07 %
9.2	For Sitagliptin		
9.2.1	Maximum single impurity	Not more than 0.2%	Not Detected
9.2.2	Total impurities	Not more than 0.5%	Not Detected

Remarks: APPROVED (Sample conforms to above Specification)
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