



SYNOKEM LIFESCIENCES PVT. LTD.
PLOT NO. 11, SECTOR-4, IIE, SIDCUL, RANIPUR, HARIDWAR -249403

CERTIFICATE OF ANALYSIS

Product Name: Sitasmart GM 1

Generic Name: Sitagliptin 50 mg, Metformin Hydrochloride 1000 mg And Glimepiride 1 mg Tablets

Batch No.:	24S3GTA277	A.R. No.:	DGCF400443
Material Code:	4010011777	Batch Size:	200000 TABLET
Sample Size:	30 tablets	Stage:	Finish
Mfg. Date:	Apr 2024	Exp. Date:	Mar 2026
Received on:	19.04.2024	Date of Release:	22.04.2024

Sr. No	Test	Result	Specification
1.	Description	Brown colour, oblong shape, biconvex, one side break line & another side plain film coated tablet.	Light Brown to brown colour, oblong shape, biconvex, one side break line & another side plain film coated tablet.
2.	Identification		
	i) Sitagliptin (by HPLC)	Complies	The retention time of the principal peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation as obtained in assay of Sitagliptin.
	(ii) Metformin Hydrochloride (By UV - VIS Spectrophotometer)	Complies	The sample shows maxima at about 233nm as is Assay of Metformin Hydrochloride
	(iii) Glimepiride IP (By HPLC)	Complies	The retention time of the principal peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation as obtained in assay of Glimepiride.
3.	Average weight	1373.80 mg	1370 mg $\pm$ 5% w/w (1301.50 mg to 1438.50 mg)
4.	Uniformity of weight	Min:-0.89%;Min:+0.91%	$\pm$ 5.0% w/w of average weight
5.	Dissolution		
	(i) Sitagliptin	Mean:99.06%; Min:97.33%; Max:100.16%	Not less than 70% (Q) of the label claim to be dissolve in 60 minutes
	(ii) Metformin Hydrochloride IP	Mean:95.52%; Min:94.96%; Max:96.23%	Not less than 70% (Q) of the label claim to be dissolve in 45 minutes
	(iii) Glimepiride IP	Mean:93.90%; Min:92.18%; Max:96.49%	Not less than 75% (Q) of the label claim to be dissolve in 90 minutes

Prepared by
Sign/Date

Checked by
Sign/Date

Approved by
Sign/Date



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6.	Related Substances by HPLC		
	Sitagliptin		
	Single Maximum unknown impurity	Not detected	Not more than 0.200 %
	Total Impurities	Not detected	Not more than 0.500 %
	Glimepiride		
	Glimepiride Impurity B	Not detected	Not more than 2.500 %
	Single Maximum unknown impurity	BDL	Not more than 0.500%
	Total Impurities (Except Impurity B)	BDL	Not more than 1.000 %
	Metformin Hydrochloride		
	Dicyandiamide	0.001%	Not more than 0.020 %
	Any individual maximum unspecified impurity	0.012%	Not more than 0.100 %
	Total Impurities	0.015%	Not more than 0.500 %
	Assay: (By HPLC)		
	Each film coated tablet on an average weight contains:		
7.	Ingredients	Obtained	Claim Limit
	Sitagliptin Phosphate IP	50.68 MG	50.00 MG 45.00 mg to 55.00 mg
	Metformin Hydrochloride IP	991.88 MG	1000.00 MG 900.00 mg to 1100.00 mg
	Glimepiride IP	0.99 MG	1.00 MG 0.90 mg to 1.10 mg

Report: In the opinion of the undersigned the sample referred above is of standard quality as defined in the act & rules made.

Remarks: The above sample/Material is Complies/~~Does not~~ comply as per approved specification IP/BP/USP/IH/JP.

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