



Synokem Lifesciences Pvt. Ltd.

Plot No. 56-57 Sector - 6 A, I.I.E, (Sidcul) Ranipur (BHEL) Haridwar (Uttarakhand) 249403
MFG Lic No. - 27/UA/2018 & 27/UA/SC/P-2018

The Drugs & Cosmetics Act 1940 and the Rules there under

CERTIFICATE OF ANALYSIS

Plant Code : 8001

Division : 10

AR. NO. : DGCF400456

MATERIAL CODE : 4010011858

MATERIAL NAME : SITASMART GM 2

GENERIC NAME : Sitagliptin 50 mg, Metformin Hydrochloride 1000 mg And Glimepiride 2 mg
Tablets

BATCH NO. : 24S3GTA292

BATCH SIZE : 200000 TABLET

RECEIVED ON : 22.04.2024

STAGE : FINISH

MFG. DATE : Apr 2024

EXP. DATE : Mar 2026

SAMPLE SIZE : 30 TABLET

TEST	RESULTS	SPECIFICATION
DESCRIPTION	Green colour, oblong shape, biconvex one side break line & another side plain film coated tablet.	Light Green to green colour, oblong shape, biconvex one side break line & another side plain film coated tablet.
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) 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.
Metformin Hydrochloride (By UV-VIS Spectrophotometer)	Complies	The sample shows maxima at about 233nm as is Assay of Metformin Hydrochloride
AVERAGE WEIGHT	1375.7 mg	1370 mg $\pm$ 5% w/w (1301.50 mg to 1438.50 mg)
UNIFORMITY OF WEIGHT	Min: -1.35%;Max: + 0.89%	$\pm$ 5.0% w/w of average weight
DISSOLUTION		
(i) SITAGLIPTIN	Mean:101.30%;Min:100.65%;Max:101.95 %	Not less than 70% (Q) of the label claim to be dissolve in 60 minutes.
(ii) METFORMIN HYDROCHLORIDE IP	Mean:96.21%;Min:95.94%;Max:96.47%	Not less than 70% (Q) of the label claim to be dissolve in 45 minutes.
(iii) GLIMEPIRIDE IP	Mean:89.72%;Min:88.89%;Max:90.79%	Not less than 75% (Q) of the label claim to be dissolve in 90 minutes.
RELATED SUBSTANCES		

PREPARED BY

[Signature]
(Sign/Date)

Date of Completion

24/04/2024

CHECKED BY

[Signature]
(Sign/Date)

APPROVED BY

[Signature]
(Sign/Date)



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TEST	RESULTS	SPECIFICATION
(i) SITAGLIPTIN		
SINGLE MAXIMUM UNKNOWN IMPURITY	Not Detected	Not more than 0.200 %
TOTAL IMPURITIES	Not Detected	Not more than 0.500 %
(ii) GLIMEPIRIDE		
GLIMEPIRIDE IMPURITY B	Not Detected	Not more than 2.500 %
SINGLE MAXIMUM UNKNOWN IMPURITY	BDL	Not more than 0.500%
TOTAL IMPURITIES (EXCEPT KNOWN IMPURITIES)	BDL	Not more than 1.000 %
(iii) METFORMIN HYDROCHLORIDE		
DICYANDIAMIDE IMPURITY	Not Detected	Not more than 0.020 %
ANY INDIVIDUAL MAXIMUM UNSPECIFIED IMPURITY	0.0250%	Not more than 0.100%
TOTAL IMPURITIES	0.032%	Not more than 0.500 %
ASSAY:		
Each film coated tablet on an average weight contains:		
Ingredients	Obtained	Claim Limit
SITAGLIPTIN PHOSPHATE IP Eq. TO SITAGLIPTIN	50.42 MG	50.00 MG 45.00-55.00 MG
METFORMIN HYDROCHLORIDE IP	1007.52 MG	1000.00 MG 900.00-1100.00 MG
GLIMEPIRIDE IP	2.03 MG	2.00 MG 1.80-2.20 MG
PREPARED BY 24/04/2024 (Sign/Date)		
CHECKED BY (Sign/Date)		
APPROVED BY (Sign/Date)		
Date of Completion 24/04/2024		



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TEST	RESULTS	SPECIFICATION
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	

PREPARED BY

[Signature]
(Sign/Date)

Date of Completion

24/04/2024

CHECKED BY

[Signature]
(Sign/Date)

APPROVED BY

[Signature]
(Sign/Date)
24/04/2024