



Synokem Lifesciences PVT. LTD

Plot No. 11 Sector - 4, IIE,(SIDCUL) Ranipur (BHEL) Haridwar (Uttarakhand) 249403
MFG Lic No. - 10/UA/2022, 7/UA/SC/P-2022

The Drugs & Cosmetics Act 1940 and the Rules there under

CERTIFICATE OF ANALYSIS

Plant Code : 8001

Division : 10

AR. NO. : DGCF300362

MATERIAL CODE : 4010011240

MATERIAL NAME : VILDASmart M 50mg/500mg

GENERIC NAME : Vildagliptin 50 mg and Metformin Hydrochloride 500 mg Tablets

BATCH NO. : 23S3GTA207

BATCH SIZE : 400000 TABLET

RECEIVED ON : 18.12.2023

STAGE : FINISH

MFG. DATE : Dec 2023

EXP. DATE : Nov 2025

SAMPLE SIZE : 30 TABLET

TEST	RESULTS	SPECIFICATION
DESCRIPTION	Yellow coloured, oval, biconvex, scored on one side, film coated tablets.	Yellow coloured, oval, biconvex, scored on one side, film coated tablets.
IDENTIFICATION		
VILDAGLIPTIN (BY HPLC)	Complies	The retention time of principal peak in the chromatogram obtained with test solution (a) corresponds to the principal peak in the chromatogram obtained with reference solution (a).
METFORMIN HYDROCHLORIDE (BY HPLC)	Complies	The retention time of principal peak in the chromatogram obtained with test solution (b) corresponds to the principal peak in the chromatogram obtained with reference solution (a).
AVERAGE WEIGHT	624.53 mg	632.00 mg $\pm$ 5.0% (600.4 to 663.6 mg)
UNIFORMITY OF WEIGHT	Min:-1.63%;Max:+ 1.25%	$\pm$ 5.0 % w/w of average weight.
DISINTEGRATION TIME	07 Min 05 Sec	NMT 30 minutes
DISSOLUTION		
VILDAGLIPTIN	Mean:98.87%;Min:95.94%;Max:102.22%	NLT 80% (Q) of labeled amount, dissolved in 30 minutes
METFORMIN HYDROCHLORIDE	Mean:101.11%;Min:98.90%;Max:104.13%	NLT 80% (Q) of labeled amount, dissolved in 30 minutes
UNIFORMITY OF CONTENT (VILDAGLIPTIN)	Mean:100.00%;Min:97.68%;Max:101.93%	85.0 - 115.0% of the average content
BENZYLTRIMETHYLAMMONIUM HYDROXIDE	Not Detected	NMT 0.4%

PREPARED BY

(Sign/Date)

Date of Completion

19/12/2023

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)



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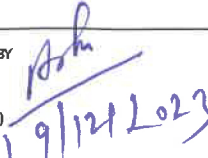
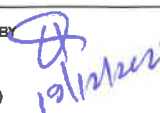
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TEST	RESULTS	SPECIFICATION
RELATED SUBSTANCES (BY HPLC)		
VILDAGLIPTIN IMPURITY A	Not Detected	NMT 1.0%
VILDAGLIPTIN IMPURITY B	Not Detected	NMT 2.0%
VILDAGLIPTIN IMPURITY C	Not Detected	NMT 1.0%
ANY OTHER SECONDARY PEAK	0.176 %	NMT 0.2%
TOTAL IMPURITIES	0.176 %	NMT 3.5%
RELATED SUBSTANCES (BY HPLC)		
DICYANDIAMIDE	Not Detected	NMT 0.02%
ANY OTHER SECONDARY PEAK	BDL	NMT 0.1%
TOTAL IMPURITIES	BDL	NMT 0.6%
ASSAY:		
Each film coated tablet contains		
Ingredients	Obtained	Claim Limit
VILDAGLIPTIN IP	50.54 MG	50.00 MG 47.50-52.50 MG
METFORMIN HYDROCHLORIDE IP	502.43 MG	500.00 MG 475.00-525.00 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/HP/JP.	
PREPARED BY	CHECKED BY	APPROVED BY
(Sign/Date) 	(Sign/Date) 	(Sign/Date) 
Date of Completion		
19/12/2023		