



SYNOKEM LIFESCIENCES PVT. LTD.

PLOT NO. 11, SECTOR-4, IIE, SIDCUL, RANIPUR, HARIDWAR -249403

CERTIFICATE OF ANALYSIS

Product Name: Vildasmart M 50 mg/ 500mg

Generic Name: Vildagliptin 50mg and metformin hydrochloride 500mg Tablets

Batch No.:	23S3GTA239	A.R. No.:	DGCF400029
Product Code:	4010011240	Batch Size:	400000 Tablet
Sample Size:	30 Tablet	Stage:	Finish
Mfg. Date:	Dec 2023	Exp. Date:	Nov 2025
Received on:	10/01/2024	Date of Release:	11/01/2024

Sr. No.	Test	Result	Specification
1.	Description	Yellow coloured, oval, biconvex, scored on one side, film coated tablets.	Yellow coloured, oval, biconvex, scored on one side, film coated tablets.
2.	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).
3.	Average weight	619.24 mg	632.00 mg $\pm$ 5.0% (600.4 to 663.6 mg)
4.	Uniformity of weight	Minimum deviation = -2.98% Maximum deviation = +2.16%	$\pm$ 5.0 % w/w of average weight.
5.	(i) DISINTEGRATION TIME	06 Min 19 Sec	NMT 30 minutes
6.	Dissolution		
	Vildagliptin	Mean:98.97%;Min:97.87%;Max:99.58%	NLT 80% (Q) of labeled amount, dissolved in 30 minutes
	Metformin hydrochloride	Mean:96.71%;Min:95.98%;Max:97.98%	NLT 80% (Q) of labeled amount, dissolved in 30 minutes.
	Uniformity of content (Vildagliptin)	Mean:100.00%;Min:98.14%;Max:102.35%	85.0- 115.0% of the average content

Prepared by
Sign/Date

Checked by
Sign/Date

Approved by
Sign/Date



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7	Benzyltri methyl ammonium hydroxide	Not detected	NMT 0.4%
8.	Related Substances (BY HPLC) (Vildagliptin)		
	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	Not Detected	NMT 0.2%
	Total impurities	Not Detected	NMT 3.5%
9.	Related Substances (BY HPLC)(metformin hydrochloride)		
	Dicyandiamide	Not detected	NMT 0.02%
	Any Other secondary peak	Not detected	NMT 0.1%
	Total impurities	Not detected	NMT 0.6%
10.	Assay: Each film coated tablet contains		
		Obtained	Claim Limit
	Vildagliptin IP	49.32 MG	50.00 MG 47.50-52.50 MG
	Metformin Hydrochloride IP	483.89 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 ☒ Complies/~~Does not comply~~ as per approved specification IP/BP/USP/IN/JP.

Atul
11/01/2024
Prepared by
Sign/Date

11/01/2024
Checked by
Sign/Date

11/01/2024
Approved by
Sign/Date