



Synokem Lifesciences Pvt. Ltd.

Plot No. 56-57 Sector - 6 A, I.I.E, (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. : DGCF401568

MATERIAL CODE : 4010010267

MATERIAL NAME : VILDASmart DAPA 100/10

GENERIC NAME : Vildagliptin(Sustained Release) 100mg and Dapagliflozin 10 mgTablets

BATCH NO. : 24S3GTA687

BATCH SIZE : 200000 TABLET

RECEIVED ON : 17.08.2024

STAGE : FINISH

MFG. DATE : Aug 2024

EXP. DATE : Jul 2026

SAMPLE SIZE : 30 TABLET

TEST	RESULTS	SPECIFICATION
DESCRIPTION	One side light yellow coloured and other side off white coloured round biconvex bi-layered film coated tablets plain on both sides.	One side light yellow to yellow coloured and other side off white to white coloured, round biconvex, bi-layered, film coated, tablets plain on both sides.
IDENTIFICATION (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 the Assay.
AVERAGE WEIGHT	620.72 mg	610 ± 5.0% w/w (579.50 mg to 640.50 mg)
UNIFORMITY OF WEIGHT	Min: -3.06%;Max: +1.33%	± 5.0% w/w of average weight
UNIFORMITY OF CONTENT (DAPAGLIFLOZIN)	Mean:100.00%;Min:95.47%;Max:103.63%	85% - 115% of average content
DISSOLUTION (BY HPLC)		
(A) DAPAGLIFLOZIN	Mean:95.99%;Min:91.72%;Max:100.91%	Not less than 70% (Q) of the label claim to be dissolve in 30 minutes.
(B) VILDAGLIPTIN		
4th HOUR	Mean:52.86%;Min:51.27%;Max:54.53%	35% - 65%
8th HOUR	Mean:74.63%;Min:72.43%;Max:77.21%	55% - 85%
16th HOUR	Mean:95.91%;Min:91.67%;Max:99.82%	Not less than 85%
RELATED SUBSTANCES (BY HPLC)		
DAPAGLIFLOZIN IMPURITY (DF-03)	Not Detected	Not more than 1.0%
DAPAGLIFLOZIN IMPURITY (DF-04)	Not Detected	Not more than 1.0%
VILDAGLIPTIN IMPURITY A	Not Detected	Not more than 1.0%

PREPARED BY

(Sign/Date)

Date of Completion

23/08/2024

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)



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SAMPLE SIZE : 30 TABLET

TEST	RESULTS	SPECIFICATION
VILDAGLIPTIN IMPURITY B	Not Detected	Not more than 2.0%
VILDAGLIPTIN IMPURITY C	Not Detected	Not more than 1.0%
SINGLE MAXIMUM UNKNOWN IMPURITY	Not Detected	Not more than 0.5%
TOTAL IMPURITIES (EXCEPT KNOWN IMPURITIES)	Not Detected	Not more than 2.0%
ASSAY		
Each film coated bilayered tablet contains:		
Ingredients	Obtained	Claim Limit
DAPAGLIFLOZIN PROPANEDIOL USP EQ. TO DAPAGLIFLOZIN	10.35 MG	10.00 MG 9.00-11.00 MG
VILDAGLIPTIN IP (AS SUSTAINED RELEASE)	104.55 MG	100.00 MG 90.00-110.00 MG
REPORT : In the opinion of the undersigned the sample referred above is of standard quality as defined in the act & rules made there under		
REMARKS : The above sample/ Material is Complies/Does not comply as per approved specification IP/BP/USP/HP/JP.		

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The Drugs & Cosmetics Act 1940 and the Rules there under

CERTIFICATE OF ANALYSIS

Plant Code : 8001
Division : 10

AR. NO. : DGCF401581
MATERIAL CODE : 4010011947
MATERIAL NAME : SUGAFLO MV

GENERIC NAME : Dapagliflozin 10 mg, Vildagliptin (SR) 100 mg and Metformin (SR) 500 mg
Tablets

BATCH NO. : 24S3GTA693
BATCH SIZE : 200000 TABLET

RECEIVED ON : 18.08.2024
STAGE : FINISH
MFG. DATE : Aug 2024
EXP. DATE : Jul 2026
SAMPLE SIZE : 30 TABLET

TEST	RESULTS	SPECIFICATION
DESCRIPTION	Light red coloured on one side & other side white coloured elongated biconvex film coated bilayered tablets plain both side.	Light red coloured on one side & other side white coloured, elongated biconvex, film coated bilayered tablets, plain both side.
IDENTIFICATION		
VILDAGLIPTIN (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 the Assay of Vildagliptin.
DAPAGLIFLOZIN PROPANEDOL	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 the Assay of Dapagliflozin.
METFORMIN HYDROCHLORIDE (BY UV-VIS SPECTROPHOTOMETER)	Complies	Should Be comply as per assay.
AVERAGE WEIGHT	1249.44 mg	1240.00 $\pm$ 5.0 % w/w
UNIFORMITY OF WEIGHT	Min: -1.09%;Max: + 0.78%	$\pm$ 5.00 % w/w of average weight
UNIFORMITY OF CONTENT (DAPAGLIFLOZIN)	Mean:100.00%;Min:99.20%;Max:100.13%	85.00 - 115.00% of average content
DISSOLUTION (BY HPLC)		
DAPAGLIFLOZIN	Mean:93.84%;Min:91.88%;Max:95.61%	Not less than 70.0% (Q) of the label claim to be dissolve in 30 minutes.
VILDAGLIPTIN		
4th HOUR	Mean:45.83%;Min:44.56%;Max:46.47%	35.0 - 65.0%

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