



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. : DGCF300347

MATERIAL CODE : 4010011167

MATERIAL NAME : VILDASMA RT TRIO

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

BATCH NO. : 23S3GTA221

BATCH SIZE : 100000 TABLET

RECEIVED ON : 13.12.2023

STAGE : FINISH

MFG. DATE : Nov 2023

EXP. DATE : Oct 2025

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	1246.33 mg	1240.00 ± 5.0 % w/w
UNIFORMITY OF WEIGHT	Min:-0.97%;Max:0.82%	± 5.00 % w/w of average weight
UNIFORMITY OF CONTENT (DAPAGLIFLOZIN)	Mean:100.00%,Min:97.73%,Max:102.00%	85.00 - 115.00% of average content
DISSOLUTION (BY HPLC)		
DAPAGLIFLOZIN	Mean:95.25%,Min:91.49%,Max:99.00%	Not less than 70.0% (D) of the label claim to be dissolve in 30 minutes.
VILDAGLIPTIN		
4th HOUR	Mean:49.05%,Min:43.63%,Max:56.09%	35.0 - 65.0%

PREPARED BY

Atul
13/12/2023
(Sign/Date)

CHECKED BY

EL
13/12/2023
(Sign/Date)

APPROVED BY

[Signature]
13/12/2023
(Sign/Date)

Date of Completion

13/12/2023



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8th HOUR	Mean:71.46%,Min:65.16%,Max:79.58%	55.0 - 85.0%
16th HOUR	Mean:98.97%,Min:94.19%,Max:103.91%	Not less than 85.0%
METFORMIN HYDROCHLORIDE		
1st HOUR	Mean:32.76%,Min:32.18%,Max:33.59%	20.0 to 45.0%
3rd HOUR	Mean:56.94%,Min:54.80%,Max:58.24%	40.0 to 80.0%
10th HOUR	Mean:98.29%,Min:96.23%,Max:99.75%	Not less than 75.0%
RELATED SUBSTANCES (BY HPLC)		
DAPAGLIFLOZIN IMPURITY (DF-03)	Not Detected	NMT 1.0%
DAPAGLIFLOZIN IMPURITY (DF-04)	Not Detected	NMT 1.0%
VILDAGLIPTIN IMPURITY A	Not Detected	NMT 1.0%
VILDAGLIPTIN IMPURITY B	Not Detected	NMT 1.0%
VILDAGLIPTIN IMPURITY C	0.002%	NMT 1.0%
SINGLE MAXIMUM UNKNOWN IMPURITY	0.010%	NMT 0.5%
TOTAL IMPURITIES (EXCEPT KNOWN IMPURITIES)	0.035%	NMT 1.0%
METFORMIN HYDROCHLORIDE		
DICYANDIAMIDE	0.001%	NMT 0.02%
ANY INDIVIDUAL MAXIMUM	0.011%	NMT 0.5%

PREPARED BY

Atul
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(Sign/Date)

CHECKED BY

LC
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CERTIFICATE OF ANALYSIS

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Division : 10

AR. NO. : DGCF300347

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MATERIAL NAME : VILDAS MART TRIO

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SAMPLE SIZE : 30 TABLET

TEST	RESULTS	SPECIFICATION
UNSPECIFIED IMPURITY		NMT 1.0%
TOTAL IMPURITIES (EXCEPT KNOWN IMPURITIES)	0.011%	
TOTAL IMPURITIES (DAPAGLIFLOZIN+ VILDAGLIPTIN+ METFORMIN HYDROCHLORIDE) EXCEPT KNOWN IMPURITIES	0.046%	NMT 2.0%
ASSAY: (BY HPLC) Each film coated bi-layered tablet on an average weight contains:		
Ingredients	Obtained	Claim Limit
VILDAGLIPTIN IP 100 MG (AS SUSTAINED RELEASE)	100.33 MG	100.00 MG 90.00-110.00 MG
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE EQ. TO DAPAGLIFLOZIN	9.86 MG	10.00 MG 9.00-11.00 MG
METFORMIN HYDROCHLORIDE IP (AS EXTENDED RELEASE FORM)	500.89 MG	500.00 MG 450.00-550.00 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

[Signature]
(Sign/Date) 13/12/2023

CHECKED BY

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(Sign/Date) 13/12/2023

APPROVED BY

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