



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. : DGCF400421

MATERIAL CODE : 4010011167

MATERIAL NAME : VILDASMA RTrio

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

BATCH NO. : 24S3GTA254

BATCH SIZE : 100000 TABLET

RECEIVED ON : 13.04.2024

STAGE : FINISH

MFG. DATE : Apr 2024

EXP. DATE : Mar 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	1249.30 MG	1240.00 ± 5.0 % w/w
UNIFORMITY OF WEIGHT	Min: -2.31%;Max: + 1.80%	± 5.00 % w/w of average weight
UNIFORMITY OF CONTENT (DAPAGLIFLOZIN)	Mean:100.00%;Min:88.30%;Max:110.05%	85.00 - 115.00% of average content
DISSOLUTION (BY HPLC)		
DAPAGLIFLOZIN	Mean:101.78%;Min:99.81%;Max:103.73%	Not less than 70.0% (Q) of the label claim to be dissolve in 30 minutes.
VILDAGLIPTIN		
4th HOUR	Mean:51.79%;Min:47.63%;Max:57.36%	35.0 - 65.0%

PREPARED BY

(Sign/Date)

Date of Completion

18/04/2024

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)



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. : DGCF400421

MATERIAL CODE : 4010011167

MATERIAL NAME : VILDAS MART TRIO

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

BATCH NO. : 24S3GTA254

BATCH SIZE : 100000 TABLET

RECEIVED ON : 13.04.2024

STAGE : FINISH

MFG. DATE : Apr 2024

EXP. DATE : Mar 2026

SAMPLE SIZE : 30 TABLET

TEST	RESULTS	SPECIFICATION
8th HOUR	Mean:75.21%;Min:69.11%;Max:81.97%	55.0 - 85.0%
16th HOUR	Mean:99.95%;Min:96.03%;Max:106.92%	Not less than 85.0%
METFORMIN HYDROCHLORIDE		
1st HOUR	Mean:36.69%;Min:35.37%;Max:38.08%	20.0 to 45.0%
3rd HOUR	Mean:57.64%;Min:55.71%;Max:59.14%	40.0 to 80.0%
10th HOUR	Mean:96.46%;Min:95.40%;Max:97.31%	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	0.001%	NMT 1.0%
VILDAGLIPTIN IMPURITY C	Not Detected	NMT 1.0%
SINGLE MAXIMUM UNKNOWN IMPURITY	0.034%	NMT 0.5%
TOTAL IMPURITIES (EXCEPT KNOWN IMPURITIES)	0.034%	NMT 1.0%
METFORMIN HYDROCHLORIDE		
DICYANDIAMIDE	Not Detected	NMT 0.02%
PREPARED BY (Sign/Date) <i>[Signature]</i> Date of Completion 18/04/2024		
CHECKED BY (Sign/Date) <i>[Signature]</i>		
APPROVED BY (Sign/Date) <i>[Signature]</i>		



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. : DGCF400421

MATERIAL CODE : 4010011167

MATERIAL NAME : VILDASMA RTIO

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

BATCH NO. : 24S3GTA254

BATCH SIZE : 100000 TABLET

RECEIVED ON : 13.04.2024

STAGE : FINISH

MFG. DATE : Apr 2024

EXP. DATE : Mar 2026

SAMPLE SIZE : 30 TABLET

TEST	RESULTS	SPECIFICATION
ANY INDIVIDUAL MAXIMUM UNSPECIFIED IMPURITY	0.029%	NMT 0.5%
TOTAL IMPURITIES (EXCEPT KNOWN IMPURITIES)	0.032%	NMT 1.0%
TOTAL IMPURITIES (DAPAGLIFLOZIN+ VILDAGLIPTIN+ METFORMIN HYDROCHLORIDE) EXCEPT KNOWN IMPURITIES	0.066%	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)	99.62 MG	100.00 MG 90.00-110.00 MG
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE EQ. TO DAPAGLIFLOZIN	10.16 MG	10.00 MG 9.00-11.00 MG
METFORMIN HYDROCHLORIDE IP (AS EXTENDED RELEASE FORM)	502.24 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 <u>Complies/Does not</u> comply as per approved specification-IP/BP/USP/IH/JP.	

PREPARED BY

(Sign/Date)

Date of Completion

18/04/2024

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)