



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. : DGCF402087
MATERIAL CODE : 4010010267
MATERIAL NAME : VILDASMA RT DAPA 100/10
GENERIC NAME : Vildagliptin(Sustained Release) 100mg and Dapagliflozin 10 mgTablets
BATCH NO. : 24S3GTA865
BATCH SIZE : 200000 TABLET

RECEIVED ON : 07.10.2024
STAGE : FINISH
MFG. DATE : Sep 2024
EXP. DATE : Aug 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	617.85 mg	610 $\pm$ 5.0% w/w (579.50 mg to 640.50 mg)
UNIFORMITY OF WEIGHT	Min: -1.3%;Max: +1.7%	$\pm$ 5.0% w/w of average weight
UNIFORMITY OF CONTENT (DAPAGLIFLOZIN)	Mean:100%;Min:95%;Max:104%	85% - 115% of average content
DISSOLUTION (BY HPLC)		
(A) DAPAGLIFLOZIN	Mean:92%;Min:85%;Max:95%	Not less than 70% (Q) of the label claim to be dissolve in 30 minutes.
(B) VILDAGLIPTIN		
4th HOUR	Mean:50%;Min:47%;Max:51%	35% - 65%
8th HOUR	Mean:72%;Min:67%;Max:81%	55% - 85%
16th HOUR	Mean:94%;Min:87%;Max:109%	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	CHECKED BY (Sign/Date)	APPROVED BY (Sign/Date)
08/10/2024	08/10/2024	08/10/2024



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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	0.083%	Not more than 0.5%
TOTAL IMPURITIES (EXCEPT KNOWN IMPURITIES)	0.136%	Not more than 2.0%
ASSAY		
Each film coated bilayered tablet contains:		
Ingredients	Obtained	Claim Limit
DAPAGLIFLOZIN PROPANEDIOL USP EQ. TO DAPAGLIFLOZIN	10.38 MG	10.00 MG 9.00-11.00 MG
VILDAGLIPTIN IP (AS SUSTAINED RELEASE)	104.79 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/ Materials Complies/Does not comply as per approved specification IP/BP/USP/HP/IP.		

PREPARED BY

(Sign/Date)

Date of Completion

08/10/2024

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)