



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. : DGCF400005
MATERIAL CODE : 4010010992
MATERIAL NAME : LINASmart DAPA 5/10
GENERIC NAME : Linagliptin 5mg and Dapagliflozin 10mg Tablets
BATCH NO. : 24S3GTA004
BATCH SIZE : 200000 TABLET

RECEIVED ON : 03.01.2024
STAGE : FINISH
MFG. DATE : Dec 2023
EXP. DATE : Nov 2025
SAMPLE SIZE : 250 TABLET

TEST	RESULTS	SPECIFICATION
DESCRIPTION	Yellow coloured, round, biconvex, plain on both side, film coated tablet.	Yellow coloured, round, biconvex, plain on both side, film coated tablet.
IDENTIFICATION (BY HPLC)		In the assay, the principal peaks in the chromatogram obtained with the test solution corresponds to the peaks in the chromatogram obtained with the standard solution.
AVERAGE WEIGHT	261.48 mg	257 mg $\pm$ 5.0% (Limit: 244.15 mg to 269.85 mg)
UNIFORMITY OF WEIGHT		$\pm$ 7.5% of average weight
DISSOLUTION (BY HPLC)	Min: -4.02%;Max:2.37%	
(i) LINAGLIPTIN	Mean:102.51%;Min:100.85%;Max:105.09 %	Not less than 70 % (Q) of the labeled claim to be dissolved in 45 minutes.
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE EQ. TO DAPAGLIFLOZIN	Mean:98.10%;Min:92.68%;Max:100.71%	Not less than 70 % (Q) of the labeled claim to be dissolved in 45 minutes.
UNIFORMITY OF CONTENTS (BY HPLC)		
(i) LINAGLIPTIN	Mean:100.00%;Min:97.72%;Max:108.05%	Between 85% to 115% of average content
(ii) DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE EQ. TO DAPAGLIFLOZIN	Mean:100.00%;Min:95.47%;Max:111.65%	Between 85% to 115% of average content
RELATED SUBSTANCES (BY HPLC)		
DF-03	0.003	Not more than 0.5%
DF-04	Not Detected	Not more than 0.5%
SINGLE MAXIMUM UNKNOWN IMPURITY	0.039	Not more than 0.2%

PREPARED BY

(Sign/Date)

Date of Completion

09/01/2024

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)



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TOTAL IMPURITIES (EXCEPT KNOWN IMPURITIES)	0.205	Not more than 2.0%
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ASSAY:

Each film coated tablet on an average weight contains:

Ingredients	Obtained	Claim	Limit
LINAGLIPTIN	5.08 MG	5.00 MG	4.75-5.25 MG
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE EQ. TO DAPAGLIFLOZIN	9.92 MG	10.00 MG	9.50-10.50 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/JP.

Deviation no: DP/PPD/001-24

PREPARED BY

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