



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. : DGCF400483
MATERIAL CODE : 4010011658
MATERIAL NAME : SITASMART-DAPA 100/10
GENERIC NAME : Sitagliptin And Dapagliflozin Tablets
BATCH NO. : 24S3GTA308
BATCH SIZE : 200000 TABLET

RECEIVED ON : 27.04.2024
STAGE : FINISH
MFG. DATE : Apr 2024
EXP. DATE : Mar 2026
SAMPLE SIZE : 100 TABLET

TEST	RESULTS	SPECIFICATION
DESCRIPTION	White coloured, round, biconvex, plain on both sides, film coated tablets.	White coloured, round, biconvex, plain on both sides, film coated tablets.
IDENTIFICATION (BYHPLC)		
(i) SITAGLIPTIN	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 assay of Sitagliptin.
(ii) DAPAGLIFLOZIN	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 assay of Dapagliflozin.
AVERAGE WEIGHT	312.03 mg	310 mg $\pm$ 5% w/w (294.50 mg to 325.50 mg)
UNIFORMITY OF WEIGHT	Min: -2.12%;Max: + 2.34%	$\pm$ 5.0% w/w of average weight
DISINTEGRATION TIME	07 Min 14 Sec	Not more than 30 minutes.
UNIFORMITY OF DOSAGE UNITS BY UNIFORMITY OF CONTENT:		
DAPAGLIFLOZIN	Av: 0.94	Maximum acceptance value for both stage L1 = 15.0 and L2 = 25.0
DISSOLUTION		
(i) SITAGLIPTIN	Mean:99.12%;Min:96.44%;Max:99.81%	Not less than 70% (Q) of the label claim to be dissolve in 30 minutes.
(ii) DAPAGLIFLOZIN	Mean:93.71%;Min:92.18%;Max:95.34%	Not less than 70% (Q) of the label claim to be dissolve in 30 minutes.
ASSAY: (BY HPLC) Each film coated on average weight		

PREPARED BY

(Sign/Date)

Date of Completion

30/04/2024

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)



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TEST

RESULTS

SPECIFICATION

contains:

Ingredients

Obtained

Claim

Limit

SITAGLIPTIN PHOSPHATE IP Eq. TO SITAGLIPTIN 100.99 MG

100.00 MG

90.00-110.00 MG

DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE 9.83 MG

10.00 MG

9.00-11.00 MG

EQ. TO DAPAGLIFLOZIN

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/IH/JP.

Note: CRN/2024/021

PREPARED BY

(Sign/Date)

Date of Completion

30/04/2024

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)