



# 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. : DGCF402030

MATERIAL CODE : 4010012305

MATERIAL NAME : VILDASMA RT TRIO FORTE

GENERIC NAME : Dapagliflozin 10mg,Vildagliptin (SR) 100mg and Metformin (SR) 1000mg  
Tablets

BATCH NO. : 24S3GTA824

BATCH SIZE : 100000 TABLET

RECEIVED ON : 28.09.2024

STAGE : FINISH

MFG. DATE : Sep 2024

EXP. DATE : Aug 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, scored on one side and plain on other side. | Light red coloured on one side & other side white coloured, elongated, biconvex, film coated bilayered tablets, scored on one side and plain on other 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 (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 Dapagliflozin. |
| METFORMIN HYDROCHLORIDE (BY UV-VIS SPECTROPHOTOMETER) | Complies                                                                                                                                                    | Should Be comply as per assay.                                                                                                                                                                         |
| AVERAGE WEIGHT                                        | 1728.91 mg                                                                                                                                                  | 1725.00 ± 5.0 % w/w (1638.75 to 1811.25)mg                                                                                                                                                             |
| UNIFORMITY OF WEIGHT                                  | Min: -1.01%;Max: + 1.07%                                                                                                                                    | ± 5.00 % w/w of average weight                                                                                                                                                                         |
| UNIFORMITY OF CONTENT (DAPAGLIFLOZIN)                 | Mean:100.0%;Min:99.8%;Max:100.4%                                                                                                                            | 85.0% - 115.0% of average content                                                                                                                                                                      |
| DISSOLUTION (BY HPLC)                                 |                                                                                                                                                             |                                                                                                                                                                                                        |
| DAPAGLIFLOZIN                                         | Mean:101%;Min:92%;Max:105%                                                                                                                                  | Not less than 70.0% (Q) of the label claim to be dissolve in 30 minutes.                                                                                                                               |
| VILDAGLIPTIN                                          |                                                                                                                                                             |                                                                                                                                                                                                        |
| 4th HOUR                                              | Mean:54%;Min:48%;Max:58%                                                                                                                                    | 35% - 65%                                                                                                                                                                                              |

PREPARED BY

(Sign/Date)

Date of Completion

08/10/2024

CHECKED BY

(Sign/Date)

APPROVED BY

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|----------------------------------------------------------|---------------------------|---------------------|
| 8th HOUR                                                 | Mean:77%;Min:69%;Max:83%  | 55% - 85%           |
| 16th HOUR                                                | Mean:95%;Min:91%;Max:101% | Not less than 85%   |
| METFORMIN HYDROCHLORIDE IP (AS<br>EXTENDED RELEASE FORM) |                           |                     |
| 1st HOUR                                                 | Mean:32%;Min:26%;Max:35%  | 20% to 45%          |
| 3rd HOUR                                                 | Mean:59%;Min:57%;Max:60%  | 40% to 80%          |
| 10th HOUR                                                | Mean:97%;Min:95%;Max:99%  | Not less than 75%   |
| 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%  |
| VILDAGLIPTIN IMPURITY B                                  | Not Detected              | Not more than 1.0%  |
| VILDAGLIPTIN IMPURITY C                                  | Not Detected              | Not more than 1.0%  |
| SINGLE MAXIMUM UNKNOWN IMPURITY                          | 0.011%                    | Not more than 0.5%  |
| TOTAL IMPURITIES (EXCEPT KNOWN<br>IMPURITIES)            | 0.027%                    | Not more than 1.0%  |
| METFORMIN HYDROCHLORIDE                                  |                           |                     |
| DICYANDIAMIDE                                            | 0.003%                    | Not more than 0.02% |

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Tablets  
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BATCH SIZE : 100000 TABLET

| TEST                                                                                                      | RESULTS                                                                                                                 | SPECIFICATION                   |
|-----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| ANY INDIVIDUAL MAXIMUM<br>UNSPECIFIED IMPURITY                                                            | 0.008%                                                                                                                  | Not more than 0.5%              |
| TOTAL IMPURITIES                                                                                          | 0.016%                                                                                                                  | Not more than 1.0%              |
| TOTAL IMPURITIES<br>(DAPAGLIFLOZIN+ VILDAGLIPTIN+ METFO<br>RMIN HYDROCHLORIDE) EXCEPT KNOWN<br>IMPURITIES | 0.043%                                                                                                                  | Not more than 2.0%              |
| ASSAY: (BY HPLC)<br>Each film coated bi-layered tablet on an<br>average weight contains:                  |                                                                                                                         |                                 |
| <b>Ingredients</b>                                                                                        | <b>Obtained</b>                                                                                                         | <b>Claim Limit</b>              |
| VILDAGLIPTIN IP 100 MG (AS SUSTAINED<br>RELEASE)                                                          | 98.26 MG                                                                                                                | 100.00 MG<br>90.00-110.00 MG    |
| DAPAGLIFLOZIN PROPANEDIOL USP EQ. TO<br>DAPAGLIFLOZIN                                                     | 10.23 MG                                                                                                                | 10.00 MG<br>9.00-11.00 MG       |
| METFORMIN HYDROCHLORIDE (AS SUSTAINED<br>RELEASE)                                                         | 1020.16 MG                                                                                                              | 1000.00 MG<br>900.00-1100.00 MG |
| <b>REPORT</b>                                                                                             | : In the opinion of the undersigned the sample referred above is of standard quality as defined in the act & rules made |                                 |
| <b>REMARKS</b>                                                                                            | : The above sample/Material is <u>Complies/Does not comply</u> as per approved specification <u>IP/BP/USP/IH/JP</u> .   |                                 |

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