



## 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. : DGCF400968

MATERIAL CODE : 4010011167

MATERIAL NAME : VILDASmart TRIO

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

BATCH NO. : 24S3GTA463

BATCH SIZE : 200000 TABLET

RECEIVED ON : 24.06.2024

STAGE : FINISH

MFG. DATE : Jun 2024

EXP. DATE : May 2026

SAMPLE SIZE : 30 TABLET

| TEST                                                  | RESULTS                                                                                                                                          | SPECIFICATION                                                                                                                                                                                          |
|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DESCRIPTION                                           | Light red coloured on one side & other side white coloured, elongated (slight mottled) biconvex, film coated bilayered tablets, plain both side. | Light red coloured on one side & other side white coloured, elongated (slight mottled) 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                                        | 1240.56 mg                                                                                                                                       | 1240.00 ± 5.0 % w/w                                                                                                                                                                                    |
| UNIFORMITY OF WEIGHT                                  | Min: -1.07%;Max: + 0.56%                                                                                                                         | ± 5.00 % w/w of average weight                                                                                                                                                                         |
| UNIFORMITY OF CONTENT (DAPAGLIFLOZIN)                 | Mean:100.00%;Min:97.49%;Max:103.34%                                                                                                              | 85.00 - 115.00% of average content                                                                                                                                                                     |
| DISSOLUTION (BY HPLC)                                 |                                                                                                                                                  |                                                                                                                                                                                                        |
| DAPAGLIFLOZIN                                         | Mean:100.14%;Min:98.75%;Max:101.62%                                                                                                              | Not less than 70.0% (Q) of the label claim to be dissolve in 30 minutes.                                                                                                                               |
| VILDAGLIPTIN                                          |                                                                                                                                                  |                                                                                                                                                                                                        |
| 4th HOUR                                              | Mean:48.85%;Min:45.69%;Max:55.44%                                                                                                                | 35.0 - 65.0%                                                                                                                                                                                           |
| PREPARED BY                                           | CHECKED BY                                                                                                                                       | APPROVED BY                                                                                                                                                                                            |
| (Sign/Date) <i>A</i> 27/06/2024                       | (Sign/Date) <i>d</i> 27/06/2024                                                                                                                  | (Sign/Date) <i>A</i> 27/06/2024                                                                                                                                                                        |
| Date of Completion                                    |                                                                                                                                                  |                                                                                                                                                                                                        |
| 27/06/2024                                            |                                                                                                                                                  |                                                                                                                                                                                                        |



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Plant Code : 8001

Division : 10

AR. NO. : DGCF400968

MATERIAL CODE : 4010011167

MATERIAL NAME : VILDAS MART TRIO

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

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| TEST                                           | RESULTS                           | SPECIFICATION       |
|------------------------------------------------|-----------------------------------|---------------------|
| 8th HOUR                                       | Mean:71.05%;Min:67.64%;Max:79.19% | 55.0 - 85.0%        |
| 16th HOUR                                      | Mean:93.22%;Min:89.65%;Max:98.06% | Not less than 85.0% |
| METFORMIN HYDROCHLORIDE                        |                                   |                     |
| 1st HOUR                                       | Mean:36.11%;Min:34.32%;Max:37.78% | 20.0 to 45.0%       |
| 3rd HOUR                                       | Mean:57.47%;Min:56.53%;Max:58.59% | 40.0 to 80.0%       |
| 10th HOUR                                      | Mean:96.65%;Min:95.61%;Max:97.64% | 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                        | Not Detected                      | NMT 1.0%            |
| VILDAGLIPTIN IMPURITY C                        | Not Detected                      | NMT 1.0%            |
| SINGLE MAXIMUM UNKNOWN IMPURITY                | 0.042%                            | NMT 0.5%            |
| TOTAL IMPURITIES (EXCEPT KNOWN IMPURITIES)     | 0.090%                            | NMT 1.0%            |
| METFORMIN HYDROCHLORIDE                        |                                   |                     |
| DICYANDIAMIDE                                  | 0.002%                            | NMT 0.02%           |
| PREPARED BY<br>(Sign/Date) <i>A 27/06/2024</i> |                                   |                     |
| CHECKED BY<br>(Sign/Date) <i>al 27/06/2024</i> |                                   |                     |
| APPROVED BY<br>(Sign/Date) <i>27/06/2024</i>   |                                   |                     |
| Date of Completion<br>27/06/2024               |                                   |                     |



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Division : 10

AR. NO. : DGCF400968

MATERIAL CODE : 4010011167

MATERIAL NAME : VILDASMA RTIO

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

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| TEST                                                                                            | RESULTS   | SPECIFICATION              |
|-------------------------------------------------------------------------------------------------|-----------|----------------------------|
| ANY INDIVIDUAL MAXIMUM UNSPECIFIED IMPURITY                                                     | 0.005%    | NMT 0.5%                   |
| TOTAL IMPURITIES (EXCEPT KNOWN IMPURITIES)                                                      | 0.007%    | NMT 1.0%                   |
| TOTAL IMPURITIES (DAPAGLIFLOZIN+ VILDAGLIPTIN+ METFORMIN HYDROCHLORIDE) EXCEPT KNOWN IMPURITIES | 0.097%    | NMT 2.0%                   |
| ASSAY: (BY HPLC)<br>Each film coated bi-layered tablet on an average weight contains:           |           |                            |
| Ingredients                                                                                     | Obtained  | Claim Limit                |
| VILDAGLIPTIN IP 100 MG (AS SUSTAINED RELEASE)                                                   | 102.16 MG | 100.00 MG 90.00-110.00 MG  |
| DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE EQ. TO DAPAGLIFLOZIN                                      | 9.94 MG   | 10.00 MG 9.00-11.00 MG     |
| METFORMIN HYDROCHLORIDE IP (AS EXTENDED RELEASE FORM)                                           | 508.38 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 ~~Complies/Does not comply~~ as per approved specification ~~IP/BP/USP/HP~~

PREPARED BY

(Sign/Date)

Date of Completion

27/06/2024

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)