



## 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. : DGCF300365  
MATERIAL CODE : 4010011240  
MATERIAL NAME : VILDASmart M 50mg/500mg  
GENERIC NAME : Vildagliptin 50 mg and Metformin Hydrochloride 500 mg Tablets  
BATCH NO. : 23S3GTA208  
BATCH SIZE : 400000 TABLET

RECEIVED ON : 19.12.2023  
STAGE : FINISH  
MFG. DATE : Dec 2023  
EXP. DATE : Nov 2025  
SAMPLE SIZE : 30 TABLET

| TEST                                 | RESULTS                                                                   | SPECIFICATION                                                                                                                                                                        |
|--------------------------------------|---------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DESCRIPTION                          | Yellow coloured, oval, biconvex, scored on one side, film coated tablets. | Yellow coloured, oval, biconvex, scored on one side, film coated tablets.                                                                                                            |
| IDENTIFICATION                       |                                                                           |                                                                                                                                                                                      |
| VILDAGLIPTIN (BY HPLC)               | Complies                                                                  | The retention time of principal peak in the chromatogram obtained with test solution (a) corresponds to the principal peak in the chromatogram obtained with reference solution (a). |
| METFORMIN HYDROCHLORIDE (BY HPLC)    | Complies                                                                  | The retention time of principal peak in the chromatogram obtained with test solution (b) corresponds to the principal peak in the chromatogram obtained with reference solution (a). |
| AVERAGE WEIGHT                       | 625.53 mg                                                                 | 632.00 mg $\pm$ 5.0% (600.4 to 663.6 mg)                                                                                                                                             |
| UNIFORMITY OF WEIGHT                 | Min:-1.02%;Max:+ 0.89%                                                    | $\pm$ 5.0 % w/w of average weight.                                                                                                                                                   |
| DISINTEGRATION TIME                  | 05 min 32 sec                                                             | NMT 30 minutes                                                                                                                                                                       |
| DISSOLUTION                          |                                                                           |                                                                                                                                                                                      |
| VILDAGLIPTIN                         | Mean:101.57%;Min:99.79%;Max:103.14%                                       | NLT 80% (Q) of labeled amount, dissolved in 30 minutes                                                                                                                               |
| METFORMIN HYDROCHLORIDE              | Mean:102.65%;Min:101.17%;Max:105.67%                                      | NLT 80% (Q) of labeled amount, dissolved in 30 minutes.                                                                                                                              |
| UNIFORMITY OF CONTENT (VILDAGLIPTIN) | Mean:100.00%;Min:97.39%;Max:101.66%                                       | 85.0 - 115.0% of the average content                                                                                                                                                 |
| BENZYLTRIMETHYLAMMONIUM HYDROXIDE    | Not Detected                                                              | NMT 0.4%                                                                                                                                                                             |

PREPARED BY

(Sign/Date)

Date of Completion

20/12/2023

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)



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| TEST                                                                                                                                           | RESULTS                                          | SPECIFICATION                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|------------------------------------------------------|
| RELATED SUBSTANCES (BY HPLC)                                                                                                                   |                                                  |                                                      |
| VILDAGLIPTIN IMPURITY A                                                                                                                        | Not Detected                                     | NMT 1.0%                                             |
| VILDAGLIPTIN IMPURITY B                                                                                                                        | Not Detected                                     | NMT 2.0%                                             |
| VILDAGLIPTIN IMPURITY C                                                                                                                        | Not Detected                                     | NMT 1.0%                                             |
| ANY OTHER SECONDARY PEAK                                                                                                                       | Not Detected                                     | NMT 0.2%                                             |
| TOTAL IMPURITIES                                                                                                                               | Not Detected                                     | NMT 3.5%                                             |
| RELATED SUBSTANCES (BY HPLC)                                                                                                                   |                                                  |                                                      |
| DICYANDIAMIDE                                                                                                                                  | Not Detected                                     | NMT 0.02%                                            |
| ANY OTHER SECONDARY PEAK                                                                                                                       | 0.023%                                           | NMT 0.1%                                             |
| TOTAL IMPURITIES                                                                                                                               | 0.023%                                           | NMT 0.6%                                             |
| ASSAY:                                                                                                                                         |                                                  |                                                      |
| Each film coated tablet contains                                                                                                               |                                                  |                                                      |
| Ingredients                                                                                                                                    | Obtained                                         | Claim Limit                                          |
| VILDAGLIPTIN IP                                                                                                                                | 49.21 MG                                         | 50.00 MG 47.50-52.50 MG                              |
| METFORMIN HYDROCHLORIDE IP                                                                                                                     | 483.23 MG                                        | 500.00 MG 475.00-525.00 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 <del>Material</del> is <del>Complies/Does not comply</del> as per approved specification <del>IP/BP/USP/HP/JP</del> |                                                  |                                                      |
| PREPARED BY<br><i>Atul</i><br>(Sign/Date) 20/12/2023                                                                                           | CHECKED BY<br><i>d</i><br>(Sign/Date) 20/12/2023 | APPROVED BY<br><i>Atul</i><br>(Sign/Date) 20/12/2023 |
| Date of Completion<br>20/12/2023                                                                                                               |                                                  |                                                      |