



# Synokem Pharmaceuticals 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 : 9002

Division : 20

AR. NO. : DHLF401221

MATERIAL CODE : 4010003088

MATERIAL NAME : ESTRAHEAL 2 MG

GENERIC NAME : ESTRADIOL VALERATE TABLETS 2MG

BATCH NO. : 24S2HTA870

BATCH SIZE : 500000 TABLET

RECEIVED ON : 06.10.2024

STAGE : FINISH

MFG. DATE : Sep 2024

EXP. DATE : Aug 2026

SAMPLE SIZE : 84 TABLET

| TEST                  | RESULTS                                                                                                                                                        | SPECIFICATION                                                                                                                                                  |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DESCRIPTION           | Purple coloured, round, biconvex, film coated tablets, scored on one side.                                                                                     | Purple coloured, round, biconvex, film coated tablets, scored on one side.                                                                                     |
| IDENTIFICATION        | In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution. | In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution. |
| AVERAGE WEIGHT        | 64.11 mg                                                                                                                                                       | 61.75 - 68.25 mg                                                                                                                                               |
| UNIFORMITY OF WEIGHT  | -3.75%; +3.57%                                                                                                                                                 | ±10% w/w of average weight                                                                                                                                     |
| UNIFORMITY OF CONTENT | 95.39 - 102.32 %                                                                                                                                               | 85 - 115 %                                                                                                                                                     |
| DISINTEGRATION TIME   | 1 - 2 minutes                                                                                                                                                  | NMT 30 minutes                                                                                                                                                 |

### ASSAY:

Each film coated tablet on an average weight contains:

| Ingredients            | Obtained | Claim   | Limit        |
|------------------------|----------|---------|--------------|
| ESTRADIOL VALERATE USP | 2.002 MG | 2.00 MG | 1.80-2.20 MG |

**REPORT** : In the opinion of the undersigned the sample referred above is of standard quality as defined in the act & rules made there under

**REMARKS** : The above sample/Material is ☒ Complies/~~Does not comply~~ as per approved specification IP/BP/USP/HP/JP.

SPECIFICATION NO.: DV/QC/SPEC/MOA/FPE/003-04

PREPARED BY

(Sign/Date)

Date of Completion

07/10/2024

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)