



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. : DHLF400597

MATERIAL CODE : 4010003088

MATERIAL NAME : ESTRAHEAL 2 MG

GENERIC NAME : ESTRADIOL VALERATE TABLETS 2MG

BATCH NO. : 24S2HTA431

BATCH SIZE : 500000 TABLET

RECEIVED ON : 09.06.2024

STAGE : FINISH

MFG. DATE : Jun 2024

EXP. DATE : May 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	63.72 mg	61.75 - 68.25 mg
UNIFORMITY OF WEIGHT	-2.07%; +3.26%	±10% w/w of average weight
UNIFORMITY OF CONTENT	97.19 - 102.23 %	85 - 115 %
DISINTEGRATION TIME	2 - 3 minutes	NMT 30 minutes

ASSAY:

Each film coated tablet on an average weight contains:

Ingredients	Obtained	Claim	Limit
ESTRADIOL VALERATE USP	2.000 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 ~~JP/BP/USP/IH/JP~~.

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

10/06/2024

PREPARED BY

(Sign/Date)

Date of Completion

10/06/2024

10/06/2024

CHECKED BY

(Sign/Date)

10/06/2024

APPROVED BY

(Sign/Date)