

**F. & A. PHARMA-Handels-GmbH**

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CERTIFICATE OF ANALYSIS**Product name:** Estradiol Valerate**Molecular formula:** C₂₃H₃₂O₃**M.W.:** 356,50**CAS Number:** 979-32-8**Release date:** 25/01/2021**Batch number:** 003721**Net weight:** 1000 GR**Manufacturing date:** 15/01/2021**Retest date:** 15/01/2026

Test	Specifications	Results
Appearance	USP: White crystalline powder. Is usually odorless but may have a faint, fatty odor. EP: White or almost white, crystalline powder or colourless crystals.	Complies
Identification		
IR	Complies	Complies
HPLC	Complies	Complies
Specific Optical Rotation (methanol, 25°C) USP	+41 ÷ +47 °	46 °
Specific Optical Rotation (methanol, 20°C) EP	+41 ÷ +47 °	46 °
Clarity and degree of opalescence of solution	Solution S is clear and colourless	Complies
Water content (KF)	Not more than 0.1 %	0.0 %
Loss on drying	Not more than 1.0 %	0.2 %
Free acid	Not more than 0.5 %	0.0
Assay HPLC EP	97.5 ÷ 102.0% (o.d.b)	99.8 %
Assay HPLC USP	98.0 ÷ 102.0% (o.a.b)	100.1 %
Residual solvents (GC)		
Ethyl acetate	Not more than 5000 ppm	Below detection limit
Methanol	Not more than 3000 ppm	280 ppm
Related substances (HPLC)		
Impurity A	Not more than 0.2 %	Below reporting threshold
Impurity C	Not more than 0.2 %	Below reporting threshold
Impurity D	Not more than 0.4 %	Below reporting threshold
Impurity E	Not more than 0.15 %	Below detection limit
Any unknown impurity	Not more than 0.10%	max 0.07%
Total amount	Not more than 0.5 %	0.33 %

Notes: This batch has been manufactured according to ICH Q7 guideline.

Issued on 07/04/2021

The Head of Q.C.:

Joseph Da Lio
Qualified Person