

METAPHARMACEUTICAL

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03/09/2025

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	Estriol	Batch No.	ETL20250502
Manuf. Date	2025-05-13	Expiry Date	2029-05-12
Batch Quantity	32Kgs	Test Standard	EP10

TEST	SPECIFICATIONS	RESULTS
Appearance	Off white or white crystalline powder	conform
Identification	A: IR B:HPLC	conform conform
Solubility	Practically insoluble in water, sparingly soluble in ethanol (96 per cent)	conform
Specific rotation	+60 °~ +65°	+61.5°
Loss on drying	≤0.5%	0.15%
Related substances	Impurity A≤0.2% Impurity D ≤0.2% Impurity E ≤0.3% Impurity F≤0.5% Any single impurity ≤0.1% Total impurities ≤1.0%	0.10% Not detected 0.03% Not detected Conform 0.46%
Assay (dried basis)	97. 5%~102. 0%	99.5%

Conclusion: The product complies with the requirements of EP10 standard

Quality Manager:

朱永军

Rechecker:

易洪斌

Analyst:

刘英

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