

METAPHARMACEUTICAL

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31/07/2025

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	Estradiol valerate	Batch No.	EDV20250302
Manuf. Date	2025-03-11	Expiry Date	2028-03-10
Batch Quantity	45Kgs	Test Standard	EP10

TEST	SPECIFICATIONS	RESULTS
Appearance	White or almost white, crystalline powder or colourless crystals.	conform
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in ethanol (96 per cent).	conform
Identification	A:IR B:The retention time of the major peak of the sample solution corresponds to that of the standard solution,as obtained in the Assay.	Conform conform
Appearance of solution	Solution is clear and colourless	conform
Specific optical rotation	+41° ~+47°	+43.0°
Loss on drying	≤1.0%	0.10%
Related substances	Impurities A RRT0.1≤0.2% Impurity C RRT0.9≤0.2% Impurity D RRT1.3≤0.4% Impurity E RRT1.7≤0.15% Unspecified impurities≤0.10% Total impurities≤0.5%	Not detected 0.03% Not detected Not detected Not detected 0.25%
Assay	97.5%~ 102.0%	99.18%

Conclusion: The product complies with the requirements of EP10 standard

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