

METAPHARMACEUTICAL

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05/05/2025

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	Estriol	Batch No.	ETL20250301
Manuf. Date	2025-03-05	Expiry Date	2029-03-04
Batch Quantity	25Kgs	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°	+61.0°
Loss on drying	≤0.5%	0.19%
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%	0.11% Not detected 0.04% Not detected Conform 0.47%
Assay (dried basis)	97. 5%~102. 0%	99.45%

Conclusion: The product complies with the requirements of EP10 standard

Quality Manager:

宋家豪

Rechecker:

易洪成

Analyst:刘琪

Add:No. 138 YuWu Road, XinMin Town, DianJiang 408302, chongqing,china

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Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	Liothyronine sodium	Batch No.	LIS20250101
Manuf. Date	2025-01-11	Expiry Date	2028-01-10
Batch Quantity	1090g	Test Standard	EP10

ANALYSIS ITEM	SPECIFICATION	RESULT
Appearance	Light yellow to buff-colored powder	Conform
Identification	UV spectrum conform to the standard	Conform
	IR spectrum conform to the standard	Conform
	Violet Vapors of Iodine should be positive	Conform
	Sodium test conform the requirements	Conform
Specific rotation	Between +18° and +22°	+20.4°
Chloride	≤ 2.0%	1.1%
Loss on Drying	≤ 4.0%	0.62%
Related substances	Impurity A ≤ 1.0%	0.52%
	Impurity E ≤ 0.5%	0.1%
	Impurity B ≤ 0.3%	Not detected
	Impurity C ≤ 0.3%	Not detected
	Impurity D ≤ 0.2%	Not detected
	Any other impurity ≤ 0.05%	0.02%
	Total impurity ≤ 2.0%	0.95%
Assay	Liothyronine Sodium ≥ 95.0% and ≤ 102.0%	98.4%
Storage	In an airtight container, protected from light, at a temperature between 2 °C and 8 °C.	
CONCLUSION	COMPLIES WITH EP10 STANDARD	

Quality Manager:

朱永军

Rechecker:

易洪斌

Analyst:

刘琪

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