

METAPHARMACEUTICAL

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03S0524

31/05/2024

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS-revised

Product name	Levothyroxine sodium CAS 55-03-8	Batch No.	LTS20240105
Manuf. Date	2024-01-26	Expiry Date	2027-01-25
Batch Quantity	5.85Kg	Test Standard	EP10

ANALYSIS ITEM	SPECIFICATION	RESULT
Appearance	Almost white to light yellow crystalline powder	Conform
Identification	A conform	Conform
	B conform	Conform
Specific rotation	+16°~ +20°	+18.4°
Water	6.0% ~ 12.0%	7.08%
Related substances	Impurity A ≤1.0%	0.5%
	Impurity F ≤0.5%	0.1%
	Impurity G ≤0.3%	Conform
	Unspecified impurities ≤0.2%	Conform
	Total impurity ≤2.0%	0.80%
Assay	97.0- 103.0 %	99.50%
Storage	In an airtight container, protected from light, at a temperature between 2 °C and 8 °C.	
CONCLUSION	COMPLIES WITH EP10 STANDARD	

Quality Manager:

Rechecker:

Analyst:

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

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