

METAPHARMACEUTICAL

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02/05/2022

HALLOCHEM

Hallochem Group

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	Liothyronine sodium	Batch No.	LIS20220402
Manuf. Date	2022-04-11	Expiry Date	2025-04-10
Quantity	100g	Test Standard	EP10

ANALYSIS ITEM	SPECIFICATION	RESULT
Appearance	Light yellow to buff-colored powder	buff-colored powder
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°	+19°
Chloride	$\leq 2.0\%$	1.0%
Loss on Drying	$\leq 4.0\%$	2.9%
Related substances	Impurity A $\leq 1.0\%$	0.5%
	Impurity E $\leq 0.5\%$	0.1%
	Impurity B $\leq 0.3\%$	Not detected
	Impurity C $\leq 0.3\%$	Not detected
	Impurity D $\leq 0.2\%$	Not detected
	Any other impurity $\leq 0.05\%$	0.02%
	Total impurity $\leq 2.0\%$	0.90%
Assay	Liothyronine Sodium $\geq 95.0\%$ and $\leq 102.0\%$	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:

吴永章

Rechecker:

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Analyst:

刘洪

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