



杭州泽尔瑞化学有限公司

HANGZHOU ZEERRUI CHEMICAL CO., LTD

Certificate of Analysis

COA No:ZER12001021

Product Name	Levothyroxine Sodium
CAS No	25416-65-3
Molecular Weight	798.85
Batch No	ZERLS20190116
Manufacturing date	20190116
Shelf life	2 years

Index Name	Specification	Result
Appearance	light yellow to buff-colored, odorless, tasteless, hygroscopic powder, stable in dry air but may assume a slight pink color upon exposure to light.	almost white Crystalline Powder, odorless, tasteless, hygroscopic, stable in dry air
Identification 1) Iodine 2) colour	1) (flame decomposes and liberates iodine vapors) 2) (add solution, a pink colour produced)	1) Pass 2) 2) pass
solubility	1) (very slightly soluble in water) 2) (soluble in solutions of Alkali hydroxides and in hot solutions of Alkali carbonates) 3) (slightly solution in Alcohol) 4) (Insoluble in Acetone, chloroform and in Ether)	1) Pass 2) 2) Pass 3) 3) Pass 4) 4) Pass
Specific rotation $[\alpha]_D^{20}$	-5.0 ~ -6.0° (C=3, in 1N NaOH: C ₂ H ₅ OH=1: 2)	-5.5°
Loss on drying	≤11.0%	10.2%
Assay	98.5-103.0%	99.18%
Purity	≥98.5%	99.6%
Inorganic iodides	≤0.08%	<0.08%
Ethanol	≤0.10%	0.008%
Liothyronine sodium	≤2.0%	0.82%
Conclusion	Conforms to the standard of USP30	

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CHIEF:

CHECK:



INSPECTION:

