

常州市天华制药有限公司

CHANGZHOU TIANHUA PHARMACEUTICAL CO., LTD

产品检验报告单 CP03-2111002

CERTIFICATE OF ANALYSIS

品名: 甲巯咪唑	生产日期: 20211117	
Name: Methimazole	Manufacturing Date:	
批号: CP03-211102	报告日期: 20211126	
Batch No.:	Date of Test:	
检验依据:	USP2021,In-house	
Inspection basis:		
项目 Items	标准 Specifications	结果 Results
性状 Appearance	White to pale buff, crystalline,powder, having a faint, characteristic odor	Almost white crystalline,powder, having a faint, characteristic odor
溶解性 Solubility	Freely soluble in water, in alcohol, and in chloroform; slightly soluble in ether	Freely soluble in water, in alcohol, and in chloroform; slightly soluble in ether
鉴别 Identification	IR:Infrared absorption spectrum should be consistent with the reference chromatogram	Complies
干燥失重 Loss on drying	≤0.5 %	0.2%
灼烧残渣 Residue on ignition	≤ 0.1 %	0.05%
苯 Benzene	≤0.0002%	None detected
硒 Selenium	≤0.003 %	Complies
有机杂质 Organic impurities	Methimazole related compound A≤0.1% 1-Methlimdazole≤0.1% Methimazole related compound C≤0.1% Any other individual impurity≤0.1% Total impurities ≤0.5%	None detected None detected None detected 0.005% 0.005%
残留溶剂 Residual Solvents	Methanol ≤ 0.3%	0.005%
含量 Assay	98.0 ~ 101.0 %(on the dried basis)	99.8%
有效期 Date of Expiry	20231116	
结论 CONCLUSION	Conforms to USP2021,In-house	



QA: 蒋爱华

QC: 周利民

联系人: 李剑平

电话: 0519-82891186

手机: 13906147316

传真: 0519-82899734

E-mail: tianhuachem@gmail.com

网址: <http://www.tianhuachem.com>

Storage Condition: Preserve in well-closed, light-resistant containers, and the temperature is not higher than 30°C

Add: 3# Houyang chemical zone, Jintan Jiangsu China