

# HANGZHOU THINK CHEMICAL CO., LTD.

ADD: ROOM 501-502,TOWER E,YUANJIAN BUILDING,YUANYANG INTERNATIONAL CENTER,HANGZHOU-310011,CHINA

## CERTIFICATE OF ANALYSIS

验品名称 Name	枸橼酸铋钾 Bismuth Subcitrate Potassium	批号 Batch No.	20190101
包装规格 Package	12kg/桶 12kg/Drum	报告日期 Report date	JAN.15, 201
生产日期 Date of manufacture	JAN.09, 2019	有效期 Expiry date	DEC. 2021
检验依据 Test reference	企 业 内 控 标 准TS-ZL(06)004-01;《中国药典》2015 年第二部 In-house Standard TS-ZL(06)004-01;CP2015, Appendix II		
检验项目 Items	标准规定 standard	检验结果 Result	
【性状】 【Description】	The product should be white powder, have saline taste and have hygroscopic property. Very soluble in water, very slightly soluble in ethanol	The product is white powder, have saline taste and have hygroscopic property Very soluble in water, very slightly soluble in ethanol	
引湿性 Hygroscopic property	引湿增重应为 2%~15% Weight increase by moisture 2%~15%	10%	
【鉴别】 【Identification】	应符合规定 Should comply with specification	符合规定 conforms	
(1)	应呈正反应 Should show positive reaction	呈正反应 conforms	
(2)	应呈正反应 Should show positive reaction	呈正反应 conforms	
(3)	应呈正反应 Should show positive reaction	呈正反应 conforms	
【检查】 【Inspection】	应符合规定 Should comply with specification	符合规定 conforms	
酸碱度 PH	PH 6.0-8.0	6.7	
硫酸盐 sulfate salt	应不超过 0.04% No more than 0.04%	符合规定 conforms	
硝酸盐 nitrate salt	接界面应不得立即显棕色 The interface should not show brown immediately	符合规定 conform	
干燥失重 Loss on drying	减失重量应不得超过 4% not more than 4%	2.7%	
铜盐 copper salt	不显色。若显色, 应不得超过 0.0025% Almost no color reaction. If color reaction, it should be not more than 0.0025%	符合规定 conform	

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铅盐 Plumbum salt	应不得超过 0.002% No more than 0.002%	符合规定 conform
含氮量 Nitrogen content	2%-6%	2.7%
【含量测定】 Assay	按干燥品计算, 含铋 (Bi) 应为 35%-38.5% The content of Bi should be 35%~38.5% on drying base	36.0%
微生物限度检查 Microbial limit	应符合规定 Should comply with specification	符合规定 conform
细菌数 Bacterial count	应不超过 800cf u/g Not more than 800cf u/g	小于 10 cf u/g <10 cf u/g
霉菌和酵母菌数 Mould and yeast count	应不超过 80cf u/g Not more than 80cf u/g	小于 10 cf u/g <10 cf u/g
大肠埃希菌 Escherichia coli	应不得检出 Should not be detected	未检测出 Negative
结论 Conclusion	本品按企业内控标准 TS-ZL(06)004-01, 《中国药典》2015 年第二部检验, 结果均符合规定 The product complies with standard of In-house Standard TS-ZL(06)004-01; CP2015, Appendix II	

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HANGZHOU THINK CHEMICAL CO., LTD.

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