

分析报告单

CERTIFICATE OF ANALYSIS

生产日期:

有效日期:

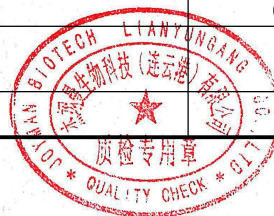
报告日期:

Manufacture date: Apr.27,2019

Expiry date: Apr.26,2022

Report date: Apr.27,2019

品名 Product Name	5-氨基水杨酸(美沙拉嗪) 5-Aminosalicylic Acid (Mesalazine)		批号 Batch No.	20190426
CAS NO.	89-57-6		Total weight	500KG
Molecular Formula	C ₇ H ₇ NO ₃		Molecular wt.	153.14
项目 Items	标准 Standard		检验结果 Results	
外观 Appearance	几乎白色或浅灰色或浅粉红色结晶性粉末 almost white or light grey or light pink powder or crystals		符合 Complies	
溶液澄清度 Clarity of Solution	澄清 Clear		澄清 Clear	
溶解度 Solubility	溶于稀盐酸和稀碱性氢氧化物, 微溶于水, 微溶于甲醇, 无水乙醇, 丙酮, 几乎不溶于正丁醇, 三氯甲烷, 乙醚, 乙酸乙酯, 正己烷, 二氯甲烷和正丙醇 soluble in dilute hydrochloric acid and in dilute alkali hydroxides, slightly soluble in water, very slightly soluble in methanol, in dehydrated alcohol, and in acetone, practically insoluble in n-butyl alcohol, in chloroform, in ether, in ethyl acetate, in n-hexane, in methylene chloride, and in n-propyl alcohol		符合 Complies	
鉴别 Identification	红外线吸收 Infra red absorption	Infrared absorption spectrum in KBr dispersion of sample should be concordant with the spectrum of Mesalamine USP working standard.	符合 Complies	
	The main peak retention time of sample solution is consistent with retention time of the standard solution.		符合 Complies	
硫化氢和二氧化硫 Hydrogen Sulfide and Sulfur dioxide	醋酸铅试纸不变色 The moistened lead acetate test paper does not become discolored		符合 Complies	
干燥失重 Loss on drying	≤ 0.5%		0.15%	
重金属 Heavy Metals	≤ 10ppm		< 10ppm	
PH 值 PH Value	3.5~4.5		4.1	
硫酸盐 Sulfate	≤ 0.2%		< 0.2%	
氯化物 Chloride	≤ 0.1%		< 0.1%	
堆积密度 Bulk density	0.2~ 0.3g/ml		符合 Complies	
敲击密度 Tapped density	0.4 ~ 0.6 g/ml		符合 Complies	
颗粒度 Particle size	120 ~150mesh		符合 Complies	
炽灼残渣 Residue on ignition	≤ 0.2%		0.01%	
含量测定 Assay	98.5~101.5%		99.8%	



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有关化合物 Related Compounds	3-氨基水杨酸 3-aminosalicylic acid	≤0.2%	0.04%
	其他杂质 other impurity	≤0.2%	0.03%
	总杂质 total impurity	≤1.0%	0.2%
	苯胺 aniline	≤5ppm	Not detected
	2-氨基苯酚 2-aminophenol	≤200ppm	Not detected
	4-氨基苯酚 4-aminophenol	≤200ppm	Not detected
残留溶剂 Residual solvents	工艺过程不使用有机溶剂 Nf (no organic solvents used during the process)		
贮藏 Storage	避光密封贮藏 Store Protected Prom Light and dry place		

结论：经检验符合 USP39 标准 Determination: Complies with USP39 Standards

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质检科长：任建华
Analyst: Jianhua Ren

