

检验报告单

CERTIFICATE OF ANALYSIS

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品名 Name of product	磺胺嘧啶 Sulfadiazine	报告日期 Report Date	2020年09月02日 September 2, 2020
批号 Lot NO.	200615	生产日期 Manufacture Date	2020年06月10日 June 10, 2020
数量 Net weight	1000kg	有效期至 Retest Date	2023年06月09日 June 9, 2023
检验项目 ANALYTICAL ITEMS	标准规定值 SPECIFICATION		检验结果 ANALYTICAL RESULTS
外观 Appearance	应为白色、淡黄白色或带粉白色结晶性粉末或结晶 White, yellowish white or pinkish-white crystalline powder or crystals		淡黄白色粉末 Yellowish white powder
溶解度 Solubility	应符合规定 Complies		符合 Complies
鉴别 Identification	A:样品的红外吸收光谱应与磺胺嘧啶对照品的红外光谱一致 A: The infrared absorption spectrum concordant with the spectrum of sulfadiazine CRS B:呈正反应 B:Positive reaction		与对照品图谱一致 The IR spectrum of the sample corresponds to the IR spectrum of the RS 呈正反应 Positive reaction
酸度 Acidity	不得过 0.2ml Not more than 0.2ml		小于 0.2ml Less than 0.2ml
普通杂质 Ordinary Impurities	应不得过 2.0% Not more than 2.0%		符合 Conforms
溶液颜色 Color of the solution	不深于Y Not more than of Reference solution Y		不深于对照溶液Y Not more intensely coloured than reference solution Y
溶液澄清度 Clarity of the solution	应澄清 Clear		澄清 Clear
硒 Selenium	不得过 30 ppm Not more than 30 ppm		小于 30 ppm Less than 30 ppm
干燥失重 Loss on drying	不得过 0.5% Not more than 0.5%		0.3%
硫酸盐灰分 Sulphated ash	不得过 0.1% Not more than 0.1%		0.06%
残留溶剂 Residual solvent	甲醇不得过3000 ppm Methanol Not more than 3000 ppm		ND
	乙酸不得过5000 ppm Acetic acid Not more than 5000 ppm		ND
	DMF不得过880 ppm DMF Not more than 880 ppm		ND
含量 Assay	以干品计, 含 C <sub>10</sub> H <sub>10</sub> N <sub>4</sub> O <sub>2</sub> S 应不小于 98.0%且不大于 102.0% NLT 98.0% and NMT 102.0% of C <sub>10</sub> H <sub>10</sub> N <sub>4</sub> O <sub>2</sub> S, Calculated on the dried basis		99.6%
检验依据 According to	美国药典 USP43		
结论 Conclusion	合格 Complies		



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2020.09.02