

佛山市南海北沙制药有限公司

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检 验 报 告 单

Certificate of Analysis



品 名 磺 胺 嘧 啶

Product. Sulfadiazine

批 号

Batch No. 612004088

批 数 量

Quantity (kg) 1000 Kg

检 验 依 据

Test Basis E.P. 9.0 specifications

报告日期 2020-05-04
Report Date: 2020-05-04

生 产 日 期

Manufacturing Date: 2020-04

复 测 日 期

Re-test Date: 2023-03

检 验 项 目 : Analysis content	检 验 标 准 Specifications	检 验 结 果 Analysis results
性 状 Characteristics	White, yellowish-white or pinkish-white crystalline powder or crystals	Meets
鉴 别 Identification	A. The infrared absorption spectrum; B. The thin-layer chromatography; C. Sublimate melts at 123°C to 127°C; D. The reaction of primary aromatic amines.	Meets Meets 123~124°C Meets
溶液颜色 Appearance of solution	Not more intensely coloured than Y5, BY5 or GY5	Meets
酸 度 Acidity	≤ 0.2 ml	0.08ml
有关物质 Related substances(HPLC)	Impurity A (Pyrimidin-2-amine)≤0.3% Impurity B (Sulfanilic acid)≤0.3% Impurity E (Acetylsulfadiazine)≤0.2% Impurity F (Unknown structure)≤0.15% Unspecified impurities≤0.05% Total impurities≤0.5%	Not detected Not detected Not detected 0.07% Not detected 0.07%
干燥失重 Loss on drying	Not more than 0.5%	0.16%
硫酸盐灰分 Sulphated ash	Not more than 0.1%	0.05%
含 量 Assay	99.0%~101.0 % (The dried substance)	99.8% (The dried substance)
结 论 Conclusion	Meets E.P.9.0 specifications	

检 验 者:
Analyst

复 核 者:
Checker

负 责 人:
Supervisor