

佛山市南海北沙制药有限公司

NANHAI BEISHA PHARMACEUTICAL CO., LTD.

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检验报告单

Certificate of Analysis



品名 磺胺嘧啶

Product. Sulfadiazine

批号 612004085

批数量 1000 Kg

检验依据 E.P. 9.0 specifications

报告日期 2020-05-04

生产日期 2020-04

复测日期 2023-03

检验项目:	检验标准	检验结果
Analysis content	Specifications	Analysis results
性状		
Characteristics	White, yellowish-white or pinkish-white crystalline powder or crystals	Meets
鉴别		
Identification	A. The infrared absorption spectrum;	Meets
	B. The thin-layer chromatography;	Meets
	C. Sublimate melts at 123°C to 127°C;	123~124°C
	D. The reaction of primary aromatic amines.	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%	Not detected
	Impurity B (Sulfanilic acid)≤0.3%	Not detected
	Impurity E (Acetylsulfadiazine)≤0.2%	Not detected
	Impurity F (Unknown structure)≤0.15%	0.07%
	Unspecified impurities≤0.05%	0.04%
	Total impurities≤0.5%	0.10%
干燥失重		
Loss on drying	Not more than 0.5%	0.17%
硫酸盐灰分		
Sulphated ash	Not more than 0.1%	0.05%
含量		
Assay	99.0%~101.0 %(The dried substance)	99.7%(The dried substance)
结论		
Conclusion	Meets E.P.9.0 specifications	

检验者: 梁煥良
Analyst

复核者: 梁煥良
Checker

负责人: 梁煥良
Supervisor