

Lot: 0060318

佛山市南海北沙制药有限公司

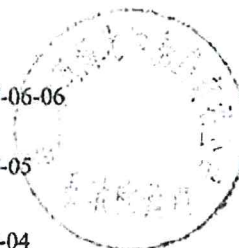
NANHAI BEISHA PHARMACEUTICAL CO., LTD.

Address: Lishui Town, Nanhai District, Foshan City, Guangdong Province, China. TEL: 0086-757-85666190. FAX: 0086-757-85669370

检 验 报 告 单

Certificate of Analysis

品 名	磺胺嘧啶	报告日期	
Product.	Sulfadiazine	Report Date :	2017-06-06
批 号		生产日期	
Batch No.	611705049	Manufacturing Date:	2017-05
批 数 量		复测日期	
Quantity (kg)	1000 Kg	Re-test Date:	2019-04
检验依据			
Test Basis	E.P. 8.0 specifications		



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	0.09ml
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%	0.10%
	Unspecified impurities≤0.05%	Not detected
	Total impurities≤0.5%	0.10%
重金属		
Heavy Metals	≤ 20 ppm	<20 ppm
干燥失重		
Loss on drying	Not more than 0.5%	0.15%
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.8.0 specifications	

检验者: 吴少明
Analyst

复核者: 梁煥良
Checker

负责人: 李少明
Supervisor