

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 611610004
Batch No.
批数量 1000 Kg
Quantity (kg)
检验依据 E.P. 8.0 specifications
Test Basis

报告日期 2016-10-08
Report Date:
生产日期 2016-09-08
Manufacturing Date:
复测日期 2018-08
Re-test Date:



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	0.10 ml
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 0.08% Not detected 0.08%
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: [Signature]
Analyst

复核者: [Signature]
Checker

负责人: [Signature]
Supervisor