

检验报告单

CERTIFICATE OF ANALYSIS

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品名 Name of product	磺胺二甲嘧啶钠 Sulfadimidine sodium	报告日期 Report Date	2022年09月06日 September 6, 2022
批号 Lot NO.	220805	生产日期 Manufacture Date	2022年08月 August, 2022
数量 Net weight	300kg	有效期至 Expiry Date	2025年08月 August, 2025
检验项目 ANALYTICAL ITEMS	标准规定值 SPECIFICATION	检验结果 ANALYTICAL RESULTS	
外观 Appearance	应为白色或乳白色结晶或粉末 White or creamy white crystals or powder	类白色粉末 Almost white powder	
溶解度 Solubility	易溶于水, 微溶于乙醇(96%) Freely soluble in water, sparingly soluble in ethanol (96%)	符合 Complies	
鉴别 A Identification A	应与对照品图谱一致 The IR spectrum of the sample corresponds to the IR spectrum of the RS	与对照品图谱一致 The IR spectrum of the sample corresponds to the IR spectrum of the RS	
鉴别 B Identification B	呈芳香第一胺类鉴别反应 Is the first identification of aromatic amines	呈正反应 Positive reaction	
鉴别 C Identification C	钠的反应 Test for sodium	呈正反应 Positive reaction	
熔点 Melting range	197°C~200°C	197°C~198°C	
溶液澄清度 Clarity of the solution	应澄清 Clear	澄清 Clear	
溶液颜色 Color of the solution	不深于 Y ₄ Not more than of Reference solution Y ₄	不深于 Y ₄ Not more deeply colored than Y ₄	
碱度 Alkalinity	pH 10.0-11.0	10.7	
有关物质 Related substances	杂质总和不得过 0.5% Not more than 0.5% of total impurities	符合 Complies	
干燥失重 Loss on drying	不得过 2.0% Not more than 2.0%	0.3%	
含量 Assay	以干品计, 含 C ₁₂ H ₁₃ N ₄ NaO ₂ S 应不小于 99.0% 且不大于 101.0% NLT 99.0% and NMT 101.0% of C ₁₂ H ₁₃ N ₄ NaO ₂ , calculated on the dried basis	99.2%	
检验依据 According to	英国药典 BP 2002		
结论 Conclusion	合格 Complies		

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