

Art.-Nr.: 2486
Charge: 22000389

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Certificate of Analysis

ANNJ-011C

产品名称: Name of Product:	一水安乃近 METAMIZOLE SODIUM MONOHYDRATE	取样日期: Sampling Date:	2021-08-14	报告日期: Report Date:	2021-08-17
批号: Batch No:	21081227	生产日期: Date of Manufacturing:	2021-08-12	失效期: Expiry Date:	2025-08
批量: Quantity:	3184 kg	检验记录号: Record No:	216050885	报告编号: Report No:	216050885
标准依据: Reference Standard:	EP10.0/COS EP10.0 and R1-CEP2001-356-Rev04 requirements			物料代码: Product code:	013-30
检验项目 Items	检验标准 Specifications		检验结果 Results		
性状 Characters	白色或几乎白色结晶性粉末 White or almost white crystalline powder		白色结晶性粉末 White crystalline powder		
鉴别 A:IR Identification A:IR	符合对照品图谱 Comply with reference spectrum		符合对照品图谱 Comply with reference spectrum		
D: 钠盐反应 D: Reaction of sodium	呈正反应 Positive		呈正反应 Positive		
溶液澄清度 Clarity of solution	应澄清 Clear		澄清 Clear		
5%溶液色泽 5% Color of solution	≤BY6		≤BY6		
酸碱性 Acidity or alkalinity	≤0.1ml 0.02M NaOH 使溶液颜色变成粉红色 ≤0.1ml 0.02M NaOH change the colour of the indicator		符合规定 Complies		
有关物质: 杂质C (%) Related substances: Impurity C(%)	≤0.5		忽略不计 (<0.03%) Disregard (<0.03%)		
杂质E (%) Impurity E(%)	≤0.15		0.069		
未知杂质 (%) Unspecified impurities(%)	≤0.05		忽略不计 (<0.03%) Disregard (<0.03%)		
总杂质 (%) Total impurities(%)	≤0.5		0.07		
硫酸盐 (%) Sulphates (%)	≤0.1		≤0.08		
重金属 (%) Heavy metals (%)	≤0.002		≤0.001		
干燥失重 (%) Loss on drying (%)	4.9-5.3		5.14		
含量 (以干品计) (%) Assay (on dried basis)(%)	99.0-101.0		99.2		
残留溶剂: 乙醇 (ppm) Residual solvents: Ethanol (ppm)	≤1000		66		



结论:

本品按 EP10.0/COS 检验, 上述项目符合规定

Conclusion:

The product is tested in accordance with EP10.0 and R1-CEP2001-356-Rev04 requirements. The above items meet the requirement.

备注:

复验期: 36个月 (依据 CEP)

Remark:

Retest period: thirty six months according to CEP

QA放行:

QA放行章

放行日期:

2021.8.17

质检负责人:

QC Manager:

复核者:

Rechecked by:

报告者:

Reported by:

孙峰
2021.8.17

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