

山东新华制药股份有限公司
Shandong Xinhua Pharmaceutical Co., Ltd.

East Chemical Zone of Zibo High & New Technology Development Zone, Zibo, Shandong, P. R. China

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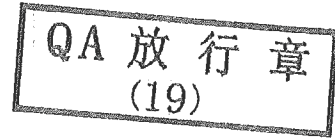
Certificate of Analysis

JKBFG-005E

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产品名称: 聚卡波非钙 Name of Product: CALCIUM POLYCARBOPHIL	取样日期: Sampling Date 2021-12-07	报告日期: Report Date 2021-12-10
批号: Batch No.	生产日期: Date of Manufacturing 2021-10-22	复验期: Retest Date 2025-10
批 量: Quantity 1001.2 kg	检验记录号: Record No.	报告编号: Report No.
标准依据: Reference Standard	USP2021, 客户标准 USP2021 and Client's requirement	物料代码: Product code 055-07-1

项 目 Items	指 标 Specifications	检 验 结 果 Results
性状 Appearance	白色至乳白色粉末 White to creamy white powder	乳白色粉末 Creamy white powder
鉴别 Identification	应符合规定 Conform	符合规定 Conform
干燥失重 (%) Loss on drying (%)	≤10.0	4.86
吸水力 (干晶计) (g/g) Absorbing power (g/g) (on dried basis)	≥35	43.3
钙含量 (干晶计) (%) Assay of calcium (%) (on dried basis)	18.0-22.0	20.5
粒度: d(0.1)(um) Particle size:d(0.1)(um)	3-6	4
d(0.5)(um)	10-13	12
d(0.9)(um)	20-30	20
平均粒径 (um) average granular(um)	11-15	12



结 论: 本品按 USP2021, 客户标准 检验, 上述项目符合规定
Conclusion: The product is tested in accordance with USP2021 and Client's requirement. The above items meet the requirement.

备 注:
Remark:

QA放行人: 放行日期: 2021.12.10 质检负责人: 翔习 复核者: 干田田 报告者: 米原
Released by QA: 屈兴茹 QC Manager: 翔习 印 龙 Rechecked by: 干田田 Reported by: 米原 2021.12.10