

山东新华制药股份有限公司
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Certificate of Analysis ASPL-009B

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产品名称: 阿司匹林 Name of Product: ACETYLSALICYLIC ACID	取样日期: 2021-03-18 Sampling Date:	报告日期: 2021-03-19 Report Date:
批号: 21586 Batch No:	生产日期: 2021-03-15 Date of Manufacturing:	复验期: 2024-03 Retest Date:
批量: 4010 kg Batch Size:	检验记录号: 216024034 Record No:	报告编号: 216024034 Report No:
标准依据: EP10.0/COS(20-60目) Reference Standard: Ph.Eur.10.0 and R1-CEP2001-210-Rev05 (20-60mesh)	物料代码: 019-35 Product code:	
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或无色结晶 White or almost white crystalline powder or colourless crystal	白色结晶性粉末 white crystalline powder
鉴别: A. 红外 Identification: A. IR-spectrum	应符合规定 Complies	符合规定 Complies
B. 水杨酸熔点(°C) B. melting point of salicylic acid(°C)	156-161	160.1
C. 颜色反应 C. Coloration test	应符合规定 Complies	符合规定 Complies
D. B项下的沉淀物显水杨酸盐的鉴别反应 D. The precipitate obtained in B gives reaction (a) of salicylates	应符合规定 Complies	符合规定 Complies
硫酸盐灰分(%) Sulphated ash(%)	≤0.1	0.05
干燥失重(%) Loss on drying(%)	≤0.5	0.04
重金属(%) Heavy metals(%)	≤0.002	≤0.0010
溶液外观 Appearance of solution	应澄清, 无色 Clear and Colourless	澄清, 无色 Clear and colourless
有关物质(%) (忽略不计: <0.03%); 杂质A(%) Related substances(%) (Disregard: <0.03%); impurity A	≤0.15	忽略不计 Disregard
杂质B(%) Impurity B(%)	≤0.15	忽略不计 Disregard
杂质C(%) Impurity C(%)	≤0.15	忽略不计 Disregard
杂质D(%) Impurity D(%)	≤0.15	忽略不计 Disregard
杂质E(%) Impurity E(%)	≤0.15	忽略不计 Disregard
杂质F(%) Impurity F(%)	≤0.15	忽略不计 Disregard
未知杂质(%) Unspecified impurity(%)	≤0.05	忽略不计 Disregard
总杂质(%) Total impurities(%)	≤0.25	忽略不计 Disregard
含量(干品计, %) Assay (on dried basis, %)	99.5-101.0	100.0
粒度: 60目上(%) Particle size: on 60 mesh (%)	≥84.0	93.4



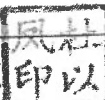
结论: 本品按 EP10.0/COS(20-60目) 检验, 上述项目符合规定
Conclusion: The product is tested in accordance with Ph.Eur.10.0 and R1-CEP2001-210-Rev05 (20-60mesh). The above items meet the requirement.

备注:

QA放行章

QA放行人: 本行 放行日期: 2021.2.22
Released by: QA 本行 Release Date: 2021.2.22

质检负责人
QC Manager



复核者:
Rechecked by:

梁素素

报告者: 本行
Reported by: 2021.2.22