

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

Hutian Chemical Industrial Zone, Zibo, Shandong, P.R.China Tel:+86-533-2166666 FAX:+86-533-2184991

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Certificate of Analysis

41082

产品名称: 阿司匹林 Name of Product: ACETYL SALICYLIC ACID	取样日期: 2015-03-27 Sampling Date:	报告日期: 2015-03-29 Report Date:
批号: 15524 Batch No:	生产日期: 2015-03-21 Date of Manufacturing:	失效期: 2019-03 Expiry Date:
批量: 3875 kg Batch Size:	检验记录号: 25011065 Record No:	报告编号: 25011065 Report No:
标准依据: BP2013/EP8.0/USP37 (20-60目) Reference Standard: BP2013/EP8.0/USP37 (20-60mesh)		物料代码: 019-07 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: (BP/EP) A. 红外 Identification (BP/EP) 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	158.1
(USP) A. 三价铁反应试验 (USP) A. Ferric Acid reaction test	应符合规定 Complies	符合规定 Complies
B. 红外 B. IR-spectrum	应符合规定 Complies	符合规定 Complies
溶液外观 Appearance of solution	应澄清, 无色 Clear and Colourless	澄清, 无色 Clear and colourless
碳酸钠试液不溶物 Substances Insoluble in Sodium Carbonate TS	应澄清 Clear	澄清 Clear
易炭化物 Readily carbonizable substances	≤对照液Q ≤Matching Fluid Q	≤对照液Q ≤Matching Fluid Q
游离水杨酸 (%) Limit of free Salicylic Acid (%)	≤0.1	≤0.03
干燥失重 (%) Loss on drying (%)	≤0.5	0.05
炽灼残渣 (%) Residue on ignition (%)	≤0.05	0.03
氯化物 (%) Chloride (%)	≤0.014	≤0.011
硫酸盐 (%) Sulfate (%)	≤0.04	≤0.02
重金属 (%) Heavy metals (%)	≤0.001	≤0.0010
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 (%) Unknown impurity (%)	≤0.05	忽略不计 Disregard
结论: 本品按 BP2013/EP8.0/USP37 (20-60目) 检验, 上述项目符合规定 Conclusion: The product is tested in accordance with BP2013/EP8.0/USP37 (20-60mesh). The above items meet the requirement.		
备注: (10) Remark:		包装量: 3875 Kg Packing Quantity

QA放行人: 李芳 放行日期: 2015.3.29 质检负责人: 李芳
Released by QA: 李芳 Release Date: 2015.3.29 QC Manager: 李芳

复核者: 李芳 报告者: 李芳
Rechecked by: 李芳 Reported by: 李芳

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检验项目 Items	检验标准 Specifications	检验结果 Results
总杂质(%) Total impurities(%)	≤0.25	忽略不计 Disregard
含量(1品计, %) Assay (on dried basis, %)	99.5-100.5	99.9
粒度: 60目上(%) Particle size: on 60 mesh (%)	≥84.0	93.2
残留溶剂(%) Residual solvents (%)	LOD≤0.5	0.05
		
FAGRON IBÉRICA, S.A.U Corresponde al lote de Fagron: 15F 09-608 Director Técnico		
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QA放行人:

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复核者:

Rechecked by:

报告者:

Reported by: