

河北敬业化工股份有限公司医药化工分公司成品检验报告
HeBei JingYe Chemical Engineering Co., Ltd, Medicine Chemical Engineering Branch
Certificate Of Analysis For Finished Products

产品名称: 阿司匹林 (20-60 日)	送验部门: 阿司匹林车间
Sample name: ASPIRIN(Acetylsalicylic Acid)	Sent By: ASPIRIN Workshop
数量: Quantity: 2MT	批号: Batch No.: 20150304
生产日期: Manufacturing date: 04.03,2015	有效日期: Expiry date: 04.03,2019
化验依据: BP2011/USP33/EP7.0	报告日期:
Specification: According to BP2011/USP33/EP7.0	Date reported: 07.03,2015

项目 Items	标准 Standard	结果 Results
外观 Appearance	白色或几乎白色结晶性粉末或无色粉末 White or almost white, crystalline powder or colourless crystals	白色结晶性粉末 White crystalline powder
鉴别(BP2011)A. 红外 Identification A. IR-Spectrum	应符合规定 Complies	符合规定 Complies
B. 分解产物水杨酸熔点 (°C) B. melting point of salicylic acid(°C)	156-161	158.0
鉴别(USP33)A. 三价铁反应实验 Identification 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 colorless	澄清无色 Clear and colorless
易炭化合物 Readily carbonizable substances	≤对照液 Q ≤Fluid Q	< 对照液 Q < Fluid Q
碳酸钠试液不溶物 Substances Insoluble in Sodium Carbonate TS	应澄清 Clear	澄清 Clear
氯化物(%) Chloride (%)	≤0.014	< 0.014
硫酸盐(%) Sulfate (%)	≤0.04	< 0.04
游离水杨酸 (%) Limit of free salicylic acid (%)	≤0.1	<0.1
重金属 Heavy metals	≤10PPM	< 10PPM
干燥失重 (%) Loss on drying (%)	≤0.5	0.2
硫酸化灰份/炽灼残渣 (%) Sulphated ash/ Residue on ignition (%)	≤0.05	0.03
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	0.03
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 impurities (%)	≤0.05	忽略不计 Disregard
总杂质(%) Total impurities (%)	≤0.25	0.03
含量% Assay (%)	99.5—100.5	100.1
残留溶剂(%) Residual Solvents (%)	USP (467)	符合规定 Complies



结论: 本品参照 BP2011/USP33/EP7.0 版检验, 结果符合规定。

Conclusion: The sample is tested in compliance with BP2011/USP33/EP7.0. the above items meet the requirement.

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