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
Tel:0533-2185101;Fax:0533-2282825

Certificate of Analysis

41082

产品名称: 咖啡因 Name of Product: CAFFEINE		取样日期: Samples Date	2011-03-08	报告日期: Report Date	2011-03-09
批　号: Batch No.	1103292	生产日期: Date of Manufacturing	2011-03-03	失效期: Expiry Date	2015-03
批　量: Quantity	2000 kg	检验记录号: Record No.	6750058	报告编号: Report No.	6750058
标准依据: Reference Standard		英国药典2011版/欧洲药典7.0版/美国药典33版 BP2011/EP7.0/USP33			

项　目 Items	指　标 Specifications	检验结果 Results
外观 Appearance	白色结晶粉末 White crystalline powder	白色结晶粉末 White crystalline powder
鉴别 Identification	应呈正反应 Complies	呈正反应 Complies
熔点(℃) Melting point (℃)	235-239	237.0
溶液外观 Appearance of solution	应澄清、无色 Clear and colorless	澄清、无色 Clear and colorless
酸度(0.01mol/L NaOH,ml) Acidity(0.01mol/L NaOH,ml)	≤0.2	符合规定 Conform
色谱纯度:单个杂质(%) Chromatographic purity:Single impurity(%)	≤0.10	0.03
总杂质(%) Total impurities (%)	≤0.1	0.03
硫酸盐(ppm) Sulfate (ppm)	≤300	≤300
重金属(以Pb计)(%) Heavy metals(on Pb basis)(%)	≤0.001	≤0.001
干燥失重(%) Loss on drying (%)	≤0.5	0.03
炽灼残渣(%) Residue on ignition (%)	≤0.1	0.06
硫酸盐灰份(%) Sulphated ash (%)	≤0.1	0.06
含量(以干品计)(%) Assay (on dried basis)(%)	98.5-101.5	99.6
残留溶剂(氯仿, ppm) Residual solvents(Chloroform,ppm)	≤60	符合规定 Conform
HPLC含量(%, 干品计) Assay (%, on dried basis) (HPLC)	98.5-101.0	99.7

QA放行章 (7)

结　论: 本品按 英国药典2011版/欧洲药典7.0版/美国药典33版 检验,上述项目符合规定
Conclusion: The product is tested in accordance with BP2011/EP7.0/USP33. The above items meet the requirement.

QA放行人: 张萍 Released by QA: 放行日期: 2011.3.10 Release Date: 质检负责人: 宋良芳 QC Manager: 复核者: 王树相 Rechecked by: 报告者: 王芳 Reported by:

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
Tel: 0533-2185101; Fax: 0533-2282825

Certificate of Analysis

41082

产品名称: Name of Product:	咖啡因 CAFFEINE	取样日期: Sampling Date	2011-03-08	报告日期: Report Date	2011-03-09
批 号: Batch No.	1103291	生产日期: Date of Manufacturing	2011-03-01	失效期: Expiry Date	2015-03
批 量: Quantity	2000 kg	检验记录号: Record No.	6750057	报告编号: Report No.	6750057
标准依据: Reference Standard	英国药典2011版/欧洲药典7.0版/美国药典33版 BP2011/EP7.0/USP33				

项 目 Items	指 标 Specifications	检验结果 Results
外观 Appearance	白色结晶粉末 White crystalline powder	白色结晶粉末 White crystalline powder
鉴别 Identification	应呈正反应 Complies	呈正反应 Complies
熔点(℃) Melting point (℃)	234-239	236.8
溶液外观 Appearance of solution	应澄清、无色 Clear and colorless	澄清、无色 Clear and colorless
酸度(0.01mol/L NaOH, ml) Acidity(0.01mol/L NaOH, ml)	≤0.2	符合规定 Conform
色谱纯度:单个杂质(%) Chromatographic purity:Single impurity(%)	≤0.10	0.03
总杂质(%) Total impurities (%)	≤0.1	0.03
硫酸盐(ppm) Sulfate (ppm)	≤500	<500
重金属(以Pb计)(%) Heavy metals(on Pb basis)(%)	≤0.001	<0.001
干燥失重(%) Loss on drying (%)	≤0.5	0.01
炽灼残渣(%) Residue on ignition (%)	≤0.1	0.04
硫酸盐灰份(%) Sulphated ash (%)	≤0.1	0.04
含量(以干品计)(%) Assay (on dried basis)(%)	98.5-101.5	99.5
残留溶剂(氯仿, ppm) Residual solvents(Chloroform, ppm)	≤60	符合规定 Conform
HPLC含量(%, 干品计) Assay (%, on dried basis) (HPLC)	98.5-101.0	99.7

QA放行章 (7)

结 论: 本品按 英国药典2011版/欧洲药典7.0版/美国药典33版 检验, 上述项目符合规定
Conclusion: The product is tested in accordance with BP2011/EP7.0/USP33. The above items meet the requirement.

QA放行人: Released by QA:	张萃	放行日期: Release Date:	2011.3.10	质检负责人: QC Manager:	良宋印芳	复核者: Rechecked by:	[illegible]	报告者: Reported by:	[illegible]