

山东新华制药股份有限公司

Shandong Xinhua Pharmaceutical Co., Ltd.

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Certificate of Analysis

41082

产品名称: 安替比林 Name of Product: PHENAZONE	取样日期: 2011-01-27 Sampling Date	报告日期: 2011-01-31 Report Date
批号: 1101017 Batch No	生产日期: 2011-01-23 Date of Manufacturing	失效期: 2016-01 Expiry Date
批量: 1005 kg Quantity	检验记录号: 3100016 Record No	报告编号: 3100016 Report No
标准依据: Ph. Eur. 7.0/COS Reference Standard: req. of Ph.Eur.7.0 and R1-CEP 2002-093-Rev01		
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 crystals	白色结晶性粉末 White crystalline powder
鉴别 A: 熔点(°C) Identification A: Melting point (°C)	109-113	111.5
B: 红外 B: IR	应与标准品的图谱一致 Identical with IR spectrum of the EP CRS	符合规定 Conform
溶液外观 Appearance of solution	应澄清, 无色 Clear and colourless	澄清, 无色 Clear and colourless
酸碱度 Acidity or alkalinity	应符合规定 Complies	符合规定 Complies
氯化物(ppm) Chloride (ppm)	≤100	≤100
硫酸盐(ppm) Sulphates (ppm)	≤100	≤80
重金属(ppm) Heavy metals(ppm)	≤20	≤10
干燥失重(%) Loss on drying(%)	≤1.0	0.01
硫酸盐灰分(%) Sulphated ash (%)	≤0.1	0.05
含量(以干品计, %) Assay (on dried basis, %)	99.0-101.0	99.6
残留溶剂(乙醇)(ppm) Residual solvents(Ethanol)(ppm)	≤1000	192
有关物质(%) (忽略不计: <0.03%); 杂质A Related substances(%) (Disregard: <0.03%); impurity A	≤0.05	未检出 Not detected
未知杂质(%) Unspecified impurity(%)	≤0.05	忽略不计 Disregard
总杂质(%) Total impurities (%)	≤0.1	忽略不计 Disregard

结论:

本品按 Ph. Eur. 7.0/COS 检验, 上述项目符合规定

Conclusion: The product is tested in accordance with req. of Ph.Eur.7.0 and R1-CEP 2002-093-Rev01. The above items meet the requirement

QA放行人:

放行日期:

质检负责人:

复核者:

报告者: 张娟娟

Released by QA: [Signature]

Release Date: 2011.2.1

QC Manager: [Signature]

Rechecked by:

Reported by:

