



HUNAN DONGTING PHARMACEUTICAL CO., LTD.
湖南洞庭药业股份有限公司

CERTIFICATE OF ANALYSIS

检验报告书

报告书编号 CDA No. 2018100034

Control Code: 18111836

品名 Product Name	氧甲环酸 Fraxemide	取样件数及批号 Pcs. Sampled & Sample Qty.	7 桶 Drums 350g
批号 Batch No.	X1809021M	接收日期 Date Sample Received	2018.09.29
包装/数量 Drums Qty.	880.5Kg 17 桶 Drums	报告日期 COA Issuing Date	2018.10.06
检验项目 Test Items	全检 All items	生产日期 Mfg. Date	2018.09.22
质量标准 Quality Specification	CLP & ZLBZ K023-7	复检期 Re-test Date	2020.09.21

检测项目 Items of Test	法定接受标准 Pharmacopoeial Criteria	检测结果 Test Result
性状 CHARACTERS	外观: 白色或类白色结晶性粉末 <i>Appearance</i> : White or almost white, crystalline powder	白色结晶性粉末 White crystalline powder
	溶解性: 易溶于水与冰醋酸, 不溶于丙酮与乙醇 (96%) <i>Solubility</i> : Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and in ethanol (96%)	合格 Pass
鉴别 IDENTIFICATION	红外吸收光谱 (2.2.17) 与氧甲环酸对照品一致 <i>Infrared</i> : Infrared Spectroscopy IR spectrum is in concordance with Fraxemide, ICRS	合格 Pass
检查 TEST	pH (2.2.3)	7.0 ~ 8.0
	有关物质 (HPLC 2.2.29) Related Substances (HPLC 2.2.29)	杂质 A: Impurity A ≤ 0.1% 杂质 B: Impurity B ≤ 0.2% 未指定杂质 ≤ 0.05% Unspecified impurities ≤ 0.05% 杂质 C: Impurity C 杂质 D: Impurity D 其它杂质 (Other Impurities) 未检出 (Not Detected)
	未指定杂质总量 ≤ 0.2% Sum of unspecified impurities ≤ 0.2%	0.05% 0.001% 0.002% 未检出 (Not Detected)
	氯化物 (2.2.4) Halides Expressed as Chlorides	≤ 140ppm
	干燥失重 (2.2.32) Loss on Drying	≤ 0.5%
	硫酸灰分 (2.4.14) Sulphated Ash	≤ 0.1%
含量/ASSAY (Titrimetry 2.2.20)	按干品计算 C ₁₁ H ₁₁ NO ₃ 应为 99.0% ~ 101.0% Should be within (Dried based) 99.0% ~ 101.0%	99.6%

结论: 本批产品按《CLP & ZLBZ K023-7》检验, 结果符合规定。

CONCLUSION: the batch complies with the prescribed specification above as per CLP & ZLBZ K023-7

QC: 解芳 2018.10.08

QA: 王娟 2018.10.08

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法定标准
Pharmacopoeial Specification