

武汉远大弘元股份有限公司
WUHAN GRAND HOYO CO., LTD

Add.: No.1 Industrial Park, Gedian Economic Development Zone, E'Zhou City, Hubei, China

质检单

CERTIFICATE OF ANALYSIS

Carbocisteine C101-1802013-2

产品名称: 羧甲司坦 Product: Carbocisteine 批号 Lot No: 201802028
重量 Quantity: 100kg 报告日期 Report Date: MAR 01, 2018

检测项目 Test Item		检测标准 Specification	检测结果 Result
性状 Description		欧洲药典 9.0 版 European Pharmacopoeia 9 TH 白色或类白色结晶性粉末, 在水或乙醇中极微溶解, 在稀酸或稀碱溶液中易溶。 A white or almost white, crystalline power, parctically insoluble in water and in alcohol .It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.	符合规定 Conforms
鉴别 Identification	Test A (Specific Optical rotation)	符合比旋度检测标准要求。 It complies with the test for specific optical rotation.	符合规定 Conforms
	Test B (IR)	样品图谱与标准图谱一致。 The IR spectrum of the sample is concordant with the spectrum of the reference standard, Carbocisteine CRS.	
	Test C(TLC)	供试液 b 的色谱主斑点应与对照液 a 产生的主斑点的位置、颜色、大小一致。 The principal spot in the chromatogram obtained with the test solution (b) is similar in position, color and size to the principal spot in the chromatogram obtained with the reference solution(a)	
	Test D(Chemical reaction)	产生深红色, 后变为褐色, 几分钟后变为黄色。 Dark red color is produced, which changes to brown and then to yellow within a few minutes.	
酸 度 pH		2.8 ~ 3.0	2.8
比旋度 Specific optical rotation [α] _D ²⁰		-32.5° ~ -35.5°	-33.6°
溶液的澄清度 State of solution (Transmittance)		溶液澄清无色 Solution S is clear and colourless 不得小于 Not less than 96.0%	Clear and colourless 98.9%
茚三酮阳性物质 Ninhydrin-positive substances		不得大于 Not more than 0.5%	<0.5%
氯化物 Chloride(Cl)		不得大于 Not more than 0.15%	<0.10%
硫酸盐 Sulfate(SO ₄)		不得大于 Not more than 0.03%	<0.03%
干燥失重 Loss on Drying		不得大于 Not more than 0.5%	0.1%
灼烧残渣 Residue on ignition(sulfated)		不得大于 Not more than 0.3%	0.04%
含 量 Assay		98.5% ~ 101.0 %	99.3%

结论: 本品按 EP9 质量标准检验, 结果符合规定。 Conclusion: Agree with the specification of EP9.

生产日期: 2018 年 02 月 25 日
Manu. Date: FEB 25, 2018

有效期: 至 2020 年 02 月 22 日
Expire Date: FEB 22, 2020

检验日期: 2018 年 02 月 26 日
Test Date: FEB 26, 2018

王云芝

胡明

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