

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

15A28-B03

武 汉 远 大 弘 元 有 限 公 司
W U H A N G R A N D H O Y O C O . , L T D .

NO.1 INDUSTRIAL PARK, GEDIAN ECONOMY DEVELOPMENT ZONE, E'ZHOU CITY, HUBEI, CHINA

质 检 单

CERTIFICATE OF ANALYSIS

Carbocysteine 05-1501004-1

产品名称: 羧甲司坦 Product: Carbocysteine		批 号 Lot No: 201411020
重 量 Quantity: 350kg		报告日期 Date: JAN 07, 2015
检测项目 Test Item	检测标准 Specification: 欧洲药典 7.0 版 European Pharmacopoeia 7 th	检测结果 Result
性状 Description	白色结晶性粉末, 不溶于水, 酒精, 乙醚, 溶于酸或碱溶液。A white, crystalline powder, practically insoluble in water, in alcohol and in ether. 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.
	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, Carbocysteine 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	2.9
旋 光 Specific rotation [α] _D ²⁰	-32.5° ~ -35.5°	-33.6°
溶液的澄清晰度 State of solution (Transmittance)	溶液澄清无色 Solution S is clear and colourless 不得小于 Not less than 95.0%	Clear and colourless 99.5%
印三酮阳性物质 Ninhydrin-positive substances	不得大于 Not more than 0.5%	符合规定 Conforms
氯化物 Chloride (Cl)	不得大于 Not more than 0.15%	<0.10%
硫酸根 Sulfate (SO ₄)	不得大于 Not more than 0.03%	<0.03%
重 金 属 Heavy metals (Pb)	不得大于 Not more than 0.001%	<0.001%
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%	0.05%
含 量 Assay	98.5% ~ 101.0%	99.8%

结论: 本品按 EP7 质量标准检验, 结果符合规定。Conclusion: Agree with the specification of EP7.

生产日期: 2014 年 11 月 28 日
Manu. Date: NOV 28, 2014

有效期至 2016 年 11 月 11 日
Expire Date: NOV 11, 2016

检验日期: 2014 年 11 月 28 日
Test Date: NOV 28, 2014

检验报告员: 段莹
Inspector:

复核人: 童利华
Auditor:

质检部负责人: 赵红收
Chief of QC: