

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

17I14-B01

武汉远大弘元股份有限公司  
W U H A N G R A N D H O Y O

有限公司  
C O D I T D .

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

质 检 单

CERTIFICATE OF ANALYSIS

Carbocisteine

产品名称: 羧甲司坦 Product: Carbocisteine		批 号 Lot No: 201708008	
重 量 Quantity: 100kg		报告日期 Date: AUG 29, 2017	
检测项目 Test Item		检测标准: 欧洲药典 9.0 版 Specification: European Pharmacopoeia 9 <sup>TH</sup>	检测结果 Result
性状 Description		结晶性粉末, 不溶于水, 酒精, 乙醚. 溶于酸或碱溶液, 在酒精和乙醚中. 溶于稀矿物酸和稀碱溶液. 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.	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	2.9
比旋度 Specific optical rotation [α] <sub>D</sub> <sup>20</sup>		-32.5° ~ -35.5°	-33.5°
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 95.0%	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 <sub>4</sub> )		不得大于 Not more than 0.03%	<0.03%
铁 盐 Iron(Fe)		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%	0.07%
含 量 Assay		98.5% ~ 101.0 %	99.7%



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: 2017 年 08 月 12 日

有效期: 至 2019 年 08 月 09 日

检验日期: 2017 年 08 月 13 日

Manu. Date: AUG 12, 2017

Expire Date: AUG 09, 2019

Test Date: AUG 13, 2017

检验报告员: 王云芝  
Inspector:

复核人: 胡明华  
Auditor:

质检部负责人: 董新  
Chief of QC: