

河北圣雪大成唐山制药有限责任公司

HEBEI SHENGXUE DACHENG PHARMACEUTICAL(TANGSHAN)CO.,LTD.

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检验报告单

CERTIFICATE OF ANALYSIS

产品名称: Product name	硫酸粘菌素 Colistin sulphate	产品批号: Batch No	N1-170106-7	报告编号: Certificate No	1701-004
包装: Package	500 十亿/桶 Bou/Drum	批数量: Batch size	250 桶 Drum	净重: Net weight	22.24 Kg/桶 Kg/Drum
生产日期: Manuf. date	2017-01-01	报告日期: Report date	2017-01-08	复验期: Retest date	2019-12-31

检验项目 ITEM CONTROLLED	标准规定 STANDARD	检验数据 TEST DATA
性状 Characters	白色或类白色粉末 White or almost white Powder	白色粉末 White Powder
鉴别 Identification	符合EP规定 Conforms to EP specifications	符合 Conforms
酸碱度 (PH) PH-value	4.0~6.0	4.7
干燥失重 Loss on drying	≤3.5%	2.2 %
比旋度 Specific optical rotation	-63° ~-73°	-72 °
灰份 Sulphated Ash	≤1.0%	0.1 %
硫酸盐 Sulphate	16.0~18.0%	17.3 %
含量 (干品计) Concent(Dry Basis HPLC)	Colistin E1- I : ≤10.0%	0.4 %
	Colistin E1-7MOA: ≤10.0%	4.0 %
	Colistin E3: ≤10.0%	3.5 %
	E1+E2+E3+E1- I +E1-7MOA: ≥77.0%	89.7 %
相关物质 Related Substances	RRT0. 27: ≤3.0%	1.8 %
	RRT0. 44: ≤3.0%	1.4 %
	RRT0. 49: ≤3.0%	1.1 %
	RRT0. 67: ≤3.0%	1.1 %
	RRT0. 93: ≤3.0%	1.1 %
	其他杂质 (Any impurity) : ≤2.0%	1.0 %
	总杂质 (Total impurity) : ≤18.0%	10.2 %
效价 (湿品) Potency		22483 IU/mg
效价 (干品) Potency (Dried basis)	≥19000IU/mg	22989 IU/mg

结论: 本产品符合欧洲药典9.0版的要求及CEP(No. R1-CEP 2009-144-Rev 00)的要求

Conclusion: This product complies with EP9.0 and CEP (No. R1-CEP 2009-144-Rev 00)

声明: 本产品生产符合欧洲GMP要求

Remark: This batch was manufactured in compliance with EU-GMP guide part II requirements

检验部主任:
Director of QC Dept: Jiang Xiaoxia

报告人:
Reporter: Mu Jing

复核人:

QA放行人:
Released by QA: Xing Xiwei

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WE ARE MANUFACTURER. THE BATCH HAS BEEN MANUFACTURED IN FULL COMPLIANCE WITH GMP

REQUIREMENTS OF THE LOCAL REGULATORY AUTHORITY. GMP NO.: 50

DATE: MAR. 28, 2013 VALIDITY: MAR. 27, 2018

BATCH PRODUCTION RECORD CHECKED AND APPROVED, NO DEVIATION, NO REWORKING AND REPROCESSING.