

159653

生物制品批签发证明

Certificate for the Release of Biological Products

批签蜀检20210340

LRE20210340

产品名称	静注人免疫球蛋白 (pH4)		
Generic Name			
生产企业	成都蓉生药业有限责任公司		
Manufacturer			
地址	四川省成都市高新区起步园科技园南路7号		
Address			
收检编号	E202100458	批号	202101B007
Regis. No.		Lot No.	
剂型	注射剂 (注射液)	规格	5% 50ml 2.5g/瓶
Dosage Form		Strength	
有效期至	2024年1月28日	签发量	18275瓶
Expiry Date		Quantity	

经审查, 上述制品符合生物制品批签发的有关规定, 予以签发。

The product mentioned above complies with the relevant provisions for lot release of biological products and is approved for release.

本证明系至少基于对企业申报的产品批制造及检验记录摘要的审查而签发。

As a minimum, This certificate is based on review of the summary protocol of manufacturing and control.

签发人:

Issued by :

二〇二一年五月二十五日

25 May 2021





成都蓉生药业有限责任公司
Chengdu Rongsheng Pharmaceuticals Co., Ltd.

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产品签发合格证

Certificate for the Release of Products

证书编号/Certificate No.: RS-0212-2021042

产品名称/Name of the Product: 静注人免疫球蛋白 (pH4)
商品名/Trade Name of the Product: 蓉生静丙
产品批号/Lot No.: 202101B007
剂型/Dosage Form: 注射剂 (注射液)
规格/Strength: 5% 50ml 2.5g/瓶
生产日期/Manufacturing Date: 2021 年 1 月 29 日
有效期至/Valid Until: 2024 年 1 月 28 日
批量/出口量/Lot Quantity/Export Quantity: 18275 瓶



经生产过程质量控制和生产及检定记录审查, 本批产品符合《中国药典》2020 年版相关规定, 并取得《生物制品批签发证明》, 准予放行。

The product mentioned above has passed the check of the process quality control and the production/test records. It complies with the provisions of the release of Chinese Pharmacopoeia (2020 Edition) and obtains the certificate for the release of biological products, approved for release.



质量授权人/Qualified Person:
(official seal 公章)



2021 年 7 月 1 日 / 1st Jul. 2021

产品检定报告

Certificate of Analysis for Finished products

品名 Product Name	静注人免疫球蛋白(pH4) Human Immunoglobulin (pH4) for Intravenous Injection		剂型 Dosage Form	注射剂 (注射液) Injection (Liquids for Injection)
产品批号 Batch No.	202101B007		规格 Strength	5% 50ml 2.5g/瓶 5% 50ml 2.5g / bottle
生产日期 Manufacturing Date	29/01/2021		有效期至 Valid until	28/01/2024
检定依据 Test According to	静注人免疫球蛋白(pH4)内控质量标准 QA-Q8.2.4-009 Human Immunoglobulin(pH4) for Intravenous Injection internally controlled quality specification QA-Q8.2.4-009		报告编号 Report No.	BD2021007-016
检定项目 Test Item	标准规定 Specification		检定结果 Test Result	
白喉抗体效价(HAU/g 蛋白质) Diphtheria Antibody titer(HAU/g of protein)	≥3.0		15.2	
PKA(IU/ml)	≤30		未检出	
抗补体活性 (%)	≤50		22	
抗 A 血凝素 Anti-A Hemagglutinins	≤1:64		1:16	
抗 B 血凝素 Anti-B Hemagglutinins	≤1:64		1:8	
无菌检查 Sterility Test	应无菌生长 No microbial growth		无菌生长 No microbial growth	
异常毒性检查 Test For Abnormal Toxicity	豚鼠试验 Guinea pigs	豚鼠应全部健存, 且无异常反应, 到期时每只豚鼠体重应增加 Guinea pigs remain healthy and survive the observation period, no abnormal reaction, increase of body weight	符合规定 Conform to	
	小鼠试验 Mice	小鼠应全部健存, 且无异常反应, 到期时每只小鼠体重应增加 Mice remain healthy and survive the observation period, no abnormal reaction, increase of body weight	符合规定 Conform to	
热原检查 Pyrogen Test	应符合规定 Conform to specification		符合规定 Conform to	
HIV-1/HIV-2 抗体 HIV-1/ HIV-2 antibody test	应为阴性 Negative		阴性 Negative	
HCV 抗体 HCV antibody test	应为阴性 Negative		阴性 Negative	
IgA 残留量(μg/ml) Immunoglobulin A(μg/ml)	N/A		阴性 Negative	
检定结论 Test Conclusion:	符合规定 Conform to the specification			
报告人 Reported by	刘胜平		报告日期 Date	2021.03.13
复核人 Checked by	罗亮		质量检定部负责人 QC Department Head	722

产品检定报告

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检定项目 Test Item	标准规定 Specification		检定结果 Test Result
鉴别试验 Identity Test	免疫双扩散法 Double Immunodiffusion	仅与抗人血清或血浆产生沉淀线,与抗马、抗牛、抗猪、抗羊血清或血浆不产生沉淀线。 Only a precipitation line with anti-human serum or plasma, but no precipitation line with anti-horse, anti-bovine, anti-pig or anti-sheep serum or plasma.	符合规定 Conform to
	免疫电泳法 Immunoelectrophoresis	与正常人血清或血浆比较,主要沉淀线应为IgG The main precipitation line shall be IgG as compared with normal human plasma	符合规定 Conform to
外观 Physical Inspection		应无色或淡黄色澄明液体,可带轻微乳光,不应出现浑浊。 Clear, colourless or light yellow liquid, slightly opalescence may occur but without turbidity	符合规定 Conform to
可见异物 Test for Visible Particles		应符合规定 Conform to specification	符合规定 Conform to
不溶性微粒检查 Test for undissolvable particulate		应符合规定 Conform to specification	符合规定 Conform to
渗透压摩尔浓度 (mOsmol/Kg) Test for Osmole Concentration		≥240	340
装量(ml) Filling Quantity(ml)		≥50	符合规定 Conform to
热稳定性试验 Thermostability Test		应符合规定 Conform to specification	符合规定 Conform to
pH值		3.8~4.4	4.3
蛋白质含量 (g/L) Protein content (g/L)		≥50.0	52.7
蛋白质总量 (g/瓶) Total Protein (g/bottle)		≥2.5	2.6
纯度 (%) Purity (%)		≥96.0	99.5
糖含量(g/L) Sugar Content(g/L)		麦芽糖含量为90~110 Maltose content shall be 90~110	100
分子大小分布 (%) Distribution of molecular size (%)		IgG单体+二聚体含量≥97.0 IgG monomer+dimmer content ≥97.0	98.8
抗-HBs效价(IU/g 蛋白质) Anti-HBs Potency(IU/g of protein)		≥6.0	53.1

