



成都蓉生药业有限责任公司
Chengdu Rongsheng Pharmaceutical 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-0212-2019007

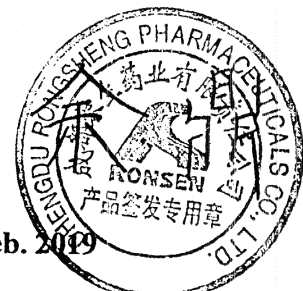
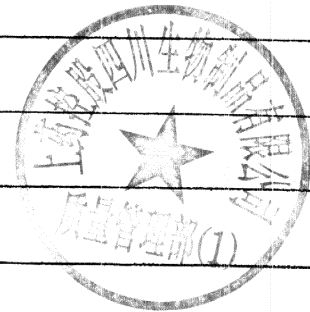
产品名称/Name of the Product:	静注人免疫球蛋白 (pH4)
商品名/Trade Name of the Product:	蓉生静丙
产品批号/Lot No.:	201809B072
剂 型/Dosage Form:	注射剂
规 格/Strength:	5% 50ml 2.5g/瓶
生产日期/Manufacturing Date:	2018年9月19日
有效期至/Valid Until:	2021年9月18日
批量/出口量/Lot Quantity/Export Quantity:	18544 瓶

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》2015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 (2015 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)

2019年2月1日 /1st Feb. 2019



生物制品批签发证明

Certificate for the Release of Biological Products

批签蜀检201900050

LRE201900050

产品名称 Generic Name	静注人免疫球蛋白 (pH4)		
生产企业 Manufacturer	成都蓉生药业有限责任公司		
地址 Address	四川省成都市高新区起步园科园南路7号		
收检编号 Regis. No	E201801530	批号 Lot No.	201809B072
剂型 Dosage Form	注射剂	规格 Strength	5% 50ml 2.5g/瓶
有效期至 Expiry Date	2021年9月18日	签发量 Quantity	18544瓶

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.

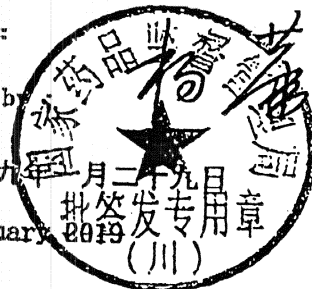
本证明系至少基于对企业申报的产品批制造及检验记录摘要的审查而签发。

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

签发人:

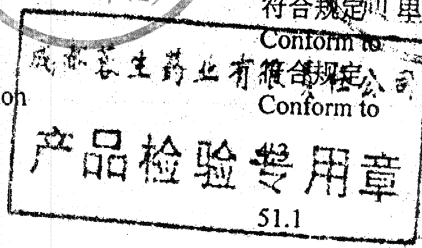
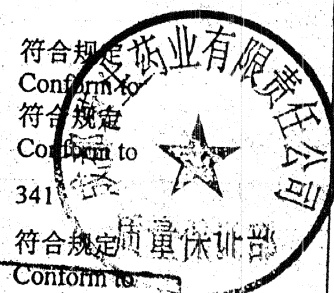
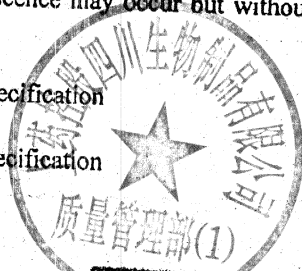
Issued by

二〇一九年一月二十九日
29 January 2019



产品检验报告
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 Injection
产品批号 Batch No.	201809B072	规格 Size	5% 50ml 2.5g/瓶 5% 50ml 2.5g / bottle
生产日期 Manufacturing Date	19/09/2018	有效期至 Valid Until	18/09/2021
检定依据 Testing According to	静注人免疫球蛋白(pH4)产品质量标准 QA-Q8.2.4-003 Human Immunoglobulin(pH4) for Intravenous Injection quality specification QA-Q8.2.4-003	报告编号 Report No.	BD2018072-083
检定项目 Test Items	标准规定 Specification	检定结果 Test Results	
鉴别试验 Identity	免疫双扩散法 Double Immunodiffusion 免疫电泳法 Immunoelectrophoresis	仅与抗人的血浆产生沉淀线 Only a precipitation line with anti-human plasma 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 符合规定 Conform to
外观 Physical Inspection	可见异物 Test for Visible Particles 不溶性微粒检查 Test for undissolvable particulate 渗透压摩尔浓度 (mOsmol/Kg) Test for Osmole Concentration 装量(ml) Filling Quantity(ml) 热稳定性试验 Thermostability Test pH	应为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 应符合规定 Conform to specification 应符合规定 Conform to specification ≥240 ≥50 应符合规定 Conform to specification 3.8~4.4	符合规定 Conform to 符合规定 Conform to 符合规定 Conform to 符合规定 Conform to 符合规定 Conform to
蛋白质含量 (g/L) Protein content (g/L)	蛋白质总量 (g/瓶) Total Protein (g/bottle)	≥50.0 ≥2.5	51.1 2.6
纯度 % Purity %	糖含量(g/L) Sugar Content(g/L)	≥95.0 麦芽糖含量为 90~110 Maltose content shall be 90~110	98.9 98
分子大小分布 % Distribution of molecular size %		IgG 单体+二聚体含量≥95.0 IgG monomer+dimmer content ≥95.0	99.1



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 Injection
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检定项目 Test Items	标准规定 Specification	检定结果 Test Results	
抗-HBs 效价(IU/g 蛋白质) Anti-HBs Potency(IU/g of protein)	≥6.0	70.5	
白喉抗体效价(HAU/g 蛋白质) Diphtheria Antibody titer(HAU/g of protein)	≥3.0	7.8	
PKA(IU/ml)	≤5		
抗补体活性(%) Anticomplement Activity(%)	≤50		
抗A血凝素 Anti-A Hemagglutinins	≤1:64		
抗B血凝素 Anti-B Hemagglutinins	≤1:64		
无菌检查 Sterility Test	应无菌生长 No microbial growth	未检出 35 符合规定 Conform to	
异常毒性检查 Test For Abnormal Toxicity	豚鼠试验 Guinea pigs 小鼠试验 Mice	豚鼠健存, 且无异常反应, 体重增加 Guinea pigs remain healthy and survive, increase of body weight 小鼠健存, 且无异常反应, 体重增加 Mice remain healthy and survive, 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	阴性 Negative	阴性 Negative	
HCV 抗体 HCV antibody test	阴性 Negative	阴性 Negative	
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检定结论: Test Conclusion:	合格 Conform to the specification		
报告人 Reported by	刘晓民	报告日期 Date	2018.10.30
复核人 Checked by	史良	质量检定部负责人 QC Dept. Head	Tyly

未检出
成都蓉生药业有限责任公司
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产品检验专用章

