

生物制品批签发证明

Certificate for the Release of Biological Products

批签蜀检201800445

LRE201800445

产品名称 Generic Name	人血白蛋白		
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	E201800742	批号 Lot No.	201804A048
剂型 Dosage Form	注射剂	规格 Strength	20% 50ml 10g/瓶
有效期至 Expiry Date	2023年4月23日	签发量 Quantity	14135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 concerned complies with the relevant provisions for lot release of biological products and is approved for release.

本证明系至少对生产企业申报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:

二〇一八年七月十八日

18 July 2018





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

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Sichuan, P.R.C
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产品签发合格证

Certificate for the Release of Products

证书编号/Certificate No.: RS-0123-2018092

产品名称/Name of the Product: 人血白蛋白
商品名/Trade Name of the Product: /
产品批号/Lot No.: 201804A048
剂型/Dosage Form: 注射剂
规格/Specification: 20% 50ml 10g/瓶
生产日期/Manufacturing Date: 2018年4月24日
有效期至/Valid Until: 2023年4月23日
批量/出口量/Lot Quantity/Export Quantity: 14135 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。

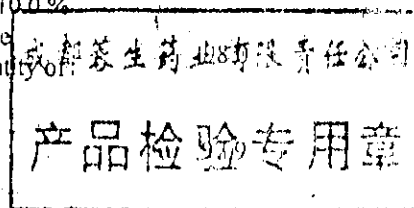
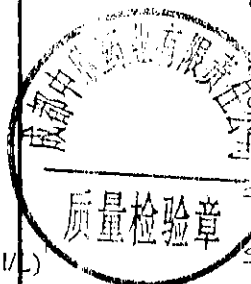
The product mentioned above has passed the check of the process quality control and the production/test records. It complies with the provisions of the release of Chinese Pharmacopoeia (2015 Edition) and obtains the certificate for the release of biological products, approved for release.

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

2018 年 7 月 24 日/24th Jul. 2018

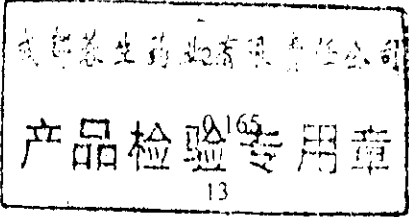
产品检定报告
Certificate of Analysis for Finished products

品名 Product Name	人血白蛋白 Human Albumin	剂型 Dosage Form	注射剂 Injection
产品批号 Batch No.	201804A048	规格 Size	20% 50ml 10g/瓶 20% 50ml 10g/ bottle
生产日期 Manufacturing Date	24/04/2018	有效期至 Valid Until	23/04/2023
检定依据 Testing According to	人血白蛋白产品质量标准 QA-Q8.2.4-001 Human Albumin quality specification QA-Q8.2.4-001	报告编号 Report No.	AD2018048-065
检定项目 Test Items	标准规定 Specification	检定结果 Test Results	
鉴别试验 Identity Test	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 主要沉淀线应为白蛋白 The main precipitation line shall be albumin as compared with normal human plasma 应为略黏稠、黄色或绿色至棕色澄明液体，不应出现浑浊。 The product shall be a clear, slightly viscous liquid without turbidity, slightly yellow, green or brown in colour.	
外观 Physical Inspection		符合规定 Conform to	
可见异物 Test for Visible Particles		符合规定 Conform to specification	
不溶性微粒检查 Test for undissolvable particulate		符合规定 Conform to specification	
渗透压摩尔浓度 (mOsmol/Kg) Test for Osmole Concentration		210~400	
装量(ml) Filling Quantity(ml)		≥50	
热稳定性试验 Thermostability Test		应符合规定 Conform to specification	
pH		6.4~7.4	
蛋白质含量 Protein content		应为标示量的 95.0%~110.0% The protein content shall be 95.0%~110.0% of the quantity of protein stated on the label	
纯度 (%) Purity (%)		≥98.0	
钠离子含量(mmol/L) Sodium Content(mmol/L)		≤160	
钾离子含量(mmol/L) Potassium Content(mmol/L)		≤2	



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检定项目 Test Items	标准规定 Specification	检定结果 Test Results	
吸光度 Absorbance	≤0.15	0.02	
多聚体含量(%) Polymer content (%)	≤5.0		
辛酸钠含量(mmol/g 蛋白质) Sodium caprylate content(mmol/g protein)	0.140~0.180		
铝残留量(μg/L) Residual aluminum content(μg/L)	≤200		
PKA(IU/ml)	≤35		
HBsAg	阴性 Negative		
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	豚鼠健存, 且无异常反应, 体重增加 Guinea pigs remain healthy and survive, increase of body weight	
	小鼠试验 Mice	小鼠健存, 且无异常反应, 体重增加 Mice remain healthy and survive, increase of body weight	
热原检查 Pyrogen Test	应符合规定 Conform to specification	应符合规定 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	陆梓好	报告日期 Date	2018.06.05
复核人 Checked by	罗 磊	质量检定部负责人 QC Dept. Head	孙 磊