

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-0123-2018107

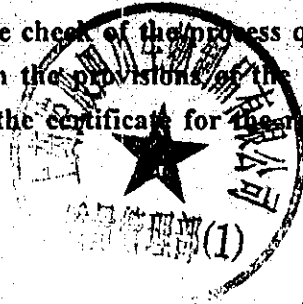
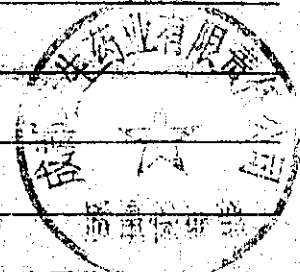
产品名称/Name of the Product:	人血白蛋白
商品名/Trade Name of the Product:	/
产品批号/Lot No.:	201805A063
剂型/Dosage Form:	注射剂
规格/Specification:	20% 50ml 10g/瓶
生产日期/Manufacturing Date:	2018年5月29日
有效期至/Valid Until:	2023年5月28日
批量/出口量/Lot Quantity/Export Quantity:	14135 瓶

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9月3日/3rd Sep. 2018



生物制品批签发证明

Certificate for the Release of Biological Products

批签蜀检201800526

LRE201800526

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技园南路7号		
收检编号 Regis. No	E201800899	批号 Lot No.	201805A063
剂型 Dosage Form	注射剂	规格 Strength	20% 50ml 10g/瓶
有效期至 Expiry Date	2023年5月23日	签发量 Quantity	14135瓶

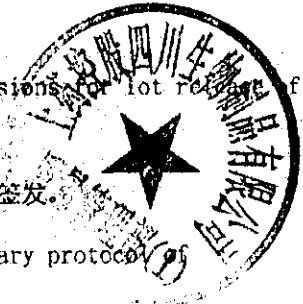
经审查，上述制品符合生物制品批签发的有关规定，予以签发。

The product mentioned above complies with the relevant provisions of the State Drug Administration 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。

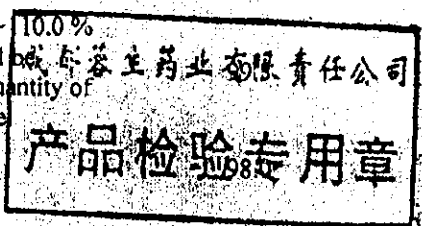
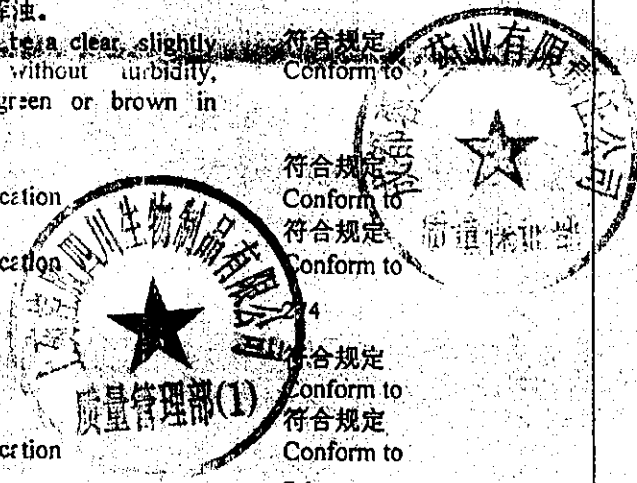
As a minimum, this certificate is based on review of the summary protocol of manufacturing and control.

签发人：[Signature]
Issued by:
批签发专用章
21 August 2018



产品检验报告
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.	201805A063	规格 Size	20% 50ml 10g/瓶 20% 50ml 10g/ bottle
生产日期 Manufacturing Date	29/05/2018	有效期至 Valid Until	28/05/2023
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.	AD2018063-080
检定项目 Test Items	标准规定 Specification	检定结果 Test Results	
鉴别试验 Identity Test	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	符合规定 Conform to	
外观 Physical Inspection	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.	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	210~400	符合规定 Conform to	
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	6.4~7.4	7.1	
蛋白质含量 Protein content	应为标示量的 95.0%~10.0% The protein content shall be 95.0%~10.0% of the quantity of protein stated on the label	符合规定 Conform to	
纯度 (%) Purity (%)	≥96.0	符合规定 Conform to	
钠离子含量(mmol/L) Sodium Content(mmol/L)	≤160	126	
钾离子含量(mmol/L) Potassium Content(mmol/L)	≤2	0	



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.	201805A063	规格 Size	20% 50ml 10g/瓶 20% 50ml 10g/ bottle
生产日期 Manufacturing Date	29/05/2018	有效期至 Valid Until	28/05/2023
检定依据 Testing According to	人血白蛋白产品质量标准 QA-Q8.2.4-301 Human Albumin quality specification QA-Q8.2.4-001	报告编号 Report No.	AD2018063-080
检定项目 Test Items	标准规定 Specification	检定结果 Test Results	
吸光度 Absorbance	≤0.15	0.04	
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(ug/L)	≤200		
PKA(IU/ml)	≤35	<10	
HBsAg	阴性 Negative	阴性 Negative	
无菌检查 Sterility Test	应无微生物生长 No microbial growth	应无微生物生长 No microbial growth	
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	
热原检查 Pyrogen Test	应符合规定 Conform to specification	应符合规定 Conform to specification	
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	陆婷婷	报告日期 Date	2018.07.05
复核人 Checked by	吴高	质量检定部负责人 QC Dept. Head	孙勇

