



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-0123-2017114

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.: 201706A064

剂型/Dosage Form: 注射剂

规格/Specification: 20% 50ml 10g/瓶

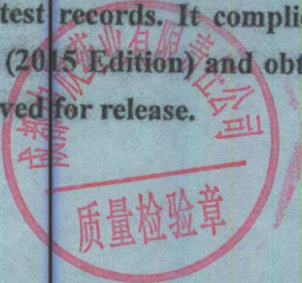
生产日期/Manufacturing Date: 2017年6月1日

有效期至/Valid Until: 2022年5月31日

批量/出口量/Lot Quantity/Export Quantity: 14100 瓶

经生产过程质量控制和制造及检定记录审查, 本批产品符合《中国药典》2015年
版相关规定, 并取得批签发合格证明, 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 certification for the release of biological
products, approved for release.



质量受权人/Qualified Person :
(official seal 公章)



2017年8月28日/28th Aug. 2017

生物制品批签发合格证

Certificate for the Release of Biological Products

批签蜀检201700538

LRE201700538

制品名称 Name of the Product	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. Code	E201700861	批号 Lot No.	201706A064
剂型 Dosage Form	注射剂	规格 Strength	20% 50ml 10g/瓶
有效期至 Valid until	2022年5月31日	批量/进口量 Quantity	14100瓶

经审查，上述制品符合生物制品批签发的有关规定，判定合格。

The product mentioned above complies with the provisions for the release of biological products and has been approved for release.

本证明系基于对企业申报的制品批制造及检验记录摘要的审查和实验室检定(蛋白质含量, 激肽释放酶原激活剂含量, 无菌检查, 热原检查)而签发。

This certificate is based on examination of summary manufacturing protocol and laboratory test (Protein content, PKA, Sterility, Pyrogen).

质量检验章

签发人:

Issued

二〇一七年八月二十五日

25 August

批签发专用章
(川)

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.	201706A064	规格 Size	20% 50ml 10g/瓶 20% 50ml 10g/ bottle
生产日期 Manufacturing Date	01/06/2017	有效期至 Valid Until	31/05/2022
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.	AD2017064-083
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 Immunelectrophoresis	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 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	255
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	6.8
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	98.9%
纯度 (%) Purity (%)		≥96.0	97.9
钠离子含量(mmol/L) Sodium Content(mmol/L)		≤160	134
钾离子含量(mmol/L) Potassium Content(mmol/L)		≤2	0

