

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-0123-2019001

|                                      |                |
|--------------------------------------|----------------|
| 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.:                        | 201807A083     |
| 剂型/Dosage Form:                      | 注射剂            |
| 规格/Specification:                    | 20% 50ml 10g/瓶 |
| 生产日期/Manufacturing Date:             | 2018年7月14日     |
| 有效期至/Valid Until:                    | 2023年7月13日     |
| 批量/出口量/Lot Quantity/Export Quantity: | 14310 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1月3日/3<sup>rd</sup> Jan. 2019



生物制品批签发证明

Certificate for the Release of Biological Products

批签蜀检201800758

LRE201800758

|              |                    |          |                |
|--------------|--------------------|----------|----------------|
| 产品名称         | 人血白蛋白              |          |                |
| 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园南路7号 |          |                |
| Address      |                    |          |                |
| 收检编号         | E201801405         | 批号       | 201807A083     |
| Regis. No    |                    | Lot No.  |                |
| 剂型           | 注射剂                | 规格       | 20% 50ml 10g/瓶 |
| Dosage Form  |                    | Strength |                |
| 有效期至         | 2023年7月13日         | 签发量      | 14310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 :

二〇一八年十二月二十日

20 December 2018



## 产品检定报告

Certificate of Analysis for Finished products

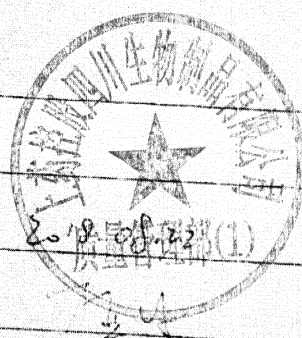
|                              |                                                                                   |                     |                                        |
|------------------------------|-----------------------------------------------------------------------------------|---------------------|----------------------------------------|
| 品 名<br>Product Name          | 人血白蛋白<br>Human Albumin                                                            | 剂 型<br>Dosage Form  | 注射剂<br>Injection                       |
| 产品批号<br>Batch No.            | 201807A083                                                                        | 规 格<br>Size         | 20% 50ml 10g/瓶<br>20% 50ml 10g/ bottle |
| 生产日期<br>Manufacturing Date   | 14/07/2018                                                                        | 有效期至<br>Valid Until | 13/07/2023                             |
| 检定依据<br>Testing According to | 人血白蛋白产品质量标准 QA-Q8.2.4-001<br>Human Albumin quality specification<br>QA-Q8.2.4-001 | 报告编号<br>Report No.  | AD2018083-100                          |

| 检定项目<br>Test Items                                            | 标准规定<br>Specification                                                                                        | 检定结果<br>Test Results             |
|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|----------------------------------|
| 吸光度<br>Absorbance                                             | ≤0.15                                                                                                        | 0.03                             |
| 多聚体含量(%)<br>Polymer content (%)                               | ≤5.0                                                                                                         | 2.6                              |
| 辛酸钠含量(mmol/g 蛋白质)<br>Sodium caprylate content(mmol/g protein) | 0.140~0.180                                                                                                  | 0.158                            |
| 铝残留量(μg/L)<br>Residual aluminum content(μg/L)                 | ≤200                                                                                                         | 19                               |
| PKA(IU/ml)                                                    | ≤35                                                                                                          | <10                              |
| HBsAg                                                         | 阴性<br>Negative                                                                                               | 阴性<br>Negative                   |
| 无菌检查<br>Sterility Test                                        | 应无菌生长<br>No microbial growth                                                                                 | 符合规定<br>Conform to specification |
| 异常毒性检查<br>Test For Abnormal Toxicity                          | 豚鼠试验<br>Guinea pigs<br>豚鼠健存, 且无异常反应, 体重增加<br>Guinea pigs remain healthy and survive, increase of body weight | 符合规定<br>Conform to specification |
|                                                               | 小鼠试验<br>Mice<br>小鼠健存, 且无异常反应, 体重增加<br>Mice remain healthy and survive, increase of body weight               | 符合规定<br>Conform to specification |
| 热原检查<br>Pyrogen Test                                          | 应符合规定<br>Conform to specification                                                                            | 符合规定<br>Conform to specification |
| HIV-1/HIV-2 抗体<br>HIV-1/ HIV-2 antibody test                  | 阴性<br>Negative                                                                                               | 阴性<br>Negative                   |
| HCV 抗体<br>HCV antibody test                                   | 阴性<br>Negative                                                                                               | 阴性<br>Negative                   |
| (以下空白) blank below                                            |                                                                                                              |                                  |

|                           |                                     |                           |            |
|---------------------------|-------------------------------------|---------------------------|------------|
| 检定结论:<br>Test Conclusion: | 合 格<br>Conform to the specification |                           |            |
| 报 告 人<br>Reported by      | 文晓民                                 | 报 告 日 期<br>Date           | 2018-08-22 |
| 复 核 人<br>Checked by       | 文晓民                                 | 质量检定部负责人<br>QC Dept. Head | (1)        |





## 产品检定报告

Certificate of Analysis for Finished products

| 品名<br>Product Name                                   | 人血白蛋白<br>Human Albumin                                                            | 剂型<br>Dosage Form                                                                                                                                                                                                                                                                                                                                                                                                                       | 注射剂<br>Injection                       |
|------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| 产品批号<br>Batch No.                                    | 201807A083                                                                        | 规格<br>Size                                                                                                                                                                                                                                                                                                                                                                                                                              | 20% 50ml 10g/瓶<br>20% 50ml 10g/ bottle |
| 生产日期<br>Manufacturing Date                           | 14/07/2018                                                                        | 有效期至<br>Valid Until                                                                                                                                                                                                                                                                                                                                                                                                                     | 13/07/2023                             |
| 检定依据<br>Testing According to                         | 人血白蛋白产品质量标准 QA-Q8.2.4-001<br>Human Albumin quality specification<br>QA-Q8.2.4-001 | 报告编号<br>Report No.                                                                                                                                                                                                                                                                                                                                                                                                                      | AD2018083-100                          |
| 检定项目<br>Test Items                                   | 标准规定<br>Specification                                                             | 检定结果<br>Test Results                                                                                                                                                                                                                                                                                                                                                                                                                    |                                        |
| 鉴别试验<br>Identity Test                                | 免疫双扩散法<br>Double Immunodiffusion<br>免疫电泳法<br>Immunoelectrophoresis                | 仅与抗人的血浆产生沉淀线<br>Only a precipitation line with anti-human plasma<br>主要沉淀线应为白蛋白<br>The main precipitation line shall be albumin as compared with normal human plasma<br>应为略黏稠、黄色或绿色至棕色澄明液体，不应出现浑浊。<br>The product shall be a clear, slightly viscous liquid without turbidity, slightly yellow, green or brown in colour.<br>应符合规定<br>Conform to specification<br>应符合规定<br>Conform to specification<br>应符合规定<br>Conform to specification |                                        |
| 外观<br>Physical Inspection                            |                                                                                   | 符合规定<br>Conform to                                                                                                                                                                                                                                                                                                                                                                                                                      |                                        |
| 可见异物<br>Test for Visible Particles                   |                                                                                   | 符合规定<br>Conform to                                                                                                                                                                                                                                                                                                                                                                                                                      |                                        |
| 不溶性微粒检查<br>Test for undissolvable particulate        |                                                                                   | 符合规定<br>Conform to                                                                                                                                                                                                                                                                                                                                                                                                                      |                                        |
| 渗透压摩尔浓度 (mOsmol/Kg)<br>Test for Osmole Concentration |                                                                                   | 210~400                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                        |
| 装量(ml)<br>Filling Quantity(ml)                       |                                                                                   | ≥50                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                        |
| 热稳定性试验<br>Thermostability Test                       |                                                                                   | 应符合规定<br>Conform to specification                                                                                                                                                                                                                                                                                                                                                                                                       |                                        |
| pH                                                   |                                                                                   | 6.4~7.4                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                        |
| 蛋白质含量<br>Protein content                             |                                                                                   | 应为标示量的 95.0 %~110.0 %<br>The protein content shall be 95.0%~110.0% of the quantity of protein stated on the label                                                                                                                                                                                                                                                                                                                       |                                        |
| 纯度 (%)<br>Purity (%)                                 |                                                                                   | ≥96.0                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                        |
| 钠离子含量(mmol/L)<br>Sodium Content(mmol/L)              |                                                                                   | ≤160                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                        |
| 钾离子含量(mmol/L)<br>Potassium Content(mmol/L)           |                                                                                   | ≤2                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                        |

所属文档编号: QA-S8.2.4-007, 所属文档名称: 产品签发及放行管理工作程序, 文档名称: 产品检定报告, 文档编号: QA-S8.2.4-007-F007 版本号: A \ 1 起草人: 刘鑫 生效日期: 2015-12-2 10:48:15 当前用户: 倪静 下载时间: 2015-12-02 14:18:23 第1页共2页