成都蓉生药业有限责任公司
ChengduRongsheng 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-0123-2017032

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.：201612A108

剂型/Dosage Form：注射剂

规格/Specification：20% 50ml 10g/瓶

生产日期/ Manufacturing Date：2016年12月1日

有效期至/Valid Until：2021年11月30日

批量/出口量/Lot Quantity/Export Quantity：14479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3月17日/17th Mar. 2017

# 生物制品批签发合格证

## Certificate for the Release of Biological Products

批签蜀检201700163

LRE201700163

| | | | |
|---|---|---|---|
| 制品名称<br>Name of the Product | 人血白蛋白 | | |
| 生产企业<br>Manufacturer | 成都蓉生药业有限责任公司 | | |
| 地　　址<br>Address | 四川省成都市高新区起步园科园南路7号 | | |
| 收检编号<br>Regis. Code | E201700106 | 批　号<br>Lot No. | 201612A108 |
| 剂　　型<br>Dosage Form | 注射剂 | 规　格<br>Strength | 20% 50ml 10g/瓶 |
| 有效期至<br>Valid until | 2021年11月30日 | 批量/进口量<br>Quantity | 14479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 previsions 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).

签发人：

Issued by :

二〇一七年三月四日

14 March 2017

(川)

成都蓉生药业有限责任公司

# 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. | 201612A108 | 规　格<br>Size | 20% 50ml 10g/瓶<br>20% 50ml 10g/ bottle |
| 生产日期<br>Manufacturing Date | 01/12/2016 | 有效期至<br>Valid Until | 30/11/2021 |
| 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 QA-Q8.2.4-001 | 报告编号<br>Report No. | AD2017108-006 |

| 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 | 仅与抗人的血浆产生沉淀线<br>Only a precipitation line with anti-human plasma | 符合规定<br>Conform to |
| | 免疫电泳法<br>Immunoelectrophoresis | 主要沉淀线应为白蛋白<br>The main precipitation line shall be albumin as compared with normal human plasma | 符合规定<br>Conform to |
| 外观<br>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。<br>The product shall be a clear, slightly viscous liquid without turbidity, slightly yellow, green or brown in colour. | 符合规定<br>Conform to |
| 可见异物<br>Test for Visible Particles | | 应符合规定<br>Conform to specification | 符合规定<br>Conform to |
| 不溶性微粒检查<br>Test for undissolvable particulate | | 应符合规定<br>Conform to specification | 符合规定<br>Conform to |
| 渗透压摩尔浓度（mOsmol/Kg）<br>Test for Osmole Concentration | | 210～400 | 277 |
| 装量(ml)<br>Filling Quantity(ml) | | ≥50 | 符合规定<br>Conform to |
| 热稳定性试验<br>Thermostability Test | | 应符合规定<br>Conform to specification | 符合规定<br>Conform to |
| pH | | 6.4～7.4 | 6.8 |
| 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 | 98.6% |
| 纯度（%）<br>Purity（%） | | ≥96.0 | 98.0 |
| 钠离子含量(mmol/L)<br>Sodium Content(mmol/L) | | ≤160 | 138 |
| 钾离子含量(mmol/L)<br>Potassium Content(mmol/L) | | ≤2 | 0 |

成都蓉生药业有限责任公司 产品检验专用章

成都中欣药业有限责任公司 质量检验章

成都蓉生药业有限责任公司 质量保证部

成都蓉生药业有限责任公司

# 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. | 201612A108 | 规　格<br>Size | 20% 50ml 10g/瓶<br>20% 50ml 10g/ bottle |
| 生产日期<br>Manufacturing Date | 01/12/2016 | 有效期至<br>Valid Until | 30/11/2021 |
| 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 QA-Q8.2.4-001 | 报告编号<br>Report No. | AD2017108-006 |

| 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 | 2.7 |
| 辛酸钠含量(mmol/g 蛋白质)<br>Sodium caprylate content(mmol/g protein) | | 0.140～0.180 | 0.152 |
| 铝残留量(μg/L)<br>Residual aluminum content(ug/L) | | ≤200 | 41 |
| 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 | 无菌生长<br>No microbial growth |
| 异常毒性检查<br>Test For Abnormal Toxicity | 豚鼠试验<br>Guinea pigs | 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 |
| | 小鼠试验<br>Mice | 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 |
| 热原检查<br>Pyrogen Test | | 应符合规定<br>Conform to specification | 符合规定<br>Conform to |
| 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 | 刘晓民 | 报　告　日　期<br>Date | 2017.01.10 |
| 复　核　人<br>Checked by | 王一苏 | 质量检定部负责人<br>QC Dept. Head | 丁玉林 |