成都簽生药业有限责任公司 Chengdu Rongsheng Pharmaceutical Co., Ltd. 中国四川省成都市高新区起步园科园南路 7 号 No.7 Keyuan South Road, Hi-tech Zone, Chengdu, Sichuan, P.R.C.

证书编号/Certificate No.: RS-0212-2018075

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# 产品签发合格证

## Certificate for the Release of Products

静注人免疫球蛋白(pH4) 产品名称/Name of the Product: 商品名/Trade Name of the Product: 蓉生静丙 201808B061 产品批号/Lot No.: 注射剂 型/Dosage Form: 剂 5% 50ml 2.5g/瓶 格/ Specification: 规 2018年8月10日 生产日期/ Manufacturing Date 2021年8月9日 有效期至/Valid Until 批量/出口量/Lo Quantity/Export Quantity: 18159 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,准子放行。

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)

余間

2018年12月24日 /24th Dec. 2018

批签蜀检201800741 LRE201800741 A III **静**注人免疫球蛋白(pH4 产品名称 Generic Name 支都零生药业有限责任公司 生产企业 Manufacturer 四川省成都市高新区起排饲科园南路7号 Address 批号 201808B061 201801379 敢检编号 Lot No Regis, No. 想格 5% 50ml 2.5g/瓶 射剂 Strength Dosage Form 18159瓶 021年8月9日 有效期至 Quantity Expiry Date

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.

于对企业中特值等帮推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.

答发人:

Issued by:

二〇一八年十二月十二日

12 December 2018

### 产品检定报告

#### Certificate of Analysis for Finished products

| Education of the content of the cont | 静注人免疫球蛋白(                        | and the second second second second  | ysis for Finished  | 沟道   | 注射剂                                     |
|--|----------------------------------|--|--|--|---|
| 品 名<br>Product Name  | Human Immunogle                  | bulin(pl   | 1)for Intravenous  | Dosage<br>Form   | Injection                               |
| r. file life file  | Injection<br>201808B061          | or Agreement one of the Control of t |  | 舰 格<br>Size  | 5% 50ml 2.5g/拍<br>5% 50ml 2.5g / bottle |
| Batch No.  | 10/ <b>0</b> 8/2018              | engersych Activities medical gester is der Affektionen i   | and a real of the state and confirmation and the state of | 有效期至<br>Valid Until  | 09/08/2021                              |
| Manufacturing Date<br>检定依据   | 静准人免疫球蛋白<br>QA-Q8.2.4-003        | distilled  | [4] for Intravenous  | 报告编号<br>Report No.   | BD2018061-072                           |
| Testing According to   | Injection quality spo<br>之项目     | ecification  | ₩指规定   | S  | 检定结果<br>Test Results                    |
|  | st Items                         | AND THE RESIDENCE OF THE PARTY  | Specification  | And the second s | 48.9                                    |
| 亢-HBs 效价(IU/g 当<br>Anti-HBs Potency(IU<br>白喉抗体效价(IIAL/<br>Diabtheria Antibody  | /g of protein)                   | ≥6.0<br>n) ≥3.0  |  |  | 7.8                                     |
| PKA(IU/ml)   |                                  | ≤35  |  |  | 未检出                                     |
| 抗补体活性(%)<br>Anticomplement Act   | (vity(%)                         | ≤50  |  |  | 30                                      |
| 抗 A 血凝素<br>Anti-A Hemagglutin  |                                  | 51:4   | 4  |  | 1:8                                     |
| 抗B 血凝素<br>Anti-B Hemaggletin   | atins                            | 51:b   | 4<br>[衛生长 中 -  |  | 1:16<br>无菌化校                            |
| 无谐检查<br>Sterility Test   | <b>豚鼠试验</b>                      | No I<br>IR lik<br>Guir   | microbial growth<br>健存,且无异常反<br>lea pigs remain heal   | 应,体重增加<br>thy and surviv   | No microbial growth.  符合规定  Conform to  |
| 异常毒性检查<br>Test For Abnorma<br>Toxicity   | Guinea pigs<br>I<br>小鼠试验<br>Mice | 小水   | ease of body weight<br>健存。且无异常反<br>e remain<br>ive increase of body  | healthy a  | Conform to                              |
| 热原检查<br>Pyrogen Test   |                                  | M. K<br>Con  | f合规定<br>form to specification  |  | 符合规定<br>Conform to<br>图性                |
| HIV-1/HIV-2 抗体<br>HIV-1/HIV-2 antibo   | ody test                         |  | E<br>gative E = 1  |  | Negative<br>別代                          |
| HCV 抗体<br>HCV antibody test  |                                  | No.  | ntive  |  | Negative                                |
| (以下空的)Flan   | ik helding                       |  | en van de de mei en en soon de men van de soon van en en en en de van de van de van de van de van de van de va   | enterministra (ar.) Santaniano enterministra (arterior) (ar. en enterministra (ar.) (ar. enterministra (ar.) (a  |   |
| A STATE OF THE STA |                                  |  | 格<br>the specification   |  | 7                                       |
| Test Conclusion: 报告人   | ्या भीट                          | onform to<br>区   | 机 背 Da   |  | 2018.09.19                              |
| Reported by 复核人  | VG 3                             | A comment of the comm |  | 部负责人<br>nt. Head   | 7211                                    |

所屬文档编号: QA-88. 2. 4-007,所属文档名称: 产品签发及放行管理工作程序, 又档名称: 产品检定报告 文档编号: QA-88. 2. 4-007-F007 版本号: A \ 1 起草人: 刘鑫 生效日期: 2015-12-2 10:48:15 当前用户名。倪静 下载时间: 2015 12-02 14:18:21 「雙 2 页\共 2 页]

#### 产品检定报告

#### Certificate of Analysis for Finished products

| Duadust Nome  | 静注人免疫球蛋白<br>Humar Immunog<br>Injection  | (pH4)<br>lobulin(pH4) or Intravenous   | 剂 型<br>Dosage Form   | 注射剂<br>Injection                        |
|---|---|--|----------------------|---|
| Coll Hib Co.  | 20180 <b>\$</b> B061                    |  | 规 修<br>Size          | 5% 50ml 2.5g/瓶<br>5% 50ml 2.5g / bottle |
| 但产日则<br>Manufacturing Date  | 10/08/2018                              |  | 有效期至<br>Valid Until  | 09/08/2021                              |
| 检定依据<br>Testine According to  | QA-Q <b>8</b> .2.4-003<br>Human Immunog | I(pH4)で品がは特別組<br>Jobulin(pH4) for Intraverous<br>ectification QA-Q8.2.4-003                                  | 报告编号<br>Report No.   | BD2018061-072                           |
| Ingection quarry spe<br>  検定項目<br>  Test Items                            |   | 物質を配置<br>  Specification   |                      | 检定结果<br>Test Results                    |
| 免投双扩散法<br>Double Immunodiffusion  |   | 以与抗人的主教产生的迷线<br>Only a precipitation line with anti-human<br>plasma  |                      | 符合规定<br>Conform to                      |
| 整射试验<br>Identity 免疫电泳法<br>Immunoelectrophoresis                           |   | 主要流旋或应为 IgG The main precipitation line shall be IgG as compared with normal human plasma 应为无色戈淡黄色沧明液体,可带轻微乳 |                      | 符合规定<br>Conform to                      |
| 外观<br>Physical Inspection   |   | 並列集色 Xik 集色が 可収<br>光、本屋出現洋海。<br>Clear colo irless or light<br>slightly opalescence may of<br>turbidity       | 符合规定<br>Conform to   |   |
| 可见异物  |   | 规律管理 盖   | 一符合规范》 "一个人"         |   |
| Test for Visible Particles 不溶性微粒检查  |   | Conform to specification   | Conform to ?<br>符合规定 |   |
| Test for undissolvable particulate  |   | Conform to specification   | Conform to           |   |
| 渗透压摩尔浓度(mOsmot/Ag)。   |   | 2240   | 339                  |   |
| Test for Osmole Concentration<br>装量(ml)<br>Filling Quantity(ml)<br>热稳定性试验 |   | ≥50<br>飛符套規定   |                      | 符合规定<br>Conform to<br>符合规定              |
| Thermostability Test  |   | Conform to specification   |                      | Conform to                              |
| pH  |   | 3 8~ 4.4   |                      | 4.3                                     |
| 蛋白质含量 (g/L) Protein content (g/L)   |   | ≥50.0  |                      | 5.51.1 <sub>2.22.22</sub>               |
| 蛋白质总量(g/瓶)<br>Total Protein(g/bottle)                                     |   | ≥2.5   |                      | 2.6                                     |
| 純度 %  |   | >95.0  |                      | 09.1                                    |
| Purity %<br>糖含量(g/L)<br>Sugar Content(g/L)                                |   | 支援部分设为 90~ (10)<br>Malfore content shall be 90   | 100                  |   |
| 分子大小分布 %<br>Distribution of molecular size %                              |   | IgG 作体。工業体介質295<br>IgG inonomer fidamer cor  | 99.0                 |   |