



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

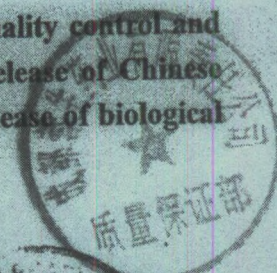
Certificate for the Release of Products

证书编号/Certificate No.: RS-0212-2017051

产品名称/Name of the Product: 静注人免疫球蛋白 (pH4)
 商品名/Trade Name of the Product: 蓉生静丙
 产品批号/Lot No.: 201703B018
 剂 型/Dosage Form: 注射剂
 规 格/Specification: 5% 50ml 2.5g/瓶
 生产日期/Manufacturing Date: 2017年3月15日
 有效期至/Valid Until: 2020年3月14日
 批量/出口量/Lot Quantity/Export Quantity: 18952 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5月18日 / 18th May. 2017

生物制品批签发合格证

Certificate for the Release of Biological Products

批签蜀检201700312

LRE201700312

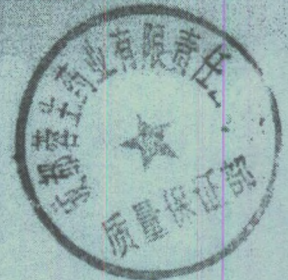
| | | | |
|---------------------|---------------------|----------|----------------|
| 制品名称 | 静注人免疫球蛋白 (pH4) | | |
| Name of the Product | | | |
| 生产企业 | 成都蓉生药业有限责任公司 | | |
| Manufacturer | | | |
| 地址 | 四川省成都市高新区起步园科技园南路7号 | | |
| Address | | | |
| 收检编号 | E201700388 | 批号 | 201703B018 |
| Regis. Code | | Lot No. | |
| 剂型 | 注射剂 | 规格 | 5% 50ml 2.5g/瓶 |
| Dosage Form | | Strength | |
| 有效期至 | 2020年3月14日 | 批量/进口量 | 18952瓶 |
| Valid until | | Quantity | |

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, 无菌检查, 异常毒性检查, 热原检查)而签发。

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

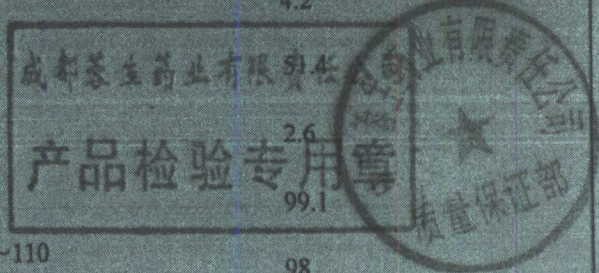
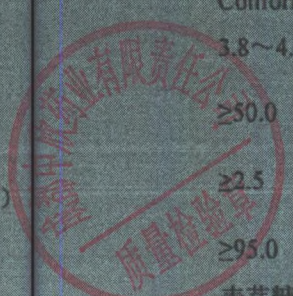




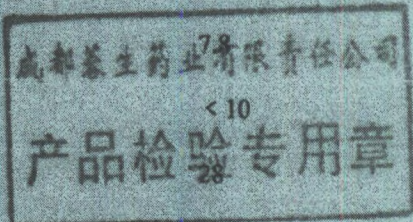
产品检定报告

Certificate of Analysis for Finished products

| | | | |
|--|--|---|--|
| 品名 Product Name | 静注人免疫球蛋白(pH4) Human Immunoglobulin(pH4)for Intravenous Injection | 剂型 Dosage Form | 注射剂 Injection |
| 产品批号 Batch No. | 201703B018 | 规格 Size | 5% 50ml 2.5g/瓶 5% 50ml 2.5g / bottle |
| 生产日期 Manufacturing Date | 15/03/2017 | 有效期至 Valid Until | 14/03/2020 |
| 检定依据 Testing According to | 静注人免疫球蛋白(pH4)产品质量标准 QA-Q8.2.4-003 Human Immunoglobulin(pH4)for Intravenous Injection quality specification QA-Q8.2.4-003 | 报告编号 Report No. | BD2017018-030 |
| 检定项目 Test Items | 标准规定 Specification | 检定结果 Test Results | |
| 鉴别试验 Identity | 免疫双扩散法 Double Immunodiffusion 免疫电泳法 Immunoelectrophoresis | 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IgG The main precipitation line shall be IgG as compared with normal human plasma | 符合规定 Conform to 符合规定 Conform to |
| 外观 Physical Inspection | | 应无色或淡黄色澄明液体,可带轻微乳光,不应出现浑浊。 Clear, colourless or light yellow liquid, slightly opalescence may occur but without turbidity | 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 | | ≥240 | 321 |
| 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 | | 3.8~4.4 | 4.2 |
| 蛋白质含量 (g/L) Protein content (g/L) | | ≥50.0 | 26 |
| 蛋白质总量 (g/瓶) Total Protein (g/bottle) | | ≥2.5 | 2.6 |
| 纯度 % Purity % | | ≥95.0 | 99.1 |
| 糖含量(g/L) Sugar Content(g/L) | | 麦芽糖含量为 90~110 Maltose content shall be 90~110 | 98 |
| 分子大小分布 % Distribution of molecular size % | | IgG 单体+二聚体含量≥95.0 IgG monomer+dimmer content ≥95.0 | 99.1 |



产品检定报告
Certificate of Analysis for Finished products

| | | | |
|--|--|---|--|
| 品名 Product Name | 静注人免疫球蛋白(pH4) Human Immunoglobulin(pH4)for Intravenous Injection | 剂型 Dosage Form | 注射剂 Injection |
| 产品批号 Batch No. | 201703B018 | 规格 Size | 5% 50ml 2.5g/瓶 5% 50ml 2.5g / bottle |
| 生产日期 Manufacturing Date | 15/03/2017 | 有效期至 Valid Until | 14/03/2020 |
| 检定依据 Testing According to | 静注人免疫球蛋白(pH4)产品质量标准 QA-Q8.2.4-003 Human Immunoglobulin(pH4)for Intravenous Injection quality specification QA-Q8.2.4-003 | 报告编号 Report No. | BD2017018-030 |
| 检定项目 Test Items | 标准规定 Specification | 检定结果 Test Results | |
| 抗-HBs 效价(IU/g 蛋白质) Anti-HBs Potency(IU/g of protein) | ≥6.0 | 76.3 | |
| 白喉抗体效价(HAU/g 蛋白质) Diphtheria Antibody titer(HAU/g of protein) | ≥3.0 |  | |
| PKA (IU/ml) | ≤35 | | |
| 抗补体活性 (%) Anticomplement Activity(%) | ≤50 | | |
| 抗A 血凝素 Anti-A Hemagglutinins | ≤1:64 | 1:8 | |
| 抗B 血凝素 Anti-B Hemagglutinins | ≤1:64 | 1:8 | |
| 无菌检查 Sterility Test | 应无菌生长 No microbial growth | 无菌生长 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 | 符合规定 Conform to 符合规定 Conform to |
| 热原检查 Pyrogen Test | 应符合规定 Conform to specification | 符合规定 Conform to | |
| 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 | |
| (以下空白) blank below | | | |
| 检定结论: Test Conclusion: | 合格 Conform to the specification | | |
| 报告人 Reported by | 刘晓民 | 报告日期 Date | 2017.04.14 |
| 复核人 Checked by | 谭红燕 | 质量检定部负责人 QC Dept. Head | 2017.04.14 [Signature] |