



产品检验报告  
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.	201802A022	规格 Size	20% 50ml 10g/瓶 20% 50ml 10g/ bottle
生产日期 Manufacturing Date	22/02/2018	有效期至 Valid Until	21/02/2023
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.	AD2018022-039
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	仅与抗人的血浆产生沉淀线 Only a precipitation line with anti-human plasma 符合规定 Conform to	
	免疫电泳法 Immunoelectrophoresis	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	
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	254	
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	7.1	
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	98.6	
纯度 (%) Purity (%)	≥96.0	98.0	
钠离子含量(mmol/L) Sodium Content(mmol/L)	≤160	124	
钾离子含量(mmol/L) Potassium Content(mmol/L)	≤2	0	

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产品检验专用章

