

产品检定报告

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.	201906A091	规格 Strength	20% 50ml 10g/瓶 20% 50ml 10g/ bottle
生产日期 Manufacturing Date	26/06/2019	有效期至 Valid until	25/06/2024
检定依据 Test According to	人血白蛋白内控质量标准 QA-Q8.2.4-007 Human Albumin internally controlled quality specification QA-Q8.2.4-007	报告编号 Report No.	AD2019091-101

检定项目 Test Item	标准规定 Specification	检定结果 Test Result
鉴别试验 Identity Test	免疫双扩散法 Double Immunodiffusion 免疫电泳法 Immunoelectrophoresis	符合规定 Conform to
外观 Physical Inspection	仅与抗人血清或血浆产生沉淀线，与抗马、抗牛、抗猪、抗羊血清或血浆不产生沉淀线。 Only a precipitation line with anti-human serum or plasma, but no precipitation line with anti-horse, anti-bovine, anti-pig or anti-sheep serum or plasma. 与正常人血清或血浆比较，主要沉淀线应为白蛋白 The main precipitation line shall be albumin as compared with normal human plasma 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	270
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	98.8
纯度 (%) Purity (%)	≥97.0	97.4
钠离子含量(mmol/L) Sodium Content(mmol/L)	≤160	0
钾离子含量(mmol/L) Potassium Content(mmol/L)	≤2	0
吸光度 Absorbance	≤0.15	0.03