

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.	201903B023	规格 Strength	5% 50ml 2.5g/瓶 5% 50ml 2.5g / bottle
生产日期 Manufacturing Date	20/03/2019	有效期至 Valid until	19/03/2022
检定依据 Test According to	静注人免疫球蛋白(pH4)内控质量标准 QA-Q8.2.4-009 Human Immunoglobulin(pH4) for Intravenous Injection internally controlled quality specification QA-Q8.2.4-009	报告编号 Report No.	BD2019023-024
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	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 IgG The main precipitation line shall be IgG as compared with normal human plasma 应为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	
外观 Physical Inspection	应符合规定 Conform to specification	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	346	
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 值	3.8~4.4	4.3	
蛋白质含量 (g/L) Protein content (g/L)	≥50.0	51.2	
蛋白质总量 (g/瓶) Total Protein (g/bottle)	≥2.5	2.6	
纯度 % Purity %	≥96.0	99.2	
糖含量(g/L) Sugar Content(g/L)	麦芽糖含量为 90~110 Maltose content shall be 90~110	97	
分子大小分布 % Distribution of molecular Strength %	IgG 单体+二聚体含量≥97.0 IgG monomer+dimmer content ≥97.0	98.5	
抗-HBs 效价(IU/g 蛋白质) Anti-HBs Potency(IU/g of protein)	≥6.0	68.4	