

## 产品检定报告

Certificate of Analysis for Finished products

品名 Product Name	破伤风人免疫球蛋白 Human Tetanus Immunoglobulin	剂型 Dosage Form	注射剂 Injection
产品批号 Batch No.	201701F003	规格 Size	2.5ml 250IU/瓶 2.5ml 250IU/vial
生产日期 Manufacturing Date	23/01/2017	有效期至 Valid Until	22/01/2020
检定依据 Testing According to	破伤风人免疫球蛋白产品质量标准 QA-Q8.2.4-006 Human Tetanus Immunoglobulin quality specification QA-Q8.2.4-006	报告编号 Report No.	FD2017003-003
检定项目 Test Items	标准规定 Specification	检定结果 Test Results	
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	
鉴别试验 Identity	免疫电泳法 Immuno-electrophoresis 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	
外观 Physical Inspection	应为无色或淡黄色澄明液体，可带乳光，不应出现浑浊。 Clear, colourless or light yellow liquid. 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	
装量(ml) Filling Quantity(ml)	≥2.5	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	6.5	
蛋白质含量 (g/L) Protein content (g/L)	≤180	101	
纯度 % Purity %	≥90.0	97.5	
甘氨酸含量(g/L) Glycin Contents(g/L)	20~25	23	
分子大小分布 % Distribution of molecular size %	IgG 单体+二聚体含量≥90.0 IgG monomer+dimmer content ≥90.0	97.5	
破伤风抗体效价 (IU/ml) Tetanus Antibody Potency(IU/ml)	≥100	135	
破伤风抗体效价总量 (IU/瓶) Total Tetanus Antibody Potency(IU/vial)	≥250	338	
抗-HBs 效价(IU/g 蛋白质) Anti-HBs Potency(IU/g of protein)	≥1.0	76.7	

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产品检验专用章

