

JIANGSU ZHENGKANG MEDICAL APPARATUS CO., LTD.

CERTIFICATE OF ANALYSIS

Product: Syringe : 1ml, 3ml, 5ml, 10ml 20ml, 50ml Lot No.: 20201120
MFG. Date: 11.2020 EXP. Date: 11.2025
Inspection Basis: ISO7886-1:2017 Quantity: 3822200pcs

Inspection item	Technical demands	Testing result
Sterility	Sterility	Sterility
Pyrogenicity	Non-Pyrogenicity	Non-Pyrogenicity
Hemolysis	Hemolysis rate<5%	1.2%
Toxicity	Non-toxicity	Non-toxicity
Reducing matter	The total amount of potassium permanganate solution used [c(KmnO ₄)=0.002mol/l] shall not exceed 0.5ml	0.1ml
Metal ions	The intensity of the color produced in the test solution shall not be deeper than that of the standard matching solution.	Qualified
Titration acidity	No more than 1ml of either standard volumetric solution shall be required for the indicator to change to the color grey.	0.2ml
Subcutaneous stimulate	No partial subcutaneous stimulate reaction	Qualified
Color lustre	Clear and colorless	Qualified
Capacity test	1ml:±4% of expelled volume, 3ml:±4% of expelled volume, 5ml:±4% of expelled volume, 10ml:±4% of expelled volume 20ml:±4% of expelled volume 50ml:±4% of expelled volume	Qualified
Conclusion: Comply with the standard of ISO8536-1:2004		

Issuing Date: FEB.18 2021 Inspector: Li Haihong, Xiang Chunfang
Aihua

Verifier: Xie