

# JIANGSU ZHENGKANG MEDICAL APPARATUS CO., LTD.

## CERTIFICATE OF ANALYSIS

Product: Syringe : 1ml, 3ml, 5ml, 10ml 20ml, 50ml  
MFG. Date:10.2020  
Inspection Basis: ISO7886-1:2017

Lot No.: 201020  
EXP. Date:10.2025  
Quantity: 3480600pcs

| 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(KmnO4)=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,<br>3ml:±4% of expelled volume,<br>5ml:±4% of expelled volume,<br>10ml:±4% of expelled volume<br>20ml:±4% of expelled volume<br>50ml:±4% of expelled volume | Qualified        |
| Conclusion:<br>Comply with the standard of ISO8536-1:2004 |                                                                                                                                                                                        |                  |

Issuing Date: DEC.10 2020 Inspector: Li Haihong, Xiang Chunfang  
Aihua

Verifier: Xie