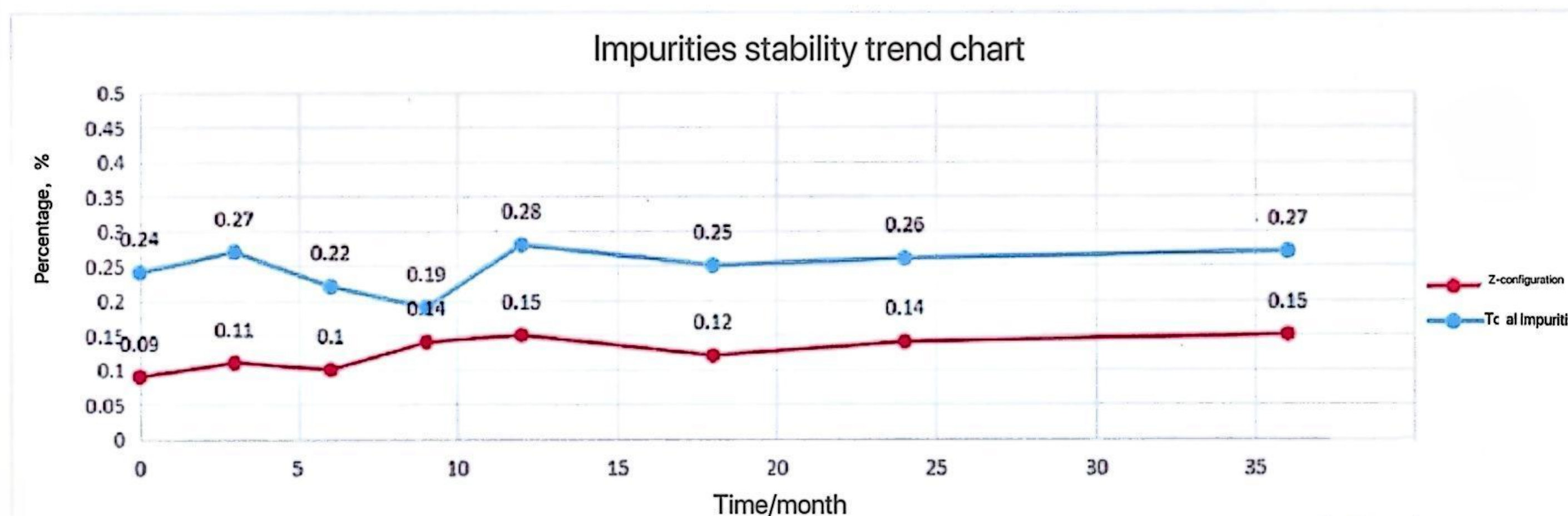
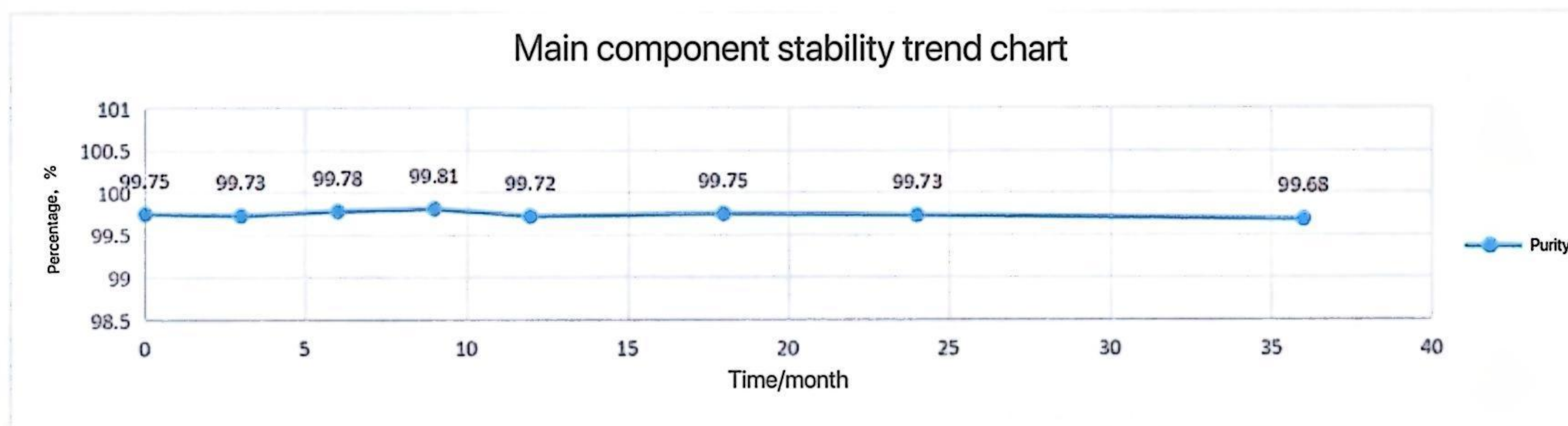


Stability Quality Analysis

Product: Trans-clomifene citrate ,CAS No.:7599-79-3



Batch number (202009001)

重庆星灿医药科技有限公司
质量部

| Test time (month) | Appearance | Purity | Z-configuration | Total impurities | Residue on ignition | Loss on drying | Heavy metal |
|----------------------|--------------------------|---------------------|--------------------|--------------------|------------------------|--------------------|---------------------|
| | Standard: White solid | Standard: ≥99.0% | Standard: ≤1.0% | Standard: ≤1.0% | Standard: ≤0.1% | Standard: ≤0.5% | Standard: ≤20ppm |
| 0 | White solid | 99.76% | 0.09% | 0.24% | 0.05% | 0.04% | <20ppm |
| 3 | White solid | 99.73% | 0.11% | 0.27% | 0.05% | 0.03% | <20ppm |
| 6 | White solid | 99.78% | 0.10% | 0.22% | 0.04% | 0.05% | <20ppm |
| 9 | White solid | 99.81% | 0.14% | 0.19% | 0.06% | 0.03% | <20ppm |
| 12 | White solid | 99.72% | 0.15% | 0.28% | 0.06% | 0.04% | <20ppm |
| 18 | White solid | 99.75% | 0.12% | 0.25% | 0.05% | 0.02% | <20ppm |
| 24 | White solid | 99.73% | 0.14% | 0.26% | 0.04% | 0.05% | <20ppm |
| 36 | White solid | 99.68% | 0.15% | 0.27% | 0.05% | 0.06% | <20ppm |
| Average value | _____ | 99.74% | 0.12% | 0.25% | 0.05% | 0.04% | _____ |
| Absolute deviation | _____ | 0.07% | 0.03% | 0.06% | 0.01% | 0.02% | _____ |

Conclusion: Based on the above chart data, it can be seen that our company's Enclomiphene has been tested for 36 months, including appearance, purity, Z-configuration chlormiphene content, total impurities, residue on ignition, drying weight loss, and weight loss
There is no significant change in the quality of the metal square, and the absolute deviation between the metal square and the periodic test results is within 0.07%, indicating that our company's Enclomiphene quality has been relatively stable for 36 months. Therefore, for the time being
The product retest period is 3 years.

Report by: 钟文彬

Report date: 2023.09.28



Reviewed by: 王瑞华

Reviewed date: 2023.09.28