**METAPHARMACEUTICAL**

N DE LOTE: 0300925

Alejandro 22/09/2023

# YANGZHOU LIBERTY PHARMACEUTICAL CO., LTD

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## CERTIFICATE OF ANALYSIS

WE , YANGZHOU LIBERTY PHARMACEUTICAL CO., LTD, , AS A MANUFACTURER OF OXYTETRACYCLINE HYDROCHLORIDE CERTIFY THAT THIS BATCH HAS BEEN MANUFACTURED BY US IN FULL COMPLIANCE WITH EU-GMP REQUIREMENTS AND GMP REQUIREMENTS OF THE LOCAL REGULATORY AUTHORITY.

REPORT NO.: 50042503016 SOPQC-FP002-19

| | | | |
|---|---|---|---|
| SAMPLE NAME | OXYTETRACYCLINE HYDROCHLORIDE | | |
| BATCH NO. | YT250302016 | TEST REQUEST UNIT | OXYTETRACYCLINE WORKSHOP |
| SPECIFICATION | PHARMACEUTICAL | MANUFACTURING DATE | 2025.02.28 |
| BATCH SIZE | 1000kg | REPORT DATE | 2025.03.06 |
| CEP NO. | R1-CEP 2010-080-Rev 03 | RETEST DATE | 2029.02.27 |

**I. ANALYTICAL METHOD:** EP11.6

**II. RESULTS OF ANALYTICAL ITEM:**

| ITEM | SPECIFICATION | RESULT |
|---|---|---|
| APPEARANCE: | YELLOW, HYGROSCOPIC, CRYSTALLINE POWDER. | COMPLIES |
| IDENTIFICATION: | B: EXAMINE THE CHROMATOGRAMS OBTAINED IN THE ASSAY | COMPLIES |
| | C: REACTION WITH SULFURIC ACID | COMPLIES |
| | D: REACTION OF CHLORIDES | COMPLIES |
| PH: | 2.3 TO 2.9 | 2.5 |
| LIGHT-ABSORBING IMPURITIES | | |
| (430nm): | NOT MORE THAN 0.50 | 0.12 |
| (490nm): | NOT MORE THAN 0.20 | 0.03 |
| RELATED SUBSTANCES: | | |
| IMPURITY A+G | NOT MORE THAN 0.5% | 0.27% |
| IMPURITY B | NOT MORE THAN 1.0% | 0.68% |
| IMPURITY C | NOT MORE THAN 2.0% | 1.59% |
| IMPURITY D | NOT MORE THAN 0.2% | <0.05% |
| IMPURITY E | NOT MORE THAN 0.2% | <0.05% |
| IMPURITY D+E+F | NOT MORE THAN 1.0% | 0.30% |
| ANY OTHER IMPURITY | NOT MORE THAN 0.1% | <0.05% |
| TOTAL OF IMPURITIES | NOT MORE THAN 3.5% | 2.84% |
| WATER: | NOT MORE THAN 2.0% | 1.3% |
| SULFATED ASH: | NOT MORE THAN 0.2% | 0.1% |
| RESIDUAL SOLVENT: | | |
| METHANOL: | NOT MORE THAN 3000 ppm | 757ppm |
| ASSAY (ANHYDROUS SUBSTANCE): CONTENT OF $C_{22}H_{25}ClN_2O_9$ | 94.5% TO 102.0% | 97.3% |

**III: RESULT AND CONCLUSION:** PASS

**APPROVED BY :** 2025.03.06 **DRAFTED BY :** 2025.03.06 **CHECKED BY :** 2025.03.06