

Certificate of Analysis

TETRACYCLINE HCI

Catalog # Size IB02200 25 gm

Signature: <u>K.McCarthy</u>

Date: 09/24/2014

Catalog Number: IB02200

<u>Lot Number</u>: 20100613

Molecular Formula: C₂₂H₂₄N₂O₈HCl

Molecular Weight: 480.90

Appearance: Yellow, crystalline powder

| Assay | <u>Min</u> | <u>Max</u> | Actual | <u>Units</u> | Disposition |
|------------------------------------|------------|-------------|---------------|--------------|--------------------|
| Identification | PASS | | PASS | P/F | PASS |
| Crystallinity | PASS | | PASS | P/F | PASS |
| pН | 1.8 | 2.8 | 2.5 | | PASS |
| Specific Rotation | -255 | -240 | -244 | 0 | PASS |
| Related Substances: | | | | | |
| 4-Epitetracycline | | 3.0 | 1.3 | % | PASS |
| Anhydrotetracycline | | 0.5 | 0.12 | % | PASS |
| 4-Epianhydrotetracycline | 0.5 | 0.03 | % | PASS | |
| 2-Acetyl-2-decarbamoyltetracycline | | 1.5 | 0.85 | % | PASS |
| Heavy Metals | | 50 | Conforms | ppm | PASS |
| Loss on Drying | | 2.0 | 0.45 | % | PASS |
| Sulphate Ash | | 0.5 | 0.06 | % | PASS |
| Assay (on dried basis) | 95.0 | 102.0 | 96.7 | % | PASS |
| Potency (on dried basis) | 900 | | 960 | mcg/mg | PASS |
| Bacterial Endotoxin | | 0.5 | < 0.5 | IU/mg | PASS |
| Retest Date | | | 01/2017 | | |

Residual Solvents Impurity Information – The following Class 1, 2, or 3 Solvents may be present in this product and are identified and quantified below. All comply with the limits prescribed in the current USP.

| Class | <u>Solvent</u> | Concentration Limit (ppm) |
|---------|----------------|----------------------------------|
| Class 3 | 1-Butanol | 5000 |
| Class 3 | Acetone | 5000 |

This signature indicates that the above material has met all quality specifications and has been reviewed by a quality representative.