# Gojira Fine Chemicals, LLC

**Quality Products & Services Meeting Customer Needs**

5386 Majestic Parkway, Suite 7, Bedford Heights, OH 44146

**www.gojirafc.com ● sales@gojirafc.com**


# Certificate of Analysis

## Gentamicin Sulfate USP/EP

**Catalog Number:** GS1006
**Lot Number:** 1012701
**CAS Number:** 1405-41-0
**Molecular Formula:** $C_{21}H_{43}N_5O_7$
**Molecular Weight:** 477.60
**Storage:** 2°C – 8°C
**Date of Manufacture:** July 25, 2017
**Retest Date:** July 24, 2021

| Test | Specification | Result |
|---|---|---|
| Appearance (EP) | White to off-white, hygroscopic powder. | Conforms |
| Potency (Dry Basis, USP) | ≥ 590μg/mg | 662μg/mg |
| Potency (Dry Basis, EP) | ≥ 590IU/mg | 674IU/mg |
| Identification A (FTIR, USP) | To match reference spectra | Conforms |
| Identification B (Sulfates, USP) | Reaction indicative of sulfates. | Conforms |
| First Identification (EP)<br>B Chromatography<br><br>C Sulfates | <br>5 principal peaks on the chromatogram match the reference solution.<br>Reaction indicative of sulfates. | <br>Conforms<br>Conforms |
| Second Identification (EP)<br>A TLC<br><br>C Sulfates | <br>3 principal spots on the chromatogram match the reference solution.<br>Reaction indicative of sulfates. | <br>Conforms<br><br>Conforms |
| Sulfate (EP) | 32.0 – 35% | 34.2% |
| Solubility (EP) | Freely soluble in water, practically insoluble in ethanol | Conforms |
| Appearance of Solution (EP) | Clear, color intensity ≤ 6 of the range of reference solutions. | Conforms |
| Specific Rotation (c=1,USP/EP) | +107.0 to +121.0° | +118.0° |
| pH (40mg/mL, USP/EP) | 3.5 – 5.5 | 4.5 |
| Composition:<br>C1a (USP)<br>C2+C2a (USP)<br>C2b+C1 (USP)<br>C1 (EP)<br>C1a (EP)<br>C2+C2a+C2b (EP) | <br>10 – 35%<br>25 – 53%<br>25 – 50%<br>25 – 45%<br>10 – 30%<br>35 – 55% | <br>22%<br>45%<br>33%<br>30.6%<br>21.6%<br>47.8% |
| Moisture (LOD, USP) | ≤ 18% | 6.4% |
| Moisture (LOD, EP) | ≤ 15% | 7.9% |

# Gojira Fine Chemicals, LLC

**Quality Products & Services Meeting Customer Needs**

5386 Majestic Parkway, Suite 7, Bedford Heights, OH 44146

**www.gojirafc.com ● sales@gojirafc.com**


| | | |
|---|---|---|
| Residue on Ignition (USP) | ≤ 1.0% | 0.2% |
| Sulfated Ash (EP) | ≤ 1.0% | 0.2% |
| Limit of Methanol (USP/EP) | ≤ 1.0% | Conforms* |
| Related Substances (EP)<br>Impurity A (Sisomicin)<br>Impurity B (Garamine)<br>Any other Impurity<br>Total impurities | <br>≤ 3.0%<br>≤ 3.0%<br>≤ 3.0%<br>≤ 10.0% | <br>Less than limit<br>Less than limit<br>0.9%<br>3.4% |
| Endotoxin (USP/EP) | ≤ 0.71IU/mg | < 0.06IU/mg |
| Total Microbial Count EP (Aerobic+Yeast+Mold) | ≤ 100cfu/g | 0 cfu/g |
| Particle Size | < 10 mm > 60%<br>< 20 mm > 75% | 76%<br>84% |
| This lot meets the specifications for USP40 and EP9.0. | | |

*Methanol is not used in production.

Approved by: Date: October 12, 2017


John Grubb, PhD
Gojira Fine Chemicals, LLC
Quality Manager
Tel: 440-539-7033 Fax: 888-211-5523
john@gojirafc.com