

Crystalgen, Inc.

CERTIFICATE OF STERILITY

Catalog No. 23-9898

Product Description: 100ml Bottle with Sodium Thiosulfate

Manufacturing Lot#: 1909109898

Material: Polystyrene

10/25/2019

Contact & Address Information:

Crystalgen, Inc. hereby certifies that all sterile and non-sterile products have been manufactured in accordance with established manufacturing guidelines and product specifications. The product conforms to all Quality requirements and is certified to be RNase, DNase, and endotoxin (pyrogen) safe. Crystalgen has a validated sterilization process and certifies the product to have a sterility assurance level of 10⁻⁶. When stored under the appropriate temperature and conditions, the unopened/undamaged sterilized products have a shelf life of up to **five years** from the sterile date.

The sterile date can be obtained from the sterile lot number. The sterile lot number shall be 10 digits.

ISO Certifications: Crystalgen products are manufactured to high standards and are certificated accordingly. Crystalgen complies with the guidelines of Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Annex III, Self-Declared. In addition, Crystalgen complies with ISO-11137-Part1, US-FDA CFR Title 21 177.1520/178.3295/178.3297/820, ISO 10993-3, USP-381 (Leachables), USP-3127 (Trace Heavy Metals (such as Lead, Fe, Ca, Ma)), There are absolutely no LATEX OR animal products or by-products used in any product, packaging, or process at Crystalgen. Clean Handling techniques are utilized in manufacturing of ALL Crystalgen Products.

Quality Control:

Fill line accuracy: 100 mL line is accurate to within +/- 2.0%

Sterility: gamma irradiation: No growth after 48 hrs incubation at 35C +/- 0.5C with sterile tryptic soy broth

Appearance: absence of nicks, scratches and cracks

Chlorine Neutralization: Sodium Thiosulfate content in tablet or liquid form, temperature range: -4°C to 35°C
Neutralize minimum 15mg/L of free chlorine in water samples

Fluorescence Test: negative

AUTHORIZED SIGNATURE: Eric Wu

TITLE: Director of Quality

DATE: 10/25/2019

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