

# Corning® Roller Bottles

Quality at a Glance

CORNING



- ▶ Virgin polystyrene bottles with virgin polyethylene caps
- ▶ One piece, seamless construction
- ▶ Manufactured under cGMP in an ISO 9001 certified facility
- ▶ Certified non-pyrogenic
- ▶ US Class I 510(k) exempt medical device
- ▶ USP Class VI certified material resin

## Physical Property Testing

- ▶ Leak testing
- ▶ Visuals and foreign materials, contaminants, particulates
- ▶ Cell culture treatment and wettability
- ▶ ISTA-1A tested packaging

## Biocompatibility

Roller bottle materials meet the requirements of USP Class VI Plastic. The final product has been tested to USP <88> conditions.

Corning maintains Certificates of Compliance and will make them available upon site visits.

## Pyrogen Testing

Roller bottles are tested for pyrogen levels to the criteria established in ANSI/AAMI ST 72: *Bacterial Endotoxins – Test Methodologies, routine monitoring, and alternative to batch testing*. Acceptance criteria: 0.1 EU/mL (4 EU/device).

## Extractable Data

All resins have been tested for extractables via USP <661>.

## Functionality Study Data

Roller bottles are tested for cell attachment and growth. Samples are subjected to typical cell culture conditions and compared to known standards.

Microscopic evaluations are performed and bottles must reach  $\geq 95\%$  confluence in all fields viewed.

Products are compatible with typical chemicals, pressure ranges, and pH levels associated with cell culture.

## Stability Data

Roller bottle materials have been tested and designated for a 3-year shelf life from the date of manufacture.

## Sterility Data

Roller bottle sterility is tested under method 1 of ANSI/AAMI/ISO 11137-2 *Sterilization of health care products – Radiation Part 2: Establishing the sterilization dose*. All samples tested have met the requirements set forth in the standard.

**Warranty/Disclaimer:** Unless otherwise specified, all products are for research use only. Not intended for use in diagnostic or therapeutic procedures. Not for use in humans. Corning Life Sciences makes no claims regarding the performance of these products for clinical or diagnostic applications.

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