465 Berry St
Brea, CA 92821
844.641.3814 Tel
844.641.3813 Fax

PRODUCT SPECIFICATION SHEET – AC & UA SERIES

FDA FACILITY REGISTRATION: MPS Pharma & Medical, Inc. # 3018125942

PRODUCT NAME: Sterile Dropper – Bottles, Tips, Caps

PRODUCT DESCRIPTION: Sterile, Non-Pyrogenic

ORIGIN: All final assembly, packaging, labeling activities, inspections, sterilization, and microbial release testing is performed in the USA.

MATERIAL SPECIFICATIONS:

Component	Material
Bottle	Low Density Polyethylene (LDPE)
Tip	Low Density Polyethylene (LDPE)
Cap	Polypropylene (PP)

**Due to the number of SKUs in the MPS catalog, detailed information (e.g. SDS sheets) have been omitted for this document as it is too numerous to list. More detailed material specification information can be provided upon an item specific request.

DROP SIZE: Drop size is dependent on several factors including the product being dispensed and the technique in which it is dispensed. The best advice for customers is to test the dropper tip with the compounded product to determine its suitability in its application.

A general water reference point can be provided to our customers as a starting guideline:

Size(s)	Drop Size
3 mL	42 ul +/- 5 uL
7, 10, 15, 30 mL	40 ul +/- 5 uL

BSE STATEMENT: No raw materials that contain, or are derived from, animals are specified in the manufacture of this product.

QUALITY CONTROL: Inspections are performed for each manufacturing batch to ensure all product specifications are satisfied.

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STERILIZATION VALIDATION SPECIFICATIONS: The products are sterilized to an SAL of 10^{-6} using ethylene oxide as the sterility method in compliance with applicable sections from:

- **ISO 11135** – *Sterilization of Healthcare Products – Ethylene Oxide*
- **ISO 10993-7** – *Ethylene Oxide Sterilization Residuals*

Sterility Assurance Level (SAL)	10^{-6} Using Biological Indicator Testing as acceptance Criterion	
Endotoxin Limits per USP 85 Requirements	≤ 0.5 IU/ml or 20 IU/device / Non-Pyrogenic	
EO Residual Limits per ISO 10993-7	EO <4 mg/device	ECH <9 mg/device
Particulate Testing Performed to USP <788> Methodology		
≥ 10 um	≤ 6000 particles/container	
≥ 25 um	≤ 600 particles/container	

SHELF LIFE: Sterile barrier testing, along with 5-year shelf-life study, has been performed in accordance with ISO 11607-1 and FDA requirements.

DIMENSIONS: Due to the number of SKUs, specific dimensions are too numerous to list and can be shared on a per item request.

This specification shall remain in effect until withdrawn by MPS Pharma & Medical, Inc.