



# PROSAT® *Sterile*™ Low Endotoxin Wipes

Polynit Heatseal wipes with 70% USP Grade IPA, 30% Water for Injection

**Manufactured with Water for Injection**

## Description

The PROSAT *Sterile* Low Endotoxin Wipes are made from 100% knitted interlock polyester, have laser-sealed edges, and are presaturated with a blend of 70% IPA and Water for Injection (WFI). These wipes have good abrasion and chemical resistance. The pouch can be easily resealed throughout use, maintaining saturation levels. Each batch of wipes has a guaranteed endotoxin level of less than 1 EU/device and is validated sterile via gamma irradiation to a Sterility Assurance Level of 10<sup>-6</sup>. Suitable for use in the most critical pharmaceutical cleanrooms.

The individual pouches of wipes are packaged to minimize the risk of contamination from viable and non-viable contaminants. Each individual pouch of PSWE0002 is double bagged. Each individual pouch of PSWE0001 and PSWE0003 is protected by three heat-sealed linear tear bags to facilitate transfer of the pouch into the most critical manufacturing zones.

## Technical Data

Wipe material	100% polyester
Wipe construction	No-run interlock knit
Solution of saturation; (blend ratio and constituents)	70% Isopropanol, 30% WFI
Solvent grade (IPA)	USP
Water quality	Water for Injection

Attribute; (units)	Value	Test Method
Basis weight; nominal (g/m <sup>2</sup> )	140	Contec Method
Non-volatile residue, NVR		IEST-RP-CC004.3, Sec. 7.1.2
In deionized water; (g/m <sup>2</sup> )	0.01	
In isopropanol; (g/m <sup>2</sup> )	0.01	
Specific ions		IEST-RP-CC004.3, Sec. 7.2.2
Sodium; (ppm)	0.18	
Chloride; (ppm)	0.003	
Particles, readily releasable		IEST-RP-CC004.2, Sec. 5.1
P ≥ 0.5µm; (x10 <sup>6</sup> /m <sup>2</sup> )	2.6	
Fibers > 100µm; (x10 <sup>3</sup> /m <sup>2</sup> )	0.142	IEST-RP-CC004.2, Sec. 5.2

*Part Numbers are on Page 2*

### Notes:

- 1) The information presented here is applicable to the part numbers shown above, as well as to any product containing the same materials and produced under the same conditions, regardless of product size or packaging configuration. Please contact a Contec sales representative for more details.
- 2) Data shown are typical values and should not be used as product specifications.
- 3) Valid product comparisons may only be obtained through side-by-side testing in the same test facility, under similar conditions.
- 4) Current and/or comparison data may be available. Please contact a Contec sales representative for details.

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Part Number	Description	EA/PCH	PCH/OB1	OB1/CS	OB2/CS	EA/CS
PSWE0002	Polynit Heatseal wipes with 70% USP Grade IPA, 30% Water for Injection, 12" x 12" (30 x 30cm), double bagged, Sterile	30	1	1	15	450

Part Number	Description	EA/PCH	PCH/OB1	OB1/OB2	OB2/OB3	OB3/CS	EA/CS
PSWE0003	Polynit Heatseal wipes with 70% USP Grade IPA, 30% Water for Injection, 12" x 12" (30 x 30cm), Half Fold, triple bagged, Sterile	10	1	1	1	30	300
PSWE0001	Polynit Heatseal wipes with 70% USP Grade IPA, 30% Water for Injection, 9" x 9" (23 x 23cm), Half Fold, triple bagged, Sterile	10	1	1	1	55	550

Key: EA = Each, PCH = Pouch, OB1 = Outer Bag 1, OB2 = Outer Bag 2, OB3 = Outer Bag 3, CS = Case

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