

DuPont™ Sontara® Nonpyrogenic Wipes

Lyocell/polyester nonpyrogenic sterile wipes

DuPont™ Sontara® Nonpyrogenic wipes are the first sterile nonwoven wiping product designed for the pharmaceutical, medical device and biotech industries. Made with DuPont™ Sontara® lyocell/polyester blend fabric, these nonpyrogenic wipes are packaged, gamma sterilized and validated by Contec, Inc.

Available in 9 x 9" (22.9 x 22.9cm) and 12 x 12" (30.5 x 30.5cm) sizes and packaged in small quantities to minimize wipe waste, these wipes are ideal for use in aseptic processing areas. Sontara® Nonpyrogenic wipes are validated per the AAMI/ISO 11137:2006 Guidelines for the sterilization of medical devices. Validation reports are available from Contec upon request.

Sontara Nonpyrogenic wipes meet the FDA standard for bacterial endotoxins using Limulus Amoebocyte Lysate at the endotoxin limit for medical devices at <20 EU/device.



Contec's innovative sterile packaging features a peelable outer bag and linear tear inner bag. Embossed lot numbers on both bags ensure lot traceability.

PRODUCT FEATURES

Sterilized by Cobalt-60 Gamma Radiation. Sontara Nonpyrogenic wipes are irradiated to a minimum dose of 25.0 kGy.

Validated sterile to 10⁻⁶ SAL (Sterility Assurance Level). A certificate of sterility is included with each case of product.

Sontara Nonpyrogenic wipes are double packaged with embossed lot numbers on both inner and outer bags, ensuring lot traceability.

Sontara Nonpyrogenic wipes have a high water and solvent sorbent capacity and rate.

Test results for the Sontara Nonpyrogenic wipes show low levels of particles and extractables.

Compatible with Class 5 Cleanroom environments, Sontara Nonpyrogenic wipes are ideal for many applications, including wiping articles prior to pass through, cleaning equipment surfaces and facilities cleaning.

TESTING

Extensive validation testing was conducted by Contec® and DuPont™ before the initial release of Sontara Nonpyrogenic wipes:

CONTEC®

- Sterility validation and dose audits on finished product
- Endotoxin testing using LAL test method on finished product
- Bioburden testing on wipes during the manufacturing process

DuPONT™

- Bioburden testing on process water and fabric
- Endotoxin testing on fabric

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Ordering Information

Part #	Description	Wipes/Bag	Inner Bags/ Outer Bag	Bags/Case
NWPZ0001	9 x 9" (22.9 x 22.9cm) nonpyrogenic wipes, sterile	25	4	10
NWPZ0002	12 x 12" (30.5 x 30.5cm) nonpyrogenic wipes, sterile	25	4	10



What are Pyrogens?

Pyrogens are fever-producing substances derived from the outer shell membranes of decaying bacteria. Bacterial endotoxins, from the outer membranes of gram-negative bacteria, are the most common pyrogens. Endotoxins are tested using a Limulus Amoebocyte Lysate (LAL) test method. The presence of pyrogens is a critical safety concern since these substances cannot be easily removed. Products contaminated with pyrogens can pose a life-threatening risk to patients. Use of nonpyrogenic sterile wipes during manufacturing reduces the potential for pyrogen contamination often observed in today's nonwoven wipes.

DuPont™ Sontara® Nonpyrogenic wipes are the first sterile nonpyrogenic nonwoven wipe designed for the medical device, pharmaceutical and biotech industries.



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