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Quality



ATMI's Quality Policy:

ATMI exists because of its customers.

To attract them, we design highly innovative products that create product or productivity opportunities.

To keep them, we are committed to the continuous improvement of quality in everything we do, so that we always meet or exceed our customers' expectations.

The "Ultraclean" Philosophy

Ultraclean components and systems are critical to the success of high-tech industries. Requirements for clean products are becoming more stringent and any step of the manufacturing process can potentially introduce contaminants.

ATMI LifeScience has the following systems in place to ensure maximum cleanliness is achieved in the manufacturing process:

- Traceability system of FDA approved raw materials
- Control of material during conversion to flexible film
- Continuous monitoring and measuring of all critical processes
- Maintaining <ISO 5 cleanroom condition protocols
- Well-trained, skilled employees

ISO Certified

ATMI LifeScience ISO Certifications include: ISO9001:2000 and 14000.

Cleanliness Level

IEST-STD-CC1246D is a standard for product cleanliness levels and contamination control program - Institute of Environmental Sciences and Technology.

This standard contains requirements for the establishment of a uniform method for specifying product cleanliness and contamination control program requirements. The focus of the program is on contaminants that cause damage through physical interactions rather than chemical interactions.

Wir verweisen auf die technischen Datenblätter des Herstellers
Erstelldatum 11/03

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Particle size	Level 50 Film	Level 100 film	Class 200 film
µm	(Mil STD 1246)	(Mil STD 1246)	(Mil STD 1246)
5	166	1780	28218
15	25	264	4180
25	7	78	1230
50	1	11	169
100		1	16
200			1

Quality Control

Quality control is exercised throughout the manufacturing process:

- Traceability, certification and specifications
- Compliance certifications backed with test data
- Validation and verification of product specifications using a variety of QA methods
- Good Manufacturing Practices (cGMP) based facilities
- ISO certified
- Good Packaging Practices (GPP) - A quality control system specifically for pharmaceutical clients, inspired by the Pharmaceutical Good Manufacturing Practices (cGMP)

Inspections

In process inspections are achieved through:

- Visual control
- Seal strength tests
- Seal pinhole tests Final inspections are achieved through:
- Tensile strength seal tests
- Particle cleanliness measurements

Irradiation

- Sterilization by gamma irradiation in conformity to EN 552 and ISO 11137
- Guaranteed dose of 25 kGy
- Delivered with certificate of sterilization

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