

STERILE & PARTICULATE CERTIFICATIONS

For customers manufacturing aseptically, PCS provides labeling with lot traceability with the expiration date and the dosimeter dot that indicates exposure to irradiation. Sterile items are released by Quality Assurance after a review of all gamma processing records.

PRUDENTIAL CR SERVICES

Lot Date
Exp Date



PRUDENTIAL CR SERVICES

Lot Date
Exp Date



STERILE LABELING
Gold: Pre-exposure
Red: Post-exposed

Prudential Cleanroom Services
Certificate of Sterilization (Gamma Irradiation)

Issue Date: XX/XX/XX	Irradiation Run Number: 1479933
Customer: ABC Inc	Irradiation Run: XX/XX/XX
PCS Lot Number: 02000-15	Number of Containers: 25
Gamma Irradiator: Steriguard	Expiration Date: XX/XX/XX
Cleanroom Processing Location: Corona, CA	Minimum Dose Received (kGy): 29.1
Sterilization Dose Range* (kGy): 22-32 kGy	Maximum Dose Received (kGy): 36.3

*Per PCS Sterilization Validation Manual, Revision Date: XX/XX/XX

Based on the minimum sterilization dose, this lot/particle is certified to meet a Sterility Assurance Level (SAL) of 10⁻⁶. Sterility validation was conducted per ANSI/AAMI Z39.5:2011.

Prudential Cleanroom Services

Quality Assurance Technicians Signature / Date: Jane Doe
Jane Doe
Quality Assurance Technicians Name (printed):
Los Angeles-15/Corona, CA
Plant Location (City and State)
Reviewed by / Date: John Doe

Form 1000, Rev. 03/13/21

Certificate of Sterilization

Issued To: ABC Inc
Account #: 1179000 Day 3 Rate: 70

Prudential Cleanroom Services

HELMKE Particle Test Certification
Date: XX/XX/XX

Product Code	Description	Run Code	Lot Code	Batch No.	Characteristics Description	Value
02010	CON-CONSERVALLS	HE2	11999000000000	0200-21	Counting of Particles @ 2.5 µm	114
					Counting of Particles @ 5 µm	300

Certification Performed by: Jane Doe
PQS Quality Assurance Technician Date: XX/XX/XX

Reviewed by: John Doe Date: XX/XX/XX

This particle generated by Prudential Cleanroom Services on the day indicated above, has been processed and tested in accordance with ASTM F51-F51M using a particle detector and particle counter. All particles were counted in a cleanroom environment. The test results are reported in the table above. The test results are reported in the table above. The test results are reported in the table above.

Plant Address: 8948 Redford Blvd., Corona, CA 92630 Phone: (951) 722-0606 Fax: (951) 722-2146 Main Office: 1987 Main

Helmk Drum Certification

Issued To: ABC Inc
Account #: 1179000 Day 3 Rate: 70

Prudential Cleanroom Services

ASTM F-51 Particle Test Certification
Date: XX/XX/XX

Product Code	Description	Run Code	Lot No.	Batch No.	Characteristics Description	Value
02010	CON-CONSERVALLS	HE2	11999000000000	0200-21	Number of Particles @ 2.5 µm	114
					Number of Particles @ 5 µm	300

Certification Performed by: Jane Doe
PQS Quality Assurance Technician Date: XX/XX/XX

Reviewed by: John Doe Date: XX/XX/XX

This particle generated by Prudential Cleanroom Services on the day indicated above, has been processed and tested in accordance with ASTM F51-F51M using a particle detector and particle counter. All particles were counted in a cleanroom environment. The test results are reported in the table above. The test results are reported in the table above. The test results are reported in the table above.

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ASTM F51-F51M Certification