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Dry Microbial Penetration Test Final Report

Test Article:	Product Name:Disposable Medical Protective Gown Model:ZKF-01 Lot No:2020080503
Purchase Order:	QHT20080426
Study Number:	1340489-S01
Study Received Date:	11 Sep 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0191 Rev 06
Deviation(s):	None

Summary: This procedure was performed to determine the migration of bacteria carried by organic or inorganic particles through a barrier material in a dry state. Test articles were conditioned then challenged with 0.5 ± 0.1 g bacteria carrying talc particles at a concentration of >10^8 colony forming units (CFU)/g. Test articles were vibrated at a level of 19,800–21,900 vibrations per minute (vpm) for 30 minutes. Sedimentation plates placed under the test articles during testing were counted after incubation, and the average counts and log of the average were calculated.

Testing was conducted in compliance with ISO 22612:2005 with the following exceptions. ISO 22612:2005 indicates testing should take place at 65 ± 5% relative humidity (RH) and 20 ± 2°C, instead the test articles were conditioned at these parameters for a minimum of 24 hours, and the testing took place at the conditions indicated below. Additional tolerance was given for incubation time and temperature (24-48 hours at 30-35°C), and vibration frequency (19,800–21,900 vpm). Furthermore, an alternate method for dryness verification (weight verification omitted) may be used. The individual changes were shown to be equivalent to ISO 22612 through internal validation.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Outside
Test Article Preparation:	~200 x 200 mm squares were aseptically cut from the Less Critical Area of the Material at Random
Conditioning Parameters:	65 ± 5% RH and 20 ± 2°C for a minimum of 24 hours
Air Pressure:	6.0 Bar
Talc Challenge Titer:	2.7 x 10^8 CFU/g
Negative Control Count:	<1 CFU
Temperature:	23.2°C

Janelle Bentz electronically approved — 09 Oct 2020 16:32 (+00:00)

Study Director — Janelle Bentz — Study Completion Date and Time

Relative Humidity: 24%

esults:

Test Article Number	Penetration (CFU Recovered)
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
Average	<1
Log_{10} CFU Average	≤1

Interpretation of Results:

EN13795:

Unit	Standard performance		High performance	
	Critical Area	Less Critical Area	Critical Area	Less Critical Area
CFU	Not Required	≤ 300	Not Required	≤ 300

EN14126:

Class	Penetration (log CFU)
3	≤ 1
2	1 < log CFU ≤ 2
1	2 < log CFU ≤ 3