

Disposable Surgical Mask

Mask Dimension: 17.5cm x 9.5cm

Product Package: 50 units per box. 40 boxes per case (2000 units per case)

Product Package Size (Case):
50x40x37cm

Product Weight (Case): Gross
Weight 8.0KGS

Net Weight 6.0KGS

Production: 200K units/day



编号 320506000201612290098



营业执照

(副本)

统一社会信用代码 91320506628397699H (1/1)

名称 苏州市特茵不织布有限责任公司
类型 有限责任公司
住所 苏州市吴中区木渎镇藏书东首
法定代表人 蒋谊耐
注册资本 515万元整
成立日期 1998年05月18日
营业期限 1998年05月18日至2028年05月17日
经营范围 生产、销售：无纺布及产品、塑料制品及手套系列；自营和代理各类商品及技术的进出口业务；经营本企业的进料加工和“三来一补”业务。（依法须经批准的项目，经相关部门批准后方可开展经营活动）



登记机关



请于每年1月1日至6月30日履行年报公示义务

2016年 12月 29日

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中华人民共和国国家工商行政管理总局监制



FINAL REPORT

prEN 14683

BACTERIAL FILTRATION EFFICIENCY
AND DIFFERENTIAL PRESSURE

PROCEDURE NO. SOP/ARO/007L.1

LABORATORY NO. 367604

PREPARED FOR:

JIANGSU TEYIN NON-WOVEN FABRICS CO., LTD
NO.2 EAST 4TH ROAD, HONGZE INDUSTRIAL ZONE,
JIANGSU PROVINCE 223100
P.R. CHINA

Model Number: HTYP-99

SUBMITTED BY:

NELSON LABORATORIES, INC.
6280 SOUTH REDWOOD ROAD
SALT LAKE CITY, UT 84123-8600
801-290-7500





BACTERIAL FILTRATION EFFICIENCY AND DIFFERENTIAL PRESSURE

LABORATORY NUMBER:	367604
PROCEDURE NUMBER:	SOP/ARO/007L.1
SAMPLE SOURCE:	Shanghai Magic Development Co., Ltd
SAMPLE IDENTIFICATION:	Refer to Table 1
DEVIATIONS:	None
SAMPLE RECEIVED DATE:	12 Mar 2007
LAB PHASE START DATE:	03 Apr 2007
LAB PHASE COMPLETION DATE:	17 Apr 2007
REPORT ISSUE DATE:	17 Apr 2007

INTRODUCTION:

This test procedure was performed to determine the bacterial filtration efficiency (BFE) of various filtration materials, employing a ratio of the bacterial challenge counts to sample effluent counts, to determine percent bacterial filtration efficiency (%BFE). This procedure provides a more severe challenge to most filtration materials than would be expected in normal use. This test procedure allowed a reproducible bacterial challenge to be delivered to test materials. This method complies with ASTM F2101.

The differential pressure (ΔP or Delta P) test determined the air exchange differential of the porous materials. The technique involved a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate. A digital manometer may be used in place of a water manometer.

ACCEPTANCE CRITERIA:

The BFE control average must be 2200 ± 500 colony forming units (CFU). A BFE run with a control average of less than 1700 shall be unacceptable. Challenges greater than 2700, but less than 3000, are, in our experience, valid. Acceptance of runs with control averages exceeding 2700 shall be at the sponsor's approval.

The mean particle size (MPS) of the challenge aerosol must be maintained at $3.0 \pm 0.3 \mu\text{m}$.

The average % BFE for the reference material must be within the upper and lower control limits established for the BFE test.

The average Delta P result for the reference material must be within the upper and lower control limits established for the Delta P test.



Jiangsu Teyin Non-woven Fabrics Co., Ltd
Lab Number 367604

Bacterial Filtration Efficiency
and Differential Pressure
Page 3 of 7

SAMPLE PREPARATION:

BFE test samples were conditioned for a minimum of 4 hours at $21 \pm 5^{\circ}\text{C}$ and $85 \pm 5\%$ relative humidity prior to testing.

TEST PROCEDURE:

A culture of *Staphylococcus aureus* ATCC #6538 was diluted in 1.5% peptone water (PEPW) to a precise concentration to yield challenge level counts of 2200 ± 500 CFU per test sample. The bacterial culture suspension was pumped through a 'Chicago' nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately $3.0 \mu\text{m}$. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. The collection flow rate through the test sample and Andersen sampler was maintained at 28.3 Liters per minute (Lpm) (1 cubic foot per minute (CFM)). Test controls and test samples were challenged for a two minute interval.

The delivery rate of the challenge also produced a consistent challenge level of 2200 ± 500 CFU on the test control plates. A test control (no filter medium in the airstream) and reference material are included after 5-11 test samples. The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six agar plates based on the size of each droplet. The agar medium used was soybean casein digest agar (SCDA). The agar plates were incubated at $37 \pm 2^{\circ}\text{C}$ for 48 ± 4 hours and the colonies formed by each bacteria laden aerosol droplet were counted and converted to probable hit values using the hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test samples. The distribution ratio of colonies for each of the six agar plates were used to calculate the MPS of the challenge aerosol.

The ΔP test simply measured the differential air pressure on either side of the test sample using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 Lpm (volumetric).

RESULTS:

The results are summarized in Table 1.



Jiangsu Teyin Non-woven Fabrics Co., Ltd
Lab Number 367604

Bacterial Filtration Efficiency
and Differential Pressure
Page 4 of 7

The filtration efficiencies were calculated as a percent difference between test sample runs and the control average using the following equation:

$$\% \text{ BFE} = \frac{C - T}{C} \times 100$$

Where: C = Average of control values.
T = Count total for test material.

The ΔP values were reported in mm water/cm² of test area and calculated using the following equation:

$$\text{DELTA } P (\Delta p) = \frac{\bar{M}}{\text{Test Area}}$$

Where: $\bar{M}$ = Average mm water of test replicates.

The sample holder used in the ΔP test has a test area of 4.9 cm².

At least one reference material is included with each set of test samples. The ΔP values for the reference material are also recorded on control charts. The individual ΔP values must be within the upper and lower control limits (± 3 standard deviations) for the test.

STATEMENT OF UNCERTAINTY:

If applicable, the statement of uncertainty is available to sponsors upon request.

J. J. H. / for
Stacey Cushing, B.S.
Study Director

20 Apr 2007
Study Completion Date

bav



Jiangsu Teyin Non-woven Fabrics Co., Ltd
Lab Number 367604

Bacterial Filtration Efficiency
and Differential Pressure
Page 5 of 7

TABLE 1. Results

SAMPLE IDENTIFICATION	ΔP (mm H ₂ O/cm ²)	PERCENT BFE
HTY P-99 - 1	2.9	99.9%
HTY P-99 - 2	2.7	>99.9%*
HTY P-99 - 3	2.9	>99.9%*
HTY P-99 - 4	3.0	99.9%
HTY P-99 - 5	2.8	99.7%
HTY P-99 - 6	2.8	99.9%
HTY P-99 - 7	2.8	99.9%
HTY P-99 - 8	2.9	99.9%
HTY P-99 - 9	2.9	99.9%
HTY P-99 - 10	2.8	>99.9%*
HTY P-99 - 11	2.8	99.9%
HTY P-99 - 12	2.9	>99.9%*
HTY P-99 - 13	3.0	99.9%
HTY P-99 - 14	2.7	>99.9%

CONTROL AVERAGE: 2660 CFU

MEAN PARTICLE SIZE: 3.2 μm

* There were no detected colonies on any of the Andersen sampler plates for this sample.



Jiangsu Teyin Non-woven Fabrics Co., Ltd
Lab Number 367604

Bacterial Filtration Efficiency
and Differential Pressure
Page 6 of 7

TABLE 1. Results (Cont.)

SAMPLE IDENTIFICATION	ΔP (mm H ₂ O/cm ²)	PERCENT BFE
HTY P-99 – 15	2.9	99.8%
HTY P-99 – 16	2.8	99.9%
HTY P-99 – 17	2.8	99.9%
HTY P-99 – 18	2.9	99.8%
HTY P-99 – 19	2.9	>99.9%*
HTY P-99 – 20	3.3	99.9%
HTY P-99 – 21	3.0	99.8%
HTY P-99 – 22	2.9	>99.9%*
HTY P-99 – 23	3.0	99.9%
HTY P-99 – 24	2.8	99.9%
HTY P-99 – 25	2.9	99.9%
HTY P-99 – 26	3.0	99.8%
HTY P-99 – 27	2.6	>99.9%
HTY P-99 – 28	2.8	99.9%

CONTROL AVERAGE: 2660 CFU

MEAN PARTICLE SIZE: 3.2 μm

* There were no detected colonies on any of the Andersen sampler plates for this sample.



Jiangsu Teyin Non-woven Fabrics Co., Ltd
Lab Number 367604

Bacterial Filtration Efficiency
and Differential Pressure
Page 7 of 7

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