



Testing Center of Sanitation & Environment technic Institute, Soochow University, Test Report

Report Number:SDWH-2009-20569

Sample Name: Lap sponge

Testing Item: Package Verification Test

Sample Supplier: Medwell Medical Products Co., Ltd

Supplementary Explanation

1. If the analysis report requires modification please raise the matter within 15 days of receiving the report, otherwise the request will not be accepted.
2. The test report is void without test center's seal.
3. The test report is only valid when signed by the persons who edited, checked and approved it.
4. Any erasure renders the report null and void.
5. The test result is only valid for the sample provided.
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Table of contents

	Page number
Vacuum leak test.....	4
Dye penetration test.....	5
Agar contact-Attack test.....	6
Tensile seal strength test.....	7
Accelerated aging test.....	8

Vacuum leak test

Sample supplier: Medwell Medical Products Co., Ltd

Sample name: Lap sponge

Size: Not supplied

Lot no: MBL090513

Received date: Jul 9, 2009

Test method: Refer to ISO11607-2006, ASTM F 1980-07, ASTM D 3078-02

Test conditions:

Accelerated Aging (60°C) , includes High RH (70-80%), Low RH(<20%) and Freezing=(<-20°C) , Q₁₀=2

5.0 Years Equivalent 145 Days
Quantity = 10
Low RH% <20%RH :65 Days
High RH% =70-80%: 70 Days
Freezing less than -20°C : 10 Days

Experimental procedure:

Immerse sealed packages in a test solution and apply vacuum (-40Kpa). When the vacuum is released, the difference in pressure will force the test solution through any openings in the package.

Results:

The following chart will give the estimated vacuum leak.

Samples No	Vacuum leak
1	—
2	—
3	—
4	—
5	—
6	—
7	—
8	—
9	—
10	—

Conclusion:

The result show no vacuum leak in the package of products.

Date completed: Dec 2, 2009

Edited by: *[Signature]*

Checked by: *Liu chun li*

Dye penetration test

Sample supplier: Medwell Medical Products Co., Ltd

Sample name: Lap sponge

Size: Not supplied

Lot no: MBL090513

Received date: Jul 9, 2009

Test method: Refer to ASTM F 1929-98, ASTM F 1980-07

Test conditions:

Accelerated Aging (60°C), includes High RH (70-80%), Low RH($<20\%$) and Freezing= $(<-20^{\circ}\text{C})$, $Q_{60}=2$

5.0 Years Equivalent 145 Days
Quantity = 10
Low RH% $<20\%$ RH :65 Days
High RH% =70-80%: 70 Days
Freezing less than -20°C : 10 Days

Procedure: Test samples are conditioned under temperature of $23 \pm 2^{\circ}\text{C}$ and $50 \pm 2\%$ of relative humidity for 24h prior testing. Take ten pieces of feeding tubes, then cut the test samples in the middle. Next make 5ml syringe draw with Toluidine blue test fluid, and drip test liquid onto the sealed parts of the packaging material and keep for 10 seconds. Observe impermeability of seal formed by fusion.

Result: packaging sealing parts of the ten packages of product, with color tests, found no leaks and spin-off phenomenon.

Conclusion: The test result shows the dye can not penetrate the seal. This means the packing material has the good scalability.

Date completed: Dec 2, 2009

Edited by:

Li Jing

Checked by:

Li Jun

Agar contact-attack test (Microbial barrier properties)

Sample supplier: Medwell Medical Products Co., Ltd

Sample name: Lap sponge

Size: Not supplied

Lot no: MBL090513

Received date: Jul 9, 2009

Test method: Refer to ISO11607-2006, ASTM F 1980-07

DIN 58953 Part 6 1987

Test conditions:

Accelerated Aging (60°C) , includes High RH (70-80%), Low RH(<20%) and Freezing=(<-20°C) , $Q_{10}=2$

5.0 Years Equivalent 145 Days
Quantity = 10
Low RH% <20%RH :65 Days
High RH% =70-80%: 70 Days
Freezing less than -20°C : 10 Days

Procedure

(1)Use inoculation loop to inoculate the bacillus subtilis strains into nutrient broth. Then put such nutrient broth in an incubator at 31°C for 24 hours.

(2)With aseptic manipulation, take a piece of sterile packing material and put it onto the surface of nutrient agar plats. Transfer 1ml broth with concentration of 5.6×10^7 cfu/ml bacillus subtilis onto the packing material using sterile pipette. Cover the plate and incubate it for 24 hours at 31°C. Precaution should be taken to avoid the bacterial solution (broth) permeation to or dropping on the edge of packing material . Finally, Observe the microorganism growth on the packing material surface contacting with agar.

Result

No bacillus subtilis growth is found on the side of packing material contacting with agar.

Conclusion

The test result shows the microbe bacillus subtilis can not penetrate the packing material, Which indicates this packing material is capable of preventing the microbial penetration.

Date completed: Dec 7, 2009

Edited by: *Yangju*

Checked by: *Liu chun li*

Tensile seal strength test

Sample supplier: Medwell Medical Products Co., Ltd

Sample name: Lap sponge

Size: Not supplied

Lot no: MBL090513

Received date: Jul 9, 2009

Test method: Refer to ASTM F 88-07, ASTM F 1980-07

Test apparatus: Digital displayed tensile tester, Model SZL-200

Test conditions:

Accelerated Aging (60°C), includes High RH (70-80%), Low RH(<20%) and Freezing=(<-20°C), $Q_{10}=2$

5.0 Years Equivalent 145 Days
Quantity = 13
Low RH% <20%RH :65 Days
High RH% =70-80%: 70 Days
Freezing less than -20°C : 10 Days

Ambient conditions during test: Temperature of 26°C and humidity of 50%.

Procedure: Take the packages and prepare the standard -size specimen. Use the Digital displayed tensile tester to measure the tensile peel strength. Holding tail methods is applied technique A. The grip separation rate is 300mm/min and the initial grip separation distance is 80mm. The seal width is 25mm.

Results: The mode of test sample failure is adhesive failure of the seal by visual determination. The peeling strength is as the following table.

Sample No	Average peeling strength (lbs/in)
1	2.08
2	1.75
3	2.09
4	1.74
5	1.70
6	1.45
7	1.81
8	1.91
9	1.51
10	1.94
11	1.97
12	2.16
13	1.56
Mean	1.82
Standard Deviation	0.23

Comments

A section of the manufacture's seal was tested for each of the thirteen units.

Date completed: Dec 2, 2009

Edited by: *[Signature]*

Checked by: *Lin Chen li*

Accelerated aging test

Sample supplier: Medwell Medical Products Co., Ltd

Sample name: Lap sponge

Size: Not supplied

Lot no: MBL090513

Received date: Jul 9, 2009

Test method: Refer to ASTM F 1980-07、ISO11737-2:1998

Test apparatus: Temperature and humidity conditioner

Test conditions:

Accelerated Aging (60°C), includes High RH (70-80%), Low RH(<20%) and Freezing($<-20^{\circ}\text{C}$), $Q_{10}=2$

5.0 Years Equivalent 145 Days
Quantity = 12
Low RH% <20%RH :65 Days
High RH% =70-80%: 70 Days
Freezing less than -20°C : 10 Days

Procedure: Then take 12 pieces of products for sterility test, observe whether or not the bacteria grows.

1. All testing operations follow the aseptical operation procedure. Sterility is conducted in a super clean working desk with 100 grade clean liness.
2. Aseptically transfer the product to media container using flame sterilized forceps and scissors.
3. Samples in SCDB are incubated at $28-32^{\circ}\text{C}$ for 14days.
4. Observe the growth of microorganisms.

Result:

Number of Articles Tested	Type of Media	Incubation Temperature ($^{\circ}\text{C}$)	Number of Days Incubated	Number of Positive Articles
12	SCDB	28~32	14	0

Conclusion: The test samples were still remained sterile after Accelerated Aging Test. This meant the packaging material had good scalability. It also indicated that in normal ambient conditions, sterility can be maintained within 60 months.

Date completed: Dec 16, 2009

Edited by: *Dongjie*
Dec 17, 2009

Checked by: *Liu Chun li*
Dec 17, 2009

Approved by: *Zhang Tongchang*
Dec 17, 2009

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