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TESTING
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Inspection and Testing Center of Soochow University Radiation Medicine Institute Test Report

Report Number: SDFY-2009-20570

Sample Name: Lap sponge

Testing Item: Validating Radiation Sterilization

Sample Supplier: Medwell Medical Products Co.,Ltd

SumJuly

This test was performed to determine the bioburden levels on the Lap sponge manufactured by Medwell Medical Products Co.,Ltd The test was based on ISO11737. A sample Item Proportion (SIP) of 1 was utilized for testing. The test included the following items: report bioburden test, determination of the correction factor , determination of the microbial resistance to radiation and sterility test.

The test results for three independent lots were:

Lot No.	average bioburden (cfu/device)
MBL090513	13630
MBL090614	7684.5
MBL090704	12690

Overall adjusted average bioburden: 11334. 83cfu/device

Correction factor: 2.35

Based on the overall average bioburden level of 11334. 83cfu/device, the verification dose was determined directly from Table 5 of the ISO 11137-2:2006 for Method 1. The verification dose for the Lap sponge is 14.4kGy. 100 product units were randomly sampled from a single manufacturing lot, exposed to the verification dose and sterility tested. The sterility test results for these 100 irradiated products were acceptable in accordance with STERILIZATION OF HEALTH CARE PRODUCTS- RADIATION – ISO-11137-2:2006.

The results of this dose verification experiment met the acceptance criteria according to ISO 11137-2:2006. The dose verification sterility test yielded zero non-sterile cultures out of the 100 units tested. This result indicates that under the conditions of the study, a minimum exposure dose of 28.9 kGy has been determined as adequate for routine sterilization. This minimum dose provides a Sterility Assurance Level (SAL) of 10^{-6} with a probability of no more than a single survivor for each one million product units exposed to the SAL dose.

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Aug 10, 2009

Aug 10, 2009



Inspection and Testing Center of Soochow University Radiation Medicine Institute(Stamp)

INTRODUCTION

The test article was received on Jul 9, 2009. This study was performed to establish a radiation dose and validate the effectiveness of gamma irradiation for sterilization of the Lap sponge. The study was based on practices recommended by the American National Standards Institute/Association for the Advancement of Medical Instrumentation /International Organization for Standardization, Sterilization of Health Care Products –Requirements For Validation and Routine Control-Radiation Sterilization (STERILIZATION OF HEALTH CARE PRODUCTS- RADIATION – ISO-11137-2:2006). Pre-sterilization bioburden levels were determined and used to select an appropriate Verification Dose for this product. Recommendations for a routine minimum sterilization dose were based upon evaluation of microbial survivors following exposure of products to the Verification Dose. The recommended full process dose is designed to provide a Sterility Assurance Level (SAL) of 10^{-6} or no more than one non-sterile unit for each one million units sterilized at that dose level.

METHOD

Finished, routine production units of the products submitted in standard, final packaging format were randomly sampled from each of the three manufacturing lots prior to sterilization. The sample item proportion (SIP) used for all testing was 1.

Bioburden testing was performed according to bioburden test specification SDFY-302-027, and an average bioburden per product was calculated. A bioburden recovery test was performed to validate the effectiveness and repeatability of this bioburden test method for this particular product .The percent (42.53%) recovery determined from this validation was factored into the average bioburden data to obtain an adjusted average bioburden per device (See SDFY-302-029). The bioburden data from three separate manufacturing lots were used to calculate the overall average bioburden per device. This overall average bioburden was used to select the appropriate verification dose from Table 5. STERILIZATION OF HEALTH CARE PRODUCTS- RADIATION – ISO-11137-2:2006 for Method 1.

100 product units from a single manufacturing lot were irradiated at WuJiang Irradiation Center of TCRSU. The delivered dose was measured using dosimeters placed by WuJiang Irradiation Center of TCRSU to assure compliance with the required verification dose within $\pm 10\%$.

Following exposure, the test units were forwarded to TCRSU for sterility testing according to Sterility Test Specification SDFY-302-024. The documented dose was compared with the acceptable dose to verify appropriate product exposure. In addition, four sterile samples were previously tested to verify that no microbiocidal or microbiostatic activity, which might have compromised the sensitivity of the sterility test method, was exhibited by the samples, or was formed by the verification dose exposure. This bacteriostasis /fungistasis test was conducted according to SDFY-302-028, using Bacillus Subtilis and Candida Albicans.

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by TCRSU. Any extrapolation of these data to other samples is the responsibility of the sponsor.

RESULTS

The bioburden results for each of the three manufacturing lots were:

Lot No.	Average Bioburden (cfu/device)
MBL090513	5800
MBL090614	3270
MBL090704	5400

Overall average bioburden: 4823.33cfu/device

Overall adjusted average bioburden: 11334. 83 cfu/device

(see SDFY-302-029)

The Guideline for Gamma Radiation Sterilization (STERILIZATION OF HEALTH CARE PRODUCTS- RADIATION – ISO-11137-2:2006) indicates that the overall adjusted average bioburden should be used to determine the verification dose unless one of the lot averages is two or more times greater than the adjusted overall average, in which case the largest lot average should be used. Based upon the bioburden data, the overall average bioburden of 11334. 83 cfu/device was used to determine the verification dose (refer to SDFY-302-031 for the dose calculation).

The selected verification dose based on the average bioburden was 14.4kGy±10% and 100 product units were exposed to 12.96-15.84 kGy (see the certificate of irradiation).

There was no bacteriostatic or fungistatic activity found to be associated with the products (refer to SDFY-302-028 for bacteriostasis/fungistasis report).

The sterility test of 100 product units exposed to the verification dose yielded zero positive culture (refer to SDFY-302-024 for sterility test results).

CONCLUSION

The results of the dose verification experiment meet the acceptance criteria as described in (STERILIZATION OF HEALTH CARE PRODUCTS- RADIATION – ISO-11137-2:2006). This indicates that, under the conditions of the study, a minimum exposure dose of 28.9 kGy has been determined for routine sterilization. This minimum dose provides a Sterility Assurance Level (SAL) of 10^{-6} (a probability of no more than a single survivor for each one million product units exposed to the SAL dose).

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated TCRSU archive files.

REFERENCES

- A. Sterilization of Health Care Products- Radiation –Part 1: Requirements for development, Validation and Routine Control of a Sterilization process for medical devices ISO-11137-1:2006
- B. Sterilization of Health Care Products- Radiation –Part 2: Establishing the Sterilization dose ISO11137-2:2006.
- C Sterilization of Medical Devices-Microbiological Method–Part 1: Determination of a Population of Microorganisms on Products, ISO11737-1:2006.
- D. Sterilization of Medical Devices-Microbiological Method–Part 2:Tests of sterility performed in the validation of a sterilization process, ISO11737-2:1998.

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Page 5 of 10

**Test of Substance Released from Product
(Product Bacteriostasis /Fungistatic Test)**

Method:

1. Preparation of standard microbial solution.

Take sub-cultured Bacillus Subtilis (ATCC 9372) and Candida Albicans to prepare the microbial solution of concentration of 100 cfu/ml.

2. Product treatment

With aseptic manipulation, take sterile products to 100ml SCDB and then incubate at 30~35°C for 24 hours.

3. Inoculation

Positive controls were set up simultaneously with each organism seeded into the culture medium. All SCDB cultures were incubated at 28~32°C until positive for microbial growth, or for not less than 7 days. The standard plate count method was used to determine the microbial count (colony forming units) challenging each test or control system.

Result:

Organism	ATCC	Inoculum Population	SCDB with product + standard bacteria	Control SCDB + standard bacteria
B.subtilis	9372	50	+	+
C.albicans	10231	60	+	+

Conclusion:

The result shows no bacteriostasis / fungistatis present in the product.

Test completed: Jul 13, 2009

Bioburden Test Specification

Procedure:

1. Wash Solution: 0.1% Peptone, 0.05% Tween-80, 0.9% Sodium chloride.
2. Sample preparation: Aseptically disassemble and transfer each sample to the wash solution, and then shake for 2 minutes.
3. Aerobic culture: Inoculate an aliquot volume of 2ml wash solution to two plates with 20ml TSA each and incubate at 30~35 °C for 48~72 h.
4. Fungi culture: Inoculate an aliquot volume of 2ml wash solution to two plates with 20ml RBA each, and incubate at 20~25 °C for 5~7 days.
5. Enumeration:

The enumeration is based on standard plate counting method. The microbial number for each product is obtained by the result of counts times dilution ratio.

Result.

Sample No.	MBL090513		MBL090614		MBL090704	
	Aerobic cfu/device	Fungi cfu/device	Aerobic cfu/device	Fungi cfu/device	Aerobic cfu/device	Fungi cfu/device
1	10000	200	800	<100	10400	<100
2	9000	<100	2800	<100	3200	<100
3	2400	<100	100	400	6800	200
4	4400	<100	3200	200	5000	<100
5	10300	200	5300	300	3600	<100
6	1600	200	5000	<100	3800	<100
7	10200	<100	7600	200	4800	200
8	4000	200	2400	<100	6000	<100
9	3100	200	2400	200	5600	200
10	2000	<100	1800	<100	4200	<100
Average	5700	100	3140	130	5340	60

(Negative control <10cfu/device)

Date completed: Jul 15, 2009

Bioburden Recovery Validation Exhaustive Method

Procedure:

Three samples were used from each lot. Add wash solution into the container containing samples shaken adequately at 2800 cycle/min for 2 min. The extraction fluid was removed and enumerated. This procedure was repeated to obtain single wash and cumulative number of recovered organisms. Refer to SDFY-302-027.

Calculation of recovery factor:

$$\frac{\text{Average wash1}}{\text{Average (wash1+wash2+wash3+wash4)}} \times 100\% = \text{Recovery factor (\%)}$$

Results:

For Aerobes count Recovery

Sample Number	Recovered CFUs per Sample		Percent Recovery Factor (%)
	Wash1	Cumulative (wash1,2,3,4)	
1	10000	19920	50.20
2	800	5545	14.43
3	10400	16521	62.95

Average Percent Recovery Factor: 42.53%

Recovery Multiplication Factor: $100 \div 42.53 = 2.35$

Date completed: Jul 15, 2009

Verification Dose Calculation

Bioburden:

The bioburden testing and the bioburden percent recovery validation on the three product lots of the Lap sponge have been completed. The average bioburden for each lot was:

Lot No	Average Bioburden cfu/device
MBL090513	5800
MBL090614	3270
MBL090704	5400
Average	4823.33

Overall adjusted average bioburden: $4823.33 \times 2.35 = 11334.83$ cfu/device

Based on the overall average bioburden level of 11334.83cfu/device, the verification dose was determined directly from Table 5 of the ISO 11137 for Method 1. The verification dose for the products is 14.4kGy.

In accordance with ISO 11137 for Method 1, 100 units of product should be randomly sampled from a single lot of product and irradiated at the verification dose of $14.4\text{kGy} \pm 10\%$. After irradiation the samples were sent to TCRSU for sterility testing.

If these 100 units which have been irradiated at 14.4kGy, meet the criteria set forth in the ISO 11137 (no more than two positives per 100 units), then the minimum sterilization dose for a 10^{-6} sterility assurance level would be 28.9 kGy, according to the ISO11137 standard.

Sterility Test

Procedure:

1. All testing operations follow the aseptic manipulation. Sterility tests were conducted in a laminar flow biological cabinet, class 100.
2. The product was aseptically transferred to the media container using flame sterilized forceps and scissors.
3. Samples in SCDB were incubated at 28-32°C for 14 days.
4. The growth of microorganisms was observed.

Result:

Articles Tested	Number of Articles Tested	Type of Media	Incubation Temperature (°C)	Number of Days Incubated	Number of Positive Articles
0.25	100	SCDB 100 ml	28-32	14	0

Conclusion: Test results meet test acceptance criteria.

Date completed: Aug 10, 2009