MHK Medikal Tekstil San. Ve. Tic. Ltd. Şti.

SHELF LIFE STUDY

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Date: 2023.05.08 10:52:30 EEST
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1. PURPOSE

The purpose of this protocol is to determine the Shelf Life of the products manufactured by MHK Medikal by performing the Accelerated Stability test.

2. SCOPE

This protocol; Includes accelerated stability test for Disposable Sterile Surgical Drapes, Gowns and Sets manufactured by MHK Medikal.

3. REFERENCES

ASTM F 1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

ISO 11737-2 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

4. DEFINITIONS

Reference Product: It is the determined load that reflects the most difficult combination of products to be sterilized

Sterile: It is the state of the medical material free from living microorganisms.

5. PROTOCOL AND REPORT

• After the last validation, 10 of the sterile products were purchased.
• Sterility Test and Package Performance Tests were carried out before aging. The test results were found to be suitable.
• Products were oven-baked to initiate the Accelerated Aging Test.
• Stability test time was determined according to the calculation method given below and the product was kept in the oven at 58 ºC ± 2 temperature.

Calculation Method;

- Desired Real Time Aging(DRTA) : 1825 GÜN/DAYS (5 YIL/YEARS)
- Ambient Temperature (AT) : 23 ºC
- Accelerated Aging Temperature (AAT) : 58 ºC
- Accelerated Aging Factor (Q10) : 2
- Accelerated Aging Rate (AAR) : Q10^((AAT-AT)/10)
- : 2^((58-23)/10) = 2^3.5=
- Accelerated Aging Time Duration (AATD) : 1825/11,29= 162 GÜN / DAYS
- Accelerated Aging Time Zero : 02.02.2020
- Accelerated Aging Time Finish : 15.07.2020
- Date of Sterility Analysis : 29.07.2020

- According to the calculation method above, the packaging and physical properties of the product, which is kept for 162 days at 58 ºC±2, are checked. There has been no change.
- After the stability, the product whose package and physical properties were suitable was taken to the sterility test. As a result of the sterility test, it was observed that the sterility of the product was preserved.
- Package Performance Tests were performed after aging. The results were evaluated and found to be appropriate.
- Product Performance tests were carried out according to ISO 13795 standard. Product performance test results were evaluated for compatibility with the standard.
- A table of conformity with the standard was drawn up with performance test results.
- No nonconformity was found in the performance of the products, and the Accelerated Aging Test was positive.

Performance Evaluation Standard Compliance Table

Performance Characteristics Table for Aprons according to EN 13795 standard

Table 1 — Characteristics to be evaluated and performance requirements for surgical gowns

Characteristic	Test method (for references, see Clause 2)	Unit	Requirement			
			Standard performance		High performance	
			Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration — Dry	EN ISO 22612	CFU	Not required	≤ 300 [a]	Not required	≤ 300 [a]
Resistance to microbial penetration — Wet	EN ISO 22610	I_B	≥ 2,8 [b]	Not required	6,0 [b c]	Not required
Cleanliness — Microbial	EN ISO 11737-1	CFU/ 100 cm^2	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness — Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	EN ISO 9073-10	$\log_{10}$ (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Resistance to liquid penetration	EN 20811	cm H_2O	≥ 20	≥ 10	≥ 100	≥ 10
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength — Wet	EN ISO 13938-1	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength — Dry	EN 29073-3	N	≥ 20	≥ 20	≥ 20	≥ 20
Tensile strength — Wet	EN 29073-3	N	≥ 20	Not required	≥ 20	Not required

[a] Test conditions: challenge concentration 10^8 CFU/g talc. and 30 min vibration time.

[b] The Least Significant Difference (LSD) for I_B when estimated using EN ISO 22610, was found to be 0,98 at the 95 % confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0,98 I_B are probably not different; materials varying by more than 0,98 I_B probably are different. (The 95 % confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives.)

[c] I_B = 6,0 for the purpose of this European Standard means: no penetration. I_B = 6,0 is the maximum achievable value.

Performance Evaluation Standard Compliance Table

ÜRÜN ADI/PRODUCT NAME		LOT NO
DISPOSABLE STERILE GENERAL SURGERY SET		13190503

Tested Product Name: Reinforced Surgical Gown L					
Tests	**Test Method**	**Unit**	**Specifications**	**Test Report**	**Evaluation**
Resistance to microbial	EN ISO 22612	CFU	≤ 300		Acceptable

penetration — Dry					
Resistance to microbial penetration — Wet	EN ISO 22610	I_B	6,0		Acceptable
Cleanliness — Particulate matter	EN ISO 9073-10	IPM	≤ 3,5		Acceptable
Linting	EN ISO 9073-10	$\log_{10}$ (lint count)	≤ 4		Acceptable
Resistance to liquid Penetration	EN 20811	cm H_2O	≥ 100		Acceptable
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	123	Acceptable
Bursting strength — Wet	EN ISO 13938-1	kPa	≥ 40	122	Acceptable
Tensile strength — Dry	EN 29073-3	N	≥ 20	103,2	Acceptable
Tensile strength — Wet	EN 29073-3	N	≥ 20	106,2	Acceptable

Performance Characteristics Table of Coverings according to EN 13795 standard

Table 2 — Characteristics to be evaluated and performance requirements for surgical drapes

Characteristic	Test method (for references, see Clause 2)	Unit	Requirement			
			Standard performance		High performance	
			Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration — Dry	EN ISO 22612	CFU	Not required	≤ 300 [a]	Not required	≤ 300 [a]
Resistance to microbial penetration — Wet	EN ISO 22610	I_B	≥ 2,8[b]	Not required	6,0 [b c]	Not required
Cleanliness — Microbial	EN ISO 11737-1	CFU/ 100 cm^2	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness — Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	EN ISO 9073-10	$\log_{10}$ (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Resistance to liquid penetration	EN 20811	cm H_2O	≥ 30	≥ 10	≥ 100	≥ 10
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength — Wet	EN ISO 13938-1	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength — Dry	EN 29073-3	N	≥ 15	≥ 15	≥ 20	≥ 20
Tensile strength — Wet	EN 29073-3	N	≥ 15	Not required	≥ 20	Not required

[a] Test conditions: challenge concentration 10^8 CFU/g talc. and 30 min vibration time.

[b] The Least Significant Difference (LSD) for I_B when estimated using EN ISO 22610, was found to be 0,98 at the 95 % confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0,98 I_B are probably not different; materials varying by more than 0,98 I_B probably are different. (The 95 % confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives.)

[c] I_B = 6,0 for the purpose of this European Standard means: no penetration. I_B = 6,0 is the maximum achievable value.

Performance Evaluation Standard Compliance Table

ÜRÜN ADI/PRODUCT NAME		REF		LOT NO	
DISPOSABLE STERILE GENERAL SURGERY SET				13190503	
Tested Product Name: Standard Surgical Drape					
Tests	**Test Method**	**Unit**	**Specifications**	**Test Report**	**Evaluation**
Resistance to microbial penetration — Dry	EN ISO 22612	CFU	≤ 300	14	
Resistance to microbial penetration — Wet	EN ISO 22610	*l*B	6,0	6,0	
Cleanliness — Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	3,3	
Linting	EN ISO 9073-10	$\log_{10}$ (lint count)	≤ 4	3,5	
Resistance to liquid Penetration	EN 20811	cm H_2O	≥ 100	100	
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	147	
Bursting strength — Wet	EN ISO 13938-1	kPa	≥ 40	129	
Tensile strength — Dry	EN 29073-3	N	≥ 20	53,6	
Tensile strength — Wet	EN 29073-3	N	≥ 20	56,8	

Herewith declare that the products

DISPOSABLE STERIL SURGICAL DRAPES AND GOWNS

have 5 years shelf-life İf steril with EO according to Accelerated Aging Test Protocol