



ISD MEDITECH SDN BHD (915725-T)

NO.3 JALAN PJS3/2, TAMAN MEDAN,
46000 PETALING JAYA, SELANGOR DARUL EHSAN

Email: info@isdmeditech.com

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AGING AND STABILITY TEST / SHELF-LIFE TEST (ACCELERATED)

To monitor the product stability for establish the shelf life. The accelerated aging is carried out according to **ASTM F1980-02** (Standard Guide for Accelerated Aging of Sterile Medical Device Packages)

Method:

Representative samples are taken for an accelerated test to assess the quality of products in a simulated aging situation.

Every batch at least 6x260g bottle product shall be taken from the production batch for the aging test.

The products are tested in a heated oven for at least 12 weeks. Each week is to simulate an accelerated aging of 3 months.

The aging test shall be performed as follows:

- 1) The sample is put into an evenly heated oven which should be capable of maintaining a constant temperature of $55 \pm 5^{\circ}\text{C}$.
- 2) The sample is kept in the oven for a total of at least 12 weeks. **(Each week is to simulate an accelerated aging of 3 months)**
- 3) End of every 2 weeks. There will be a sample taken out from the oven for evaluation on physical change, viscosity and packaging defect.

The record is maintained in traceability

***Sample report as attached

ACCELERATED AGING TIME (AAT) CALCULATOR

Reference ASTM F1980-16

$$\text{Accelerated Aging Time (AAT)} = \frac{\text{Desired Real Time (RT)}}{Q_{10}^{[(T_{AA} - T_{RT})/10]}}$$

Desired Real Time (RT): months

Accelerated Aging Temperature (T_{AA}): 55 $^{\circ}\text{C}$

Notes: WESTPAK does not recommend aging packaging materials at temperatures exceeding $+60^{\circ}\text{C}$.
Common AATs are $+50^{\circ}\text{C}$, $+55^{\circ}\text{C}$ and $+60^{\circ}\text{C}$.

Ambient Temperature (T_{RT}): 23 $^{\circ}\text{C}$

Notes: This temperature is typically between $+20^{\circ}\text{C}$ to $+25^{\circ}\text{C}$.
A temperature of $+25^{\circ}\text{C}$ is a more conservative approach.



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Sample of Calculation

Desired Real Time (RT) = 36 months (test is perform in 12 weeks, 1 week simulate an accelerated aging of 3 months)

Aging factor (Q_{10}) = 2 (this factor is typically between 1.8 – 2.5, a value of 2.0 is the most common value)

Accelerated Aging Temperature (T_{AA}) = 55 °C

Ambient Temperature (T_{RT}) = 23 °C

$$AAT = \frac{36}{2^{\left[\frac{55-23}{10}\right]}} = 119 \text{ days}$$

AGING AND STABILITY TEST / SHELF-LIFE TEST (ACCELERATED)

ISD MEDITECH SDN BHD						
ULTRASOUND TRANSMISSION GEL - AGING AND STABILITY TEST REPORT						
Product Description			SKY GEL 5000B			
Lot No			UGB05022022			
Manufacturing Date			05022022			
Oven Date			05022022			
Input Quantity			6 X 260g			
TEST SPECIFICATION						
Temperature			55 ± 5°C			
Viscosity			90 – 130 KcP			
AGING TEST						
Inspection Date	No of Week	Colour Change	Input Viscosity @ 25°C	Viscosity @ 25°C	Leaking	Remark
19/02	WEEK 2	—	113	113	—	
05/03	WEEK 4	—	113	113	—	
19/03	WEEK 6	—	113	113	—	
02/04	WEEK 8	—	113	113	—	
16/04	WEEK 10	—	113	113	—	
30/04	WEEK 12	—	113	113	—	
Remarks : 1. (/) = OK (X) = NOT OK (-) = NOT APPLICABLE 2. This stability show that the product's shelf life is 3 years						



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AGING AND STABILITY TEST / SHELF-LIFE TEST (REAL TIME)

To monitor the product stability for establish the shelf life.

Method:

Representative samples are taken for as shelf life test for 3 year.

Every batch at least 6x260g bottle product shall be taken from the production batch for the aging test.

The aging test shall be performed as follows:

- 1) The sample is storing into under selected conditions for a 3 years period which should be capable of maintaining a constant with monitoring the storage room temperature $30^{\circ}\text{C} \pm 5$ and humidity $50 \pm 5\%$.
- 2) The sample is keep for 3 year for product self life monitoring.
- 3) End of every 6 months. There will be a sample taken out for evaluation on physical change, viscosity and packaging defect.

The record is maintained in traceability.

***Sample report as attached

AGING AND STABILITY TEST / SHELF-LIFE TEST (REAL TIME)

ISD MEDITECH SDN BHD						
ULTRASOUND TRANSMISSION GEL - AGING AND STABILITY TEST REPORT						
Product Description			SKYGEL5000B			
Lot No			UGB05022022			
Manufacturing Date			05022022			
Oven Date			05022022			
Input Quantity			6 X 260g			
TEST SPECIFICATION						
Temperature			55 \pm 5°C			
Viscosity			90 – 130 KcP			
AGING TEST						
Inspection Date	No of Week	Colour Change	Input Viscosity @ 25°C	Viscosity @ 25°C	Leaking	Remark
19/02	WEEK 2	—	113	113	—	
05/03	WEEK 4	—	113	113	—	
19/03	WEEK 6	—	113	113	—	
02/04	WEEK 8	—	113	113	—	
16/04	WEEK 10	—	113	113	—	
30/04	WEEK 12	—	113	113	—	
Remarks :						
1. (/) = OK (X) = NOT OK (-) = NOT APPLICABLE						
2. This stability show that the product's shelf life is 3 years						