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中国认可
国际互认
检测
TESTING
CNAS L2954

Final Report

Report Number: SDWH-M201904568-8(E)

Accelerated Aging Test (2 Years) of Impression material

According to ASTM F1980-16

Sponsor: Zhengzhou Huaer Electro-Optics Technology Co., Ltd

Address: Floor 11, B of Building 18, the National University Science
Park of Henan Province



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Supplementary Explanation

- (1) Please apply for rechecking within 15 days of receiving the report if there are any objections.
- (2) Any erasure or without special inspection and testing seal renders the report null and void.
- (3) The report is only valid when signed by the persons who edited, checked and approved it.
- (4) The results relate only to the articles tested.
- (5) The report shall not be reproduced except in full without the written approval of the institute.

Quality Assurance Statement

The Quality Assurance Unit inspected/audited this study in compliance with the following GLP regulations:

Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA). The laboratory is exempt from the following provisions: 21 CFR Part 58.105 Test and Control Article Characterization, and Part 58.113 Mixtures of Articles with Carriers.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the Testing Facility Management.

The final report was reviewed by the Quality Assurance Unit. The final report accurately describes the test methods in accordance with standard operating procedures, and the results are consistent with raw data of non-clinical studies conducted according to the study protocol.

Inspections	Date of Inspection	Date Reported to Study Director	Date Reported to Testing Facility Management.
Study Protocol	2019-11-13	2019-11-13	2020-03-14
Study Procedure	2019-11-14	2019-11-14	2020-03-14
Raw Data	2020-03-14	2020-03-14	2020-03-14
Final Report	2020-03-14	2020-03-14	2020-03-14

Quality Assurance Unit: Zou Jing
Quality Assurance

2020-03-14
Date

GLP Compliance Statement

This study was fully in accordance with the technical requirements of the study protocol.

This study was conducted in compliance with Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA).

The laboratory is exempt from the following provisions: 21 CFR Part 58.105 Test and Control Article Characterization, and Part 58.113 Mixtures of Articles with Carriers.

Verification Dates

Test Article Receipt	2019-10-25
Protocol Effective Date	2019-11-13
Technical Initiation Date	2019-11-14
Technical Completion Date	2020-01-18
Final Report Completion Date	2020-03-14

Edited by:

Jany Jaman

2020-03-14

Date

Reviewed by:

Li Dymei
Study Director



Date

Approved by:

[Signature]
Authorized Signatory

2020-03-14

Date

Sanitation & Environment Technology Institute, Soochow University

Summary

1 Test Article

Test Article Name	impression material
Manufacturer	Zhengzhou Huaer Electro-Optics Technology Co., Ltd
Address	Floor 11, B of Building 18,the National University Science Park of Henan Province
Model	Not supplied by sponsor (N/S)
Lot/Batch	N/S

2 Main Reference

Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (ASTM F 1980-16)

3 Test Method

The test sample was accelerated aged for 65 days to simulate 2 years real time aging.

Study protocol number: SDWH-PROTOCOL- GLP-M201904568-8.

Test Report

1 Purpose

The test was designed to simulate real time aging of the test sample.

2 Reference

Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (ASTM F 1980-16)

3 Compliance

Good Laboratory Practice Regulations, 21 CFR, Part 58
ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS—CL01 Accreditation criteria for the competence of testing and calibration laboratories) China National Accreditation Service for Conformity Assessment LABORATORY ACCREDITATION CERTIFICATE Registration No. CNAS L2954
RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061

4 Identification of Test Article

Test Article Name	impression material
Manufacturer	Zhengzhou Huaer Electro-Optics Technology Co., Ltd
Address	Floor 11, B of Building 18,the National University Science Park of Henan Province
Test Article Initial State	Sterilized, Ultraviolet sterilization
CAS Code	N/S
Model	N/S
Size	N/S
Lot/Batch	N/S
Test Article Material	vinyl polysiloxane
Packaging Material	Food grade PP
Physical State	Solid
Color	blue,white
Density	1.6
Stability	24 h<0.3%.336 h<0.3%
Solubility	0
Storage Condition	Room Temperature
Intended Clinical Use	Used for all crown and bridge, edentulous, orthodontic and implant impression techniques.

The information about the test article was supplied by the sponsor wherever applicable.
The Sponsor is responsible for all test article characterization data as specified in the GLP regulations.

5 Equipment and Reagents

5.1 Equipment

Equipment Name	Equipment Number	Calibration Expire
High temperature and high humidity aging box	SDWH314	2020-10-28
High temperature and low humidity aging box	SDWH315	2020-10-28

6 Test Methods and Results

6.1 Test condition: Accelerated Aging Temperature (60°C), High RH (70%), Low RH (20%), $Q_{10}=2$

6.2 Parameters:

Q_{10}	T_{AA}	T_{RT}	AAF	Desired RT	AAT
2	60°C	25°C	11.3	730days	65days

Q_{10} : Arrhenius reaction rate function states that a 10°C increase or decrease in temperature of a homogeneous process results in approximately, a two times or 1/2-time change in the rate of a chemical reaction ($Q_{10}=2$).

T_{AA} : Selected Accelerated Aging Temperature (°C);

T_{RT} : Ambient Temperature (°C).

AAF (Accelerated Aging factor) = $Q_{10}^{[(T_{AA}-T_{RT})/10]}$.

Desired RT: Desired simulated Real Time.

AAT: Accelerated Aging Time to simulate a Desired RT; AAT = Desired RT/AAF

6.3 Calculation for accelerated aging time:

Accelerated Aging factor (AAF) = $Q_{10}^{[(T_{AA}-T_{RT})/10]} = 2^{[(60-25)/10]} = 11.3$

Accelerated Aging Time (AAT) = Desired (RT)/AAF = 730/11.3 = 65 days

6.4 Aging schedule:

2.0 years Equivalent 65 Days	Date
High RH = 70%: 32 Days	From 2019-11-14 to 2019-12-16
Low RH = 20%: 33 Days	From 2019-12-16 to 2020-01-18

7 Record Storage

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

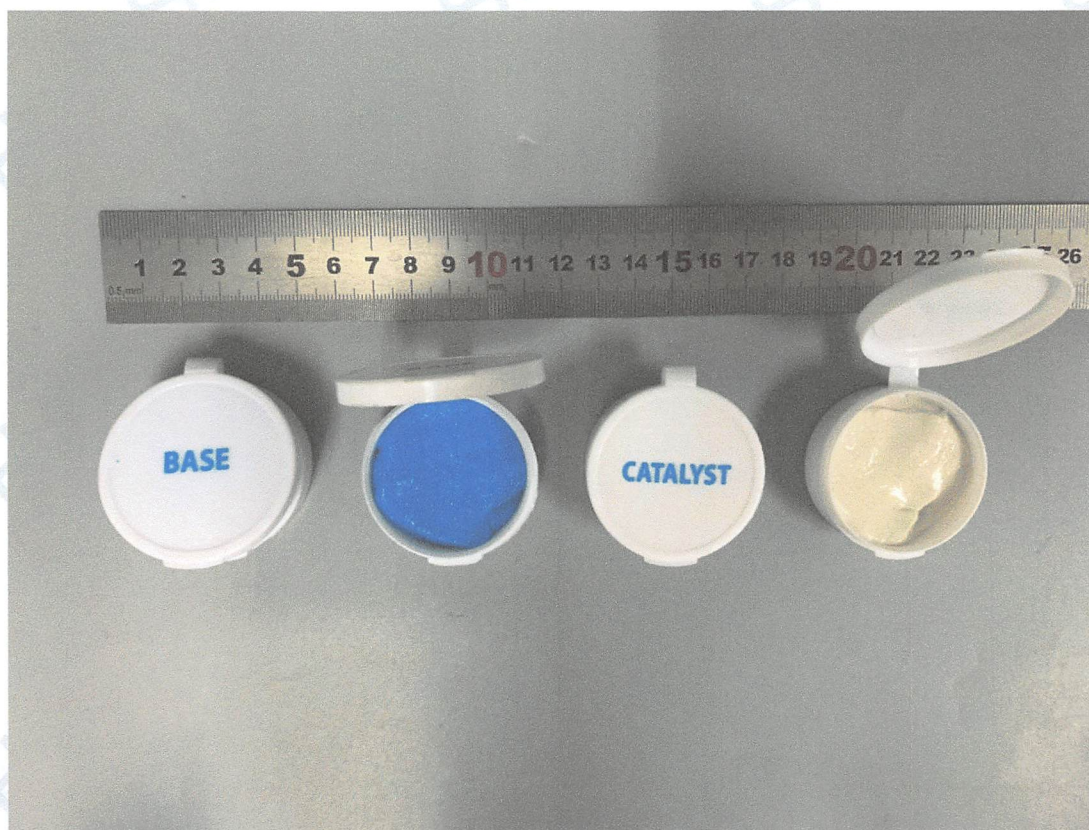
8 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

9 Deviation statement

There was no deviation from the approved study protocol which was judged to have any impact on the validity of the data.

Annex 1 Photograph of Test Article



Annex 2 Information Provided by Sponsor

1 Production Process

Not supplied by sponsor.

2 Other Information

Not supplied by sponsor.

End of Report

