GRUPPO GDA

www.gruppogda.it

SCHEDA TECNICA Art. MP9017

Produttore/Fabbricante: **XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO. LTD.**
Indirizzo: 4th Floor,No.1 Building,No.6 Ji'an Road,Tong'an District,Xiamen,Fujian,China

MASCHERINA CHIRURGICA MONOUSO IIR dim. 17,5x9,5cm (± 0,5 cm) – **MODELLO: MP9017- type IIR**

Importatore e distributore: **GDA srl**
MODELLO GDA: MP9017

Codice **CND**: T020601 - Numero di **repertorio BD/RDM**: 1968967

DESCRIZIONE: Mascherina chirurgica ad uso medico monouso 3 strati Classe I – Tipo IIR con elastici e nasello interno modellabile, non sterile, dim. 17,5x9,5cm (± 0,5 cm) col. Azzurro

Efficienza di filtrazione batterica (BFE) ≥ 99,9% - Pressione differenziale < 40 Pa/cm2

Dichiarazione conformità CE, conforme alla direttiva 93/42/CEE sui dispositivi medici di Classe I e alla normativa EN14683:2019– Rappresentate Europeo: Sungo Europe BV – Notifica NOTIS N. CIBG-20200672

Adattabile, traspirabile, confortevole, leggera, estensibile, avvolgente; priva di odore; eco-compatibile; anti PM 2.5, protezione fumo, odori, polveri, droplet, particelle non oleose, pollini.

SCADENZA : 3 ANNI

COMPOSIZIONE:

No.	materiali	specifiche
1	Primo strato Esterno : **PPspunbond**	25 gr/m2
2	Secondo strato intermedio filtrante: **PPmeltblown**	25 gr/m2
3	Terzo strato interno: **PPspunbond**	25 gr/m2
4	Elastici latex free	
5	Nasello in plastica con anima in metallo	

IMBALLAGGIO:

- 50 pezzi imbustati in scatola – 2000 pz / cartone – 40 scatole / cartone
- Misure scatola: 18,5x10x8 cm
- Dettagli cartone: 52*38*34cm - N.W. 7.0 kgs - G.W. 8.3kgs

ISTRUZIONI D'USO

1. Aprire la scatola, prendere la mascherina dai lati esterni con entrambe le mani, lato azzurro / nasello verso l'esterno
2. Distendere la mascherina appoggiandola sul viso e facendola aderire su naso, bocca, mento e fissando i laccetti dietro le orecchie

3. Adattare lo stringinaso al naso
4. Verificare che la mascherina aderisca bene al viso e sia comoda da indossare
5. Indossare correttamente come da simbologia su scatola:

6. Non toccare la parte interna della mascherina con le mani
7. Smaltimento assimilabile a quello dei rifiuti urbani indifferenziati, inserire possibilmente le mascherine monouso usate in un sacchetto.
   NON gettare la mascherina monouso in contenitori dedicati a utilizzi differenziati.

intertek
Total Quality. Assured.

TEST REPORT

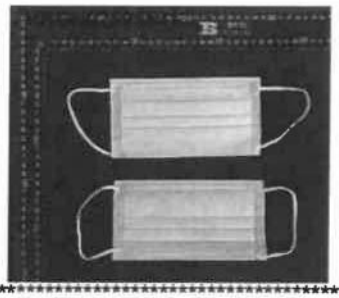
Applicant: XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD.
NO. 6, JI'AN ROAD, TONG'AN DISTRICT
XIAMEN CITY
CHINA

Number: HKGH02595531 S1

Date: May 25, 2020

This is to supersede Report No. HKGH02595531 dated May 25, 2020 due to information update

Submitted sample said to be	:
Item Name	: **Disposable Surgical Mask**
Item No.	: MP9017
Specification	: 17.5*9.5cm
Quantity	: 100 pieces
Manufacturer	: XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD.
Sample Received Date	: May 07, 2020
Testing Period	: May 07, 2020 to May 20, 2020



****

Conclusion:
The submitted sample was tested under the following requirements requested by the applicant, subject to the information stated in the remark and attached page(s) for details :

	Requirement	Result
(1)	Differential pressure [EN 14683:2019+AC:2019]	Pass
(2)	Splash resistance pressure [EN 14683:2019+AC:2019]	Pass
(3)	Bacterial filtration efficiency (BFE) [EN 14683:2019+AC:2019]	Pass
(4)	Microbial cleanliness [EN 14683:2019+AC:2019]	Pass

****

For and on behalf of :
Intertek Testing Services HK Ltd.

Cindy I.K. Chan
Vice President

Intertek Testing Services Hong Kong Limited
2/F Garment Centre
576 Castle Peak Road
Kowloon, Hong Kong
Tel +852 2173 8888
Fax +852 2786 1903
intertek.com.hk

TEST REPORT

Number : HKGH02595531 S1

(1) Differential pressure ^

Test Method: With reference to EN 14683:2019+AC:2019

Result:

Sample	Differential pressure (Pa/cm^2)	Requirement (Pa/cm^2)	Classification	Conclusion
1	32.7	<60 EN 14683:2019+AC:2019	Type II R	Pass
2	34.1			
3	33.3			
4	34.3			
5	33.5			

Remark :
^ = This is a subcontracting item

Date sample received : May 25, 2020
Testing period : May 07, 2020 to May 25, 2020

****

Intertek Testing Services Hong Kong Limited
2/F Garment Centre
576 Castle Peak Road
Kowloon, Hong Kong
Tel +852 2173 8888
Fax +852 2786 1903
intertek.com.hk

TEST REPORT

Number : HKGH02595531 S1

(2) Splash resistance pressure ^

Test Method: With reference to EN 14683:2019+AC:2019

Result:

Sample	Measured value	Requirement (kPa)	Classification	Conclusion
	Pressure			
	16.0 kPa			
1	pass	≥16.0 EN 14683:2019+AC:2019	Type II R	Pass
2	pass			
3	pass			
4	pass			
5	pass			
6	pass			
7	pass			
8	pass			
9	pass			
10	pass			
11	pass			
12	pass			
13	pass			
14	pass			
15	pass			
16	pass			
17	pass			
18	pass			

Intertek Testing Services Hong Kong Limited
2/F Garment Centre
576 Castle Peak Road
Kowloon, Hong Kong
Tel +852 2173 8888
Fax +852 2786 1903
intertek.com.hk

intertek
Total Quality. Assured.

TEST REPORT

Number : HKGH02595531 S1

Sample	Measured value	Requirement (kPa)	Classification	Conclusion
	Pressure			
19	pass			
20	pass			
21	pass			
22	pass			
23	pass			
24	pass			
25	pass			
26	pass			
27	pass			
28	pass			
30	pass			
31	pass			
32	pass			
Final result	pass			

Remark :
An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.
^ = This is a subcontracting item

Date sample received : May 25, 2020
Testing period : May 07, 2020 to May 25, 2020

****

Intertek Testing Services Hong Kong Limited
2/F Garment Centre
576 Castle Peak Road
Kowloon, Hong Kong
Tel +852 2173 8888
Fax +852 2786 1903
intertek.com.hk

TEST REPORT

Number : HKGH02595531 S1

(3) Bacterial Filtration Efficiency (BFE) ^

Test Method: With reference to EN 14683:2019+AC:2019

Dimensions of the test specimens : 175 mm x 175 mm

Result:

Sample	BFE (%)	Requirement (%)	Classification	Conclusion
1	100	≥98 EN 14683:2019+AC:2019	Type II R	Pass
2	100			
3	100			
4	100			
5	100			

Remark :
^ = This is a subcontracting item

Date sample received : May 25, 2020
Testing period : May 07, 2020 to May 25, 2020

****

Intertek Testing Services Hong Kong Limited
2/F Garment Centre
576 Castle Peak Road
Kowloon, Hong Kong
Tel +852 2173 8888
Fax +852 2786 1903
intertek.com.hk

TEST REPORT

Number : HKGH02595531 S1

(4) Microbial cleanliness ^

Test Method: With reference to EN 14683:2019+AC:2019

Result:

Sample	Microbial cleanliness (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
1	2	≤30 EN 14683:2019+AC:2019	Type II R	Pass
2	1			
3	2			
4	0			
5	0			

Remark :
^ = This is a subcontracting item

Date sample received : May 25, 2020
Testing period : May 07, 2020 to May 25, 2020

****

End of report

Intertek Testing Services Hong Kong Limited 2/F Garment Centre 576 Castle Peak Road Kowloon, Hong Kong Tel +852 2173 8888 Fax +852 2786 1903 **intertek.com.hk**

intertek
Total Quality. Assured.

To:	XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD.	Ref:	FC-2020-3708
Attention:		Date:	Jun 02, 2020

Re : Report Revision Notification

Intertek Testing Services Report Number HKGH02595531 Dated May 25, 2020

Please be informed that all the content recorded in the above captioned report will be void. This captioned report is now superseded by a revised Intertek Testing Services report, HKGH02595531 S1

Thank you for your attention.

For and on behalf of :
Intertek Testing Services HK Ltd.

Cindy I.K. Chan
Vice President

ISO9001

XIAMEN PROBTAIN NONWOVEN INC.

NO.6, JI'AN ROAD, TONG'AN DISTRICT, XIAMEN CITY, FUJIAN PROVINCE

Has been assessed by Zhongjian Certification Co., Ltd in respect of their Quality Management Systems and to comply with:

ISO9001:2015

Approval is hereby granted for registration providing the rules and conditions relating to certification are observed at all times

CERTIFICATION SCOPE:

DESIGN OF NONWOVEN AND NONWOVEN FACE MASK; PRODUCTION AND SALE OF NONWOVEN, NONWOVEN FACE MASK AND NONWOVEN PRODUCTS

(This certificate only covers the sites listed. If the covered scope involves pre-approval of administration permit or compulsory certification requirement,the scope only covers products and services within the permit license or compulsory certification scope)

Date of Issue	Valid Until
2017-10-31	**2020-10-30**

Certificate Number: **U0017Q50455R2M**

Organization Code: **91350200776019243B**

This certificate remains valid only if the certified organization accepts and passes regular surveillance audits.

Approval of the first surveillance audit	Approval of the second surveillance audit	Approval of the third surveillance audit
Zhongjian Certification Co.,Ltd.	Zhongjian Certification Co.,Ltd.	Zhongjian Certification Co.,Ltd.

UKAS MANAGEMENT SYSTEMS

0158

Lack of fulfilment of condition as set out in Condition for the Use of National Accreditation Marks by UKAS and UKAS Accredited Organizations may render this certificate invalid

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Authorised Signature for
GuangDong ZhongJian Certification Co., Ltd

This certificate remains the property of Guangdong Zhongjian Certification Co., Ltd of Quality System

The validity of this certificate could be confirmed via official Website Of CNCA (www.cnca.gov.cn)

Further to the certificate applicability, please enquire the certified organization: visit www.gzcc.org.cn or contact GZCC 020-66390902

Hunling Building, Guangzhou Dadaozhong, Guangzhou City, Guangdong Province, China (510600) Zhongjian Certification Co., Ltd.

MEDICAL DEVICES-QUALITY MANAGEMENT SYSTEMS CERTIFICATE

Certificate No.: CQC19QY20047R0S/46500

We hereby certify that

Xiamen Probtain Nonwoven INC./ Xiamen Probtain Medical Technology Co, LTD.

Unified Social Credit Code: 91350206778019243B

4th Floor,A Area 2th Floor,1th Building,Ji'An Road,Tong'An District, Xiamen,Fujian Province,P.R.China /4th Floor,1th Building,Ji'An Road,Tong'An District,Xiamen,Fujian Province,P.R.China

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

YY/T 0287-2017 / ISO 13485:2016

The Quality Management System Applies in the following area:

Manufacture of Disposable Medical Sanitary Materials and Nursing Supplies Within Qualifications

Certified since: November 20, 2019 Valid from: November 20, 2019 Valid until: November 19, 2022

After a surveillance cycle, this certificate is invalid unless used together with an Acceptance Notice of Surveillance Audit issued by CQC. Please advise your location for ongoing validity of this certificate.

Signed By: Liu Mei

CHINA QUALITY CERTIFICATION CENTRE

ISO14001
CERTIFICATE

Certificate No: 05518E20030R0M

We hereby certify that

XIAMEN PROBTAIN NONWOVEN INC.

ADDRESS: NO.6 JIANXI ROAD TONGAN DISTRICT XIAMEN,FUJIAN,P.R.CHINA

POST CODE: 361100

by reason of its

Environmental Management System

has been awarded this certificate for

compliance with the standards

GB/T24001-2016/ISO14001: 2015

The Environmental Management System applies to the following area

THE RELEVANT SITE OF XIAMEN PROBTAIN NONWOVEN INC., LOCATED AT NO.6,JIANXI ROAD,TONGAN DISTRICT, XIAMEN, FUJIAN, P.R.CHINA. THE DESIGN AND EXECUTION OF NONWOVEN,NONWOVEN FACE MASK AND NONWOVEN PRODUCTS

Date of Issue: May 2,2018

Date of Expiry: May 1,2021

Certification Body: China Environmental Protection United (Beijing) Certification Center Co., Ltd.

Certification Body Address: No.1, Yuhua South Road, Chaoyang District, Beijing, China

Issued by:

IAF CNAS

CMA
180015344189

CNAS
中国认可
国际互认
检测
TESTING
CNAS L10066

Test Report

Report Number: SSMT-R-2020-00436-02

Sample Name: Disposable Surgical Mask

Study Title: Skin Irritation Test

Standard: ISO 10993-10:2010

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD.

Area A, 2F&4F, No.1 Factory Building, No.6 Ji' an Road, Tong' an District, Xiamen, China

Contents

Explanation....3
Conclusion....4
Study verification and signature....5
Quality Assurance Statement and GLP Statement....6
1.0 Purpose....7
2.0 Reference....7
3.0 Test and control articles....7
4.0 Identification of test system....8
5.0 Animal Care and Maintenance....8
6.0 Justification of the test system....8
7.0 Equipment and Reagents....9
8.0 Experiment design and dose....9
9.0 Evaluation criteria....10
10.0 Results of the test....10
11.0 Deviation statement....11
12.0 Record....11
13.0 Confidentiality agreement....11

Explanation

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special 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 result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.
6. This experiment was carried out in the sub-site and the address is: No. 68, Yaoluo Road, Wujin District, Changzhou City.

Conclusion

The animal skin irritation test was conducted to assess the potential irritation of the test article.

Cut the test sample and control sample into about 2.5 cm×2.5 cm and applied them directly to the corresponding area of the animal's back skin for 4 hours. Observation for erythema and edema were conducted at 1 h, 24 h, 48 h and 72 h after removal of the patches.

The skin reaction on test sites did not exceed that on the control sites. The primary irritation index for the test article was calculated to be 0.

The test result showed that the applied sample did not induce skin irritation in rabbit under the test condition.

Study verification and signature

The study was carried out in accordance with the test protocol. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (ISO/IEC17025:2017, IDT) and RB/T214-2017. This study has been performed under Good Laboratory Practices regulations (FDA, 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies).

Date Received	2020-03-26
Technical Initiation Date	2020-04-07
Technical Completion Date	2020-04-10
Final Report Completion Date	2020-04-30

Edited by	Molly	2020.04.30 Date
Checked by	Suri	2020.04.30 Date
Authorized signatory	Daisy	2020.05.12 Date
FM	Daisy	2020.05.12 Date

Jiangsu Science Standard Medical Testing Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of the studies. This study has been performed under Good Laboratory Practices regulations (FDA, 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies) and in accordance to standard operating procedures and a standard protocol. The Quality Assurance Unit inspected this study on the dates listed below. Studies are inspected at time intervals to assure the quality and integrity of the study.

Phase Inspected	Date	Study Director	Management
Experimental Procedure	2020-04-07	2020-04-07	2020-04-07
Raw Data	2020-04-10	2020-04-10	2020-04-10
Final Report	2020-04-30	2020-04-30	2020-04-30

The findings of these inspections have been reported to Management and the Study Director.

QA: Ryun Zhu Date: 2020.04.30

GLP Statement

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of SSMT, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Study Director: Suri Date: 2020.04.30

1.0 Purpose

New Zealand rabbits were used to test the potential of the sample for skin irritation under test conditions.

2.0 Reference

Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization(ISO 10993-10:2010)

Biological evaluation of medical devices-Part 12:Sample preparation and reference materials(ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: Disposable Surgical Mask

Sterilization state: Unsterilized

Model: Non-Sterile/Flat/Ear Loop

Size: L

Lot/ Batch#: 20200227

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

Solubility: N/S

Test Article Material: N/S

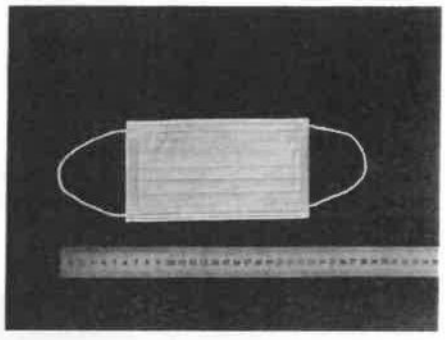
Packing Material: Plastic Bag

Storage Condition: Room Temperature

Manufacturers: XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD.

The manufacturer address: Area A, 2F&4F, No.1 Factory Building, No.6 Ji' an Road, Tong' an District, Xiamen, China

Sample photograph:



3.2 Control Article

Name: Medical gauze dressing

Manufacturer: Jiangxi David Medical Devices Co., Ltd.

Size: 5cm×7cm×8 layers

Lot/ Batch#: 20181102

Physical State: Solid

Color: White

Storage Condition: Room Temperature

4.0 Identification of test system

Species: New Zealand white rabbit

Number: 3

Sex: Female

Weight: Initial body weight not less than 2.0 kg

Health status: Healthy, young adult, nulliparous and not pregnant.

Housing: Animals were housed in groups in cages identified by a card indicating the lab number and test code.

Animal identification: Cage card

Quarantine: 5 days

5.0 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Genesc Biotechnolongy Co., Ltd <Permit Code: SCXK (SU) 2015-0002>

Bedding: NA

Feed: Rabbit Diet, Beijing Keao Xieli Feed Co., Ltd.

Water: Drinking water met the Standards for Drinking Water Quality (GB 5749-2006).

Cages: Stainless steel cage, Suzhou Fengqiao purification equipment Co., Ltd.

Environment: Temperature 16-26℃, Relative humidity 40%-70%. 12 hours of light alternating day and night.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy were selected.

Veterinarian: Vet takes care of the whole course.

Ethics: Test methods of operation were reviewed and approved by the Commission on Science Standard animal ethics.

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data.

6.0 Justification of the test system

6.1 The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control 15 % sodium dodecyl sulfate has been substantiated at SSMT with this method. Positive control test is conducted every six months. The last irritation index was 5.5 (polar test group) and the data was from the report SSMT-R-2018-00064-11 (Date: 2019-11-28). The last irritation index was 5.7 (non-polar test group) and the data was from the report SSMT-R-2018-00064-12 (Date: 2019-11-28).

6.2 The test article extract was directly applied to the rabbit skin, which is considered to be the best mean of

contact.

7.0 Equipment and Reagents

Steel straight ruler (SSMT-210)

Electronic balance (SSMT-075)

8.0 Experiment design and dose

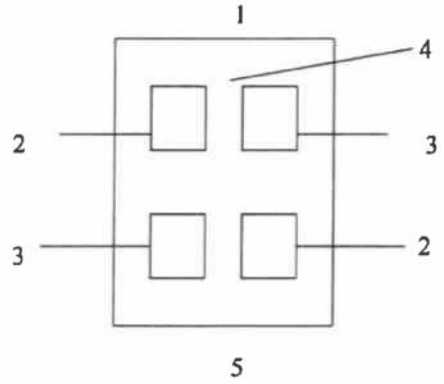
8.1 Sample preparation

The test sample and the control sample were cut randomly into 2.5 cm × 2.5 cm size and wetted with 0.9% sodium chloride injection.

8.2 Test method

Use the rabbits with healthy intact skin. Fur was generally clipped 16 h before testing on the backs of the rabbits, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10× 15 cm).

Apply the sample and the control to the skin on each side as shown in Figure 1. And then wrap the application site with a bandage (semi-occlusive) for 4 h. At the end of the contact time, remove the dressings.



1- Cranial end, 2- Test site, 3- Control site, 4- Clipped dorsal region, 5- Caudal end

Figure1 Location of skin application sites

8.3 Observation of animal

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each application site at each time interval. Record the appearance of each application site at 1 h,24 h, 48 h and 72 h following removal of the patches.

Table 1 Classification System for Skin Reaction

Reaction	Irritation score
Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3

Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Oedema Formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	**8**

NOTE: Other adverse changes at the skin sites were recorded and are reported.

8.4 Result calculation

Use only 24 h, 48 h and 72 h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades 24 h, 48 h and 72 h are totalled separately for each test sample and blank for each animal. The primary irritation score for an animal is calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index for the test sample add all the primary irritation scores of the individual animals and divide by the number of animals.

Calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.

9.0 Evaluation criteria

The primary irritation index is characterized by number (score) and description (response category) given in Table 2.

Table 2 Primary irritation index categories in a rabbit

Mean score	Response category
0-0.4	Negligible
0.5-1.9	Slight
2.0-4.9	Moderate
5-8	Severe

10.0 Results of the test

According to what observed, the response of skin on testing side did not exceed that on the control side. The primary irritation index for the test article was calculated to be 0. See Table 3.

Table 3 Dermal observations

Rabbit No	Group		Interval			
			1h	24h	48h	72h
X1501	Test Article	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0

X1502	Test Article	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
X1503	Test Article	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Negative Control	Erythema	0	0	0	0
		Oedema	0	0	0	0

Under the conditions of this study, the test article did not induce skin irritation in rabbit skin.

11.0 Deviation statement

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

12.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

13.0 Confidentiality agreement

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

CMA
180015344189

ILAC-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L10066

Test Report

Report Number: SSMT-R-2020-00436-01

Sample Name: Disposable Surgical Mask

Study Title: In Vitro Cytotoxicity Test

Standard: ISO 10993-5:2009

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.
C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD.
Area A, 2F&4F, No.1 Factory Building, No.6 Ji'an Road, Tong'an District, Xiamen,China

Contents

Explanation....3
Conclusion....4
Study verification and signature....5
Quality Assurance Statement and GLP Statement....6
1.0 Purpose....7
2.0 Standard....7
3.0 Test and control articles....7
4.0 Identification of test system....8
5.0 Justification of test system....8
6.0 Instruments and Reagents....8
7.0 Experiment design and dose....9
8.0 Evaluation criteria....10
9.0 Results of the test....10
10.0 Deviation statement....11
11.0 Record....11
12.0 Confidentiality agreement....11

Explanation

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special 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 result relate only to the articles tested.
5. The report shall not be reproduced except in full, without approval of the laboratory.

Conclusion

The study was to investigate the potential cytotoxicity of the test sample. The extract of the test article was added to L-929 cells and then incubated at 37℃ in 5% CO_2 for 24 hours. After the incubation, observe the cell morphology. The results were detected with MTT method. The results showed that the cytotoxicity ratio of the 100 % test article extract was 97.8% and the results of control groups showed the test was valid.

Under the conditions of this study, the extract of the test article did not show potential toxicity to L-929 cells.

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (IDT ISO/IEC 17025:2017) and RB/T 214-2017.This study has been performed under Good Laboratory Practices regulations (FDA, 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies).

Date Received	2020-03-26
Technical Initiation Date	2020-04-01
Technical Completion Date	2020-04-03
Final Report Completion Date	2020-04-30

Edited by Cindy 2020.04.30 Date

Checked by Bella 2020.04.30 Date

Authorized signatory Daisy 2020.04.30 Date

FM Daisy 2020.04.30 Date

Jiangsu Science Standard Medical Testing Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of the studies. This study has been performed under Good Laboratory Practices regulations (FDA, 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies) and in accordance to standard operating procedures. The Quality Assurance Unit inspected this study on the dates listed below. Studies are inspected at time intervals to assure the quality and integrity of the study.

Phase Inspected	Date	Study Director	Management
Experimental Procedure	2020-04-01	2020-04-01	2020-04-01
Raw Data	2020-04-03	2020-04-03	2020-04-03
Final Report	2020-04-30	2020-04-30	2020-04-30

The findings of these inspections have been reported to Management and the Study Director.

QA: Ryun zhu Date: 2020.04.30

GLP Statement

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of SSMT, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Study Director: Cindy Date: 2020.04.30

1.0 Purpose

The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.

2.0 Standard

Biological evaluation of medical devices Part 5: Tests for In Vitro Cytotoxicity (ISO 10993-5:2009)

Biological evaluation of medical devices Part 12: Sample preparation and reference materials (ISO 10993-12:2012)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: Disposable Surgical Mask

Sterilization state: Not sterilized

Model: Non-Sterile/Flat/Ear Loop

Size: L

Lot/ Batch#: 20200227

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

Solubility: N/S

Test Article Material: N/S

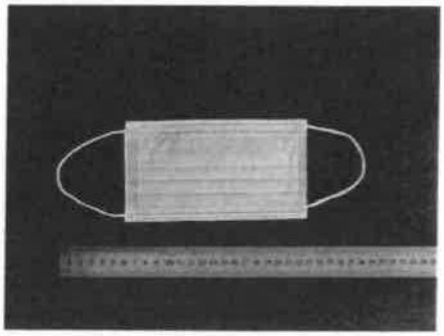
Packing Material: Plastic Bag

Storage Condition: Room temperature

Manufacturers: XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD.

Manufacturer address: Area A, 2F&4F, No.1 Factory Building, No.6 Ji'an Road, Tong'an District, Xiamen,China

Sample photograph:



3.2 Control Articles

3.2.1 Negative Control Article Name: High Density Polyethylene

Manufacturer: Jiangsu haiaosihui biotechnology co., LTD.

Size: 1.6 mm thick, 300*300 mm

Lot/ Batch#: M02F017

Physical State: Solid

Color: White

Storage Conditions: Room temperature

3.2.2 Positive Control Article Name: ZDEC

Manufacturer: Tokyo Into Industrial Co., Ltd.

Size: 25 g

Lot/ Batch#: DUDQG-JF

Physical State: Solid

Color: White

Storage Condition: Room temperature

Concentration: 0.1%

3.2.3 Blank Control Name: MEM medium, with addition 10% FBS

Physical State: Liquid

Color: Pink

Storage Condition: 4 ℃

4.0 Identification of test system

Mouse fibroblast L-929 cells obtained from ATCC CCL1 (NCTC clone 929).

5.0 Justification of test system

5.1 Historically, mouse fibroblast L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles.

5.2 The test article was extracted and administered in vitro to mouse fibroblast L-929 cells through a solvent compatible with the test system. This was the optimal route of administration available in this test system as recommended in the standard.

6.0 Instruments and Reagents

6.1Instruments

CO_2 Incubator (SSMT-279)

Biological microscope（SSMT-278）

Clean bench (SSMT-028)

Bench type low speed centrifuge (SSMT-048)

Vapour-bathing Constant Temperature Vibrator (SSMT-004)

Steel Straight Scale (SSMT-072)

Electronic Balance (SSMT-015)

Multiskan Spectrum Microplate Spectrophotometer (SSMT-139)

Mini Vibrator (SSMT-057)

6.2 Reagents

FBS

MEM

Trypsin

Penicillin, Streptomycin sulfate

PBS

MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazolium bromide)

Isopropyl alcohol

7.0 Experiment design and dose

7.1 Sample preparation

Aseptic extracting the test article (test article to volume of vehicle) according to the table below. Sealed and incubated in Vapour-bathing Constant Temperature Vibrator at 37 ℃ and 60 rpm for 24 hours. After the extraction, check the extraction changes, and immediately use for the experiment, the leach was not filtered, centrifuged or diluted. No pH adjustment.

Table 1 Sample preparation

Sampling		Aseptic Agitation Extraction In Inert Container				Final Extract
Sampling Manner	Actually sampling	Extraction solvent	Extraction ratio	Solvent volume	Condition	Clear or Not
Random sampling	18.0 cm^2	MEM medium (10% FBS)	3 cm^2 : 1 ml	6.0 ml	37 ℃, 24 h	Clear

The blank control (MEM medium, with addition 10% FBS) and negative/positive controls were prepared in the same condition.

7.2 Test method

Aseptic procedures were used for handling cell cultures.

L-929 cells were cultured in MEM medium (10% FBS, Penicillin 100 U/ml, Streptomycin sulfate 100 μg/ml) at 37℃ in a humidified atmosphere of 5% CO_2, then digested by 0.25% trypsin containing EDTA to get single cell suspension. And obtain a 1×10^5 cells/ml suspension by centrifuging (200 g, 3 min) and re-dispersing in MEM medium finally.

The suspended cells were dispensed at 100 μl per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37℃, >90%humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory.

After the cells grew to form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 μl of extract of test article (100%, 75%, 50%, 25%), control article, negative article (100%) and positive article (100%) respectively. The 96-well plate was incubated at 37℃ in cell incubator of 5% CO_2 for 24 h. Six replicates of each test were tested.

After 24 h incubation, observe the cell morphology first and then discard the culture medium. A 50 μl aliquot of MTT (1 mg/ml) was added to each well and then incubated at 37℃ in a humidified atmosphere of 5% CO_2 for 2 hours. The liquid in each well was tipped out and 100 μl isopropanol was added to each well to suspend the cell layer. The microporous plate was vibrated for 10 min and monitored by the optical density at 570 nm on the

microplate analyzer.

7.3 Statistical method

Mean±standard deviation ($\bar{x}$±s)

Viab. %=100×OD_{570e}/OD_{570b}

Where: OD_{570e}——is the mean value of the measured optical density of test sample/negative control/positive control;

OD_{570b}——is the mean value of the measured optical density of the blanks.

7.4 Observation of the cell morphology

Table 2 Observation of the cell morphology

Grade	Conditions of all cultures
0	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
1	Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Not more than 50 % of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; not more than 50 % growth inhibition observable.
3	Not more than 70 % of the cell layers contain rounded cells or are lysed; cell layers not completly destroyed, but more than 50 % growth inhibition observable.
4	Nearly complete or complete destruction of the cell layers.

8.0 Evaluation criteria

8.1 The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated.

8.2 The lower the Viab.% value, the higher the cytotoxic potential of the test article is.

8.3 If viability is reduced to < 70% of the blank, it has a cytotoxic potential.

8.4 The Viab.% of the 100% extract of the test article is the final result.

9.0 Results of the test

Table 3 Results of the cell vitality

Group	$\bar{x}$±s	Viability%	The morphology of the extracted cells was observed under the microscope
Blank control	0.699±0.026	100.0	0
Negative control	0.721±0.030	103.2	0
Positive control	0.041±0.008	5.9	4

100% test article extract	0.684±0.019	97.8	0
75% test article extract	0.687±0.022	98.2	0
50% test article extract	0.704±0.020	100.6	0
25% test article extract	0.715±0.028	102.2	0
Conclusion	Under the conditions of this study, the test article did not show potential toxicity to L-929 cells.		

10.0 Deviation statement

There was no deviation from the approved standard operating procedure which were judged to have any impact on the validity of the date.

11.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

12.0 Confidentiality agreement

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