MedGaea Life Sciences Institute

Report NO.
RE26057IR01

Intracutaneous Irritation Study in White Rabbits TPU / 70D Nylon Fabric

Study Report

GLP Compliance
Registered No. 0010

MedGaea Life Sciences Institute

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RE26057IR01

Intracutaneous Irritation Study in White Rabbits
TPU / 70D Nylon Fabric

The study complied with the Taiwan FDA GLP (2019), OECD-GLP (ENV/MC/CHEM(98)17,1997) and U.S. FDA (21 CFR Part 58, 2025) on principles of Good Laboratory Practice for Nonclinical Laboratory Studies. The study was performed in accordance with the agreed protocol and described in this report providing a true and accurate record of the results. The test article characteristics and its related properties in vehicle including purity, concentration, stability and homogeneity are provided and confirmed by the sponsor, and are excluded from GLP.

Wei-Cheng Cheng Ph.D
Study Director

04/14/2026
Date

MedGaea Life Sciences Institute

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QUALITY ASSURANCE STATEMENT

In compliance with the Taiwan FDA, OECD and U.S. FDA (21 CFR Part 58) "Good Laboratory Practice for Nonclinical Laboratory Studies", the Quality Assurance Unit conducted study-based type of audits on facility, equipment, personnel, test methods, raw data, and records regularly.

The study report had been reviewed and presented for internal approval. All parts of the experimentation involved were conducted according to the protocol. All original records, raw data, and documentations were truthfully transferred and addressed in the results of this report.

Inspection record：

Inspection Date	Inspection Phase	Date of Reports to	
		Study Director	Management
03/13/2026	Protocol	03/13/2026	03/13/2026
03/20/2026	Extraction of test article	03/23/2026	03/23/2026
03/23/2026	Administration	03/23/2026	03/23/2026
04/09/2026	Raw data	04/09/2026	04/09/2026
04/09/2026	Study report	04/09/2026	04/09/2026

Yi-Jie Liao

Quality Assurance Unit in Charge

04/14/2026
Date

MedGaea Life Sciences Institute

Test Facility: MedGaea Life Sciences Institute
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Study Director: Wei-Cheng Cheng
Address: 7F., No.45, Lane 3, Sec.1, Zhongzheng E. Rd., Tamsui Dist., New Taipei City, Taiwan

Sponsor: JIUNDAR INDUSTRIAL CO., LTD.
Address: No. 9, Aly. 2, Ln. 252, Sanjun St., Shulin Dist., New Taipei City 238024, TAIWAN

Study Announcement

The study report is valid for the test article used only.
The study report could not be recopied or extracted without the permission from MedGaea Life Sciences Ltd.
The study report is invalid without endorsement of MedGaea Life Sciences Ltd.

Protocol Number: PE26057IR01

Experimentation Staff

Test article preparation: Bo-Cheng Su, Pei-Yu Chiou
Administration: Chia-Wei Lin, Pei-Yu Chiou
Grading of skin reactions: Chia-Wei Lin, Pei-Yu Chiou
Quality assurance unit in charge: Yi-Jie Liao, Syuan-Yu Chang

Study Period

Experimental starting: 03/20/2026
Health assessment period: 03/20/2026~03/22/2026
Extraction of the test article: 03/20/2026~03/23/2026
Test article administration: 03/23/2026
Observation of skin reaction: 03/23/2026~03/26/2026
Experimental completion: 04/08/2026

CONTENTS

SUMMARY

The purpose of this study was to investigate the irritation potential in New Zealand white rabbits after intracutaneous injection of the test article “TPU / 70D Nylon Fabric” extracts. The experiment was performed following the test guideline of ISO 10993-23 (2021/Amd 1:2025).

The test article was extracted in normal saline and cottonseed oil. After the dorsal fur of the rabbits was shaved, a 0.2 mL of each test article saline extract was injected intracutaneously into five separate sites on the upper left side of the dorsal skin. Similarly, a 0.2 mL of each saline control solvent was injected on upper right side of the dorsal skin on the same rabbit. The above procedures were repeated for cottonseed oil extract and control solvent on the lower area of the dorsal skin. Each injected site was evaluated for erythema and oedema formation at (24 ± 2), (48 ± 2) and (72 ± 2) h after the injection. The results revealed that there was no obvious intracutaneous reactivity induced by the test article extracts as compared to controls. Under the conditions of this study, the test article extracts met the requirements of the test since the final test sample score was less than 1.0.

INTRODUCTION

This study was followed the test guideline of ISO 10993-23 (2021/Amd 1:2025) to evaluate skin responses to the test article extract by a single intracutaneous injection.

MATERIALS AND METHODS

1 Test Article Information
- 1.1 Name: TPU / 70D Nylon Fabric
- 1.2 Batch/Lot No.: J685-10-58-F / 70D
- 1.3 Package: Bag
- 1.4 External features: Flat
- 1.5 Color: Black
- 1.6 Major components: TPU / 70D Nylon Fabric
- 1.7 Storage condition: Room temperature
- 1.8 Receiving date: 02/12/2026
- 1.9 Labeled expiry date: 02/09/2028

The above information was enclosed in Appendix 4.

2 Extraction Solvents
- 2.1 Polar solvent: Normal saline (TAI YU CHEMICAL & PHARMACEUTICAL CO., LTD., Lot No. AK1307)
- 2.2 Non-polar solvent: Cottonseed oil (Sigma-Aldrich, Lot No. MKCT7708)

3 Animals
- 3.1 Species/Strain (sex): New Zealand white rabbits (male)
- 3.2 Source: Taiwan Livestock Research Institute, Ministry of Agriculture
- 3.3 Body weight: 3.2~3.5 kg
- 3.4 Reasons for choosing the animals: New Zealand white rabbits have been proven to be a suitable model for intracutaneous irritation studies, and have been widely used in single dose intracutaneous irritation studies.

4 Feeding and Care (SOP: MG-QP-1702)
- 4.1 Housing: Animal Center Room D, MedGaea Life Sciences Institute
- 4.2 Condition
  - 4.2.1 Temperature: 20 ± 3°C
  - 4.2.2 Humidity: 50 ± 20%
  - 4.2.3 Lighting: 12 hours (06:00 on, 18:00 off)
- 4.3 Environmental monitoring
  Temperature, humidity: Daily
- 4.4 Cage and animal no.
  - 4.4.1 Acclimation period: One rabbit per cage
  - 4.4.2 Study period: One rabbit per cage

4.5 Feeding
- 4.5.1 Name: Laboratory Rabbit Diet 5321
- 4.5.2 Brand: LabDiet, USA
- 4.5.3 Source: PMI Nutrition International, USA
- 4.5.4 Access to feed: *ad libitum*

4.6 Drinking water
- 4.6.1 Source: Reverse osmosis treated Tamsui District tap water. The treated water was fed into sterilized water bottles before use.
- 4.6.2 Access to water: *ad libitum*

5 Health Assessment

All animals underwent daily health assessment for three days before treatment. After the health assessment, only the healthy animals were selected for the study.

6 Individual and Group Identification (SOP: MG-ARS-016, MG-ARS-018)

6.1 Individual identification: The animals were identified by ear-tagging.

6.2 Group identification: The cages were properly labeled for identifications by the room number, cage number, species/strain, sex, study number, study name, study period, in-housing date, and animal I.D. number, etc.

7 Group Design (Guideline: ISO 10993-23 (2021/Amd 1: 2025); SOP: MG-QP-1850, MG-ARS-019)

Groups	Polar extraction group		Non-polar extraction group	
	Control	Treatment	Control	Treatment
Number of animals	3			
Testing sample	Normal saline	Test article saline extract	Cottonseed oil	Test article oil extract
Applied location	Right upper dorsal skin	Left upper dorsal skin	Right lower dorsal skin	Left lower dorsal skin

Remark: The test article extract and the control solvent were applied at different sites on the same rabbit. Three rabbits were tested in this study.

8 Volume of Administration

8.1 Control groups: Extraction vehicles (saline and cottonseed oil), 0.2 mL/site.

8.2 Treatment groups: Test article extracts (saline and cottonseed oil extracts), 0.2 mL/site.

9 Preparation and Administration of the Test Article Extract (SOP: MG-QP-1803)

9.1 Preparation: Normal saline and cottonseed oil are solvents used for polar and non-polar extractions in this study. According to the ISO 10993-12 (2021/Amd 1: 2025), the extraction ratio is determined as 6 cm^2/mL. Therefore, 10.0 mL of extraction solvent was used for 60 cm^2 of test article. The extraction was carried out at 50 ± 2°C for 72 ± 2 hours with constant agitation. The test article saline extract was clear and colorless, and the oil extract was clear and yellow. The extracts were directly applied to animals without centrifugation, filtering, adjusting pH and any additional processing or storage.

9.2 Method, route and frequency of administration: A single dose of the test article extract and the control solvent was injected intracutaneously into the dorsal skin of each rabbit.

9.3 Reasons for selecting the administration method: The administration method has been suggested by the test guideline of ISO 10993-23 (2021/Amd 1: 2025).

10 Procedures (SOP: MG-ADS-006)

10.1 Prior to study, the fur on the dorsal skin was clipped in one direction with an electric animal shaver. Animals with abrasions or skin diseases on the clipped skin surfaces were excluded from the study.

10.2 On the treatment day, 0.2 mL of the test article extract was injected intracutaneously into five sites on the left upper (test article saline extract) and left lower areas (test article oil extract) of the dorsal skin. Each injection site was spaced approximately 2 cm apart.

10.3 Similarly, 0.2 mL of the control solvent was injected intracutaneously into right upper (polar solvent) and right lower areas (non-polar solvent) of the dorsal skin.

11 Animal Observation and Items for Assessment

11.1 Based on the criteria of “Scoring system for intracutaneous (intradermal) reactions” (Appendix 3), the skin reactions at the treated areas were observed and recorded, including erythema, eschar formation and oedema at 0, (24 ± 2), (48 ± 2) and (72 ± 2) h after injection.

DATA MANAGEMENT

After the (72 ± 2) h grading, all erythema grades plus oedema grades (24 ± 2) h, (48 ± 2) h and (72 ± 2) h were totaled separately for each test sample or blank for each individual animal. To calculate the score of a test sample or blank on each individual animal, divided each of the totals by 15 (3 scoring time points × 5 test or blank sample injection sites). To determine the overall mean score for each test sample and each corresponding blank, added the scores for the three animals and divided by three. The final test sample score was obtained by subtracting the score of the blank from the test sample score. If at any observation period the average reaction to the test sample is questionably greater than the average reaction to the blank, repeat the test using three additional rabbits. The requirements of the test are met if the final test sample score is 1.0 or less. The test is valid when each of five normal saline control sites in each animal at all timepoints is Grade 0, and each of five cottonseed oil control sites in each animal at all timepoints is ≤ Grade 1.

AMENDMENTS / DEVIATIONS

This study was completed in accordance with the approved protocol without deviations.

ARCHIVING

All the study-related raw data, documents, records, test article, study protocol, study report and specimens are kept at MedGaea Life Sciences Institute archives D-4 and 106 for a defined period. During this period, agents authorized by the sponsor can apply to review the records.

RESULTS

This study was conducted to investigate the potential intracutaneous irritation effect of the "TPU / 70D Nylon Fabric" extracts on the skin of New Zealand white rabbits. In this study, there was no obvious intracutaneous reactivity induced by the test article extracts as compared to controls. The detail scores for intracutaneous reaction of each rabbit at (24 ± 2), (48 ± 2) and (72 ± 2) h after injection were listed in Table 1 and Appendix 2. The final test sample score was less than 1.0 in both groups injected with saline and oil extracts (Table 2).

CONCLUSION

This study was performed following the test guideline of ISO 10993-23 (2021/Amd 1: 2025). After the dorsal fur of the animals was shaved, the test article saline and oil extracts were injected intracutaneously into five separate sites on the left side of the dorsal skin. Similarly, the control solvent was injected intracutaneously on the right side of the dorsal skin. The intracutaneous reactions were observed at (24 ± 2), (48 ± 2) and (72 ± 2) h after injection.

In this study, there was no obvious intracutaneous reactivity to be observed at the injection sites of the test article extracts as compared to controls. Thus, the test article “TPU / 70D Nylon Fabric” extracts met the requirements of the intracutaneous test since the final test score of the test article was less than 1.0.

REFERENCES

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2. Animal welfare requirements. In: Biological evaluation of medical devices-Part 2, ISO 10993-2 (2022) International Standards Organization.

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4. Biological reactivity tests, In-Vivo. In: United States Pharmacopeia (USP-NF) <88>, (2025), Issue 2.

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7. Principles on good laboratory practice. (1997) Organization for Economic Cooperation and Development.

8. Skin irritation study. In: Guideline for the Nonclinical Pharmacology/Toxicology Studies Medicinal Products Applications (2014) Ministry of Health and Welfare, Executive Yuan, Taiwan.

9. Tests for irritation. In: Biological evaluation of medical devices - Part 23, ISO 10993-23 (2021/Amd 1:2025) International Standards Organization.

10. Biological evaluation of medical device－Part 12: Sample preparation and reference materials. ISO 10993 (2021/Amd 1:2025) International Standards Organization.

Table 1. Individual Animal Score of Intracutaneous Reactions[#]

Animal I.D.	Groups			
	Polar extraction		Non-polar extraction	
	Control[a]	Treatment[b]	Control[c]	Treatment[d]
2605721145	0.0	0.0	0.0	0.0
2605721147	0.0	0.0	0.0	0.0
2605721149	0.0	0.0	0.0	0.0

[#]Erythema and oedema scores for the test article extracts and control solvent were totaled and divided by 15 (3 grading points × 5 test injection sites).

[a] Normal saline

[b] Test article saline extract

[c] Cottonseed oil

[d] Test article oil extract

Table 2. The Overall Mean Score and Final Test Sample Score

Score	Groups			
	Polar extraction		Non-polar extraction	
	Control[a]	Treatment[b]	Control[c]	Treatment[d]
Overall mean score[†]	0.0	0.0	0.0	0.0
Final test sample score[‡]	0.0		0.0	

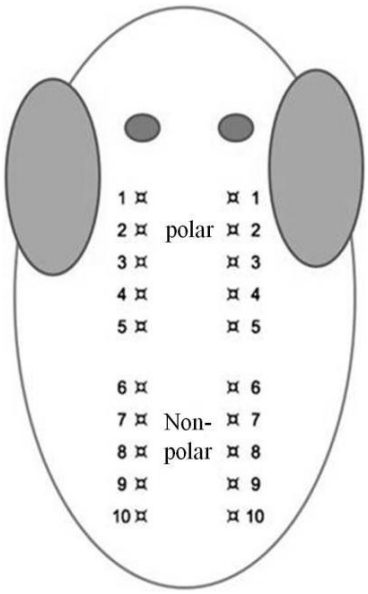
[†]Overall mean score = $\frac{\text{Sum of individual animal score}}{3}$

[‡]Final test sample score = overall mean score of test – overall mean score of control

The minimum of final test sample score is 0.

[a] Normal saline
[b] Test article saline extract
[c] Cottonseed oil
[d] Test article oil extract

Appendix 1. Arrangement of Injection Sites



Injection intracutaneously of 0.2 mL test article extract at 5 sites on left side of each rabbit (spot 1~5 for the test article saline extract, and spot 6~10 for the test article oil extract). Similarly, inject 0.2 mL of the solvent control at 5 sites on right side of each rabbit (spot 1~5 for normal saline control, and spot 6~10 for cottonseed oil control).

Appendix 2. Intracutaneous Reaction Scores in Individual Rabbit

Polar extraction

Time point (h)	Animal I.D.	Group[a]	Erythema	Oedema	Group[b]	Erythema	Oedema
	Injection sites	Spot	1 2 3 4 5	1 2 3 4 5	Spot	1 2 3 4 5	1 2 3 4 5
24	2605721145	Control	0 0 0 0 0	0 0 0 0 0	Treatment	0 0 0 0 0	0 0 0 0 0
	2605721147		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0
	2605721149		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0
48	2605721145	Control	0 0 0 0 0	0 0 0 0 0	Treatment	0 0 0 0 0	0 0 0 0 0
	2605721147		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0
	2605721149		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0
72	2605721145	Control	0 0 0 0 0	0 0 0 0 0	Treatment	0 0 0 0 0	0 0 0 0 0
	2605721147		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0
	2605721149		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0

[a] Control, normal saline (five injection sites per animal)
[b] Treatment, test article saline extract (five injection sites per animal)

Appendix 2. Intracutaneous Reaction Scores in Individual Rabbit (Cont'd)

Non-polar extraction

Time point (h)	Animal I.D.	Group[c]	Erythema	Oedema	Group[d]	Erythema	Oedema
	Injection sites	Spot	6 7 8 9 10	6 7 8 9 10	Spot	6 7 8 9 10	6 7 8 9 10
24	2605721145	Control	0 0 0 0 0	0 0 0 0 0	Treatment	0 0 0 0 0	0 0 0 0 0
	2605721147		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0
	2605721149		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0
48	2605721145	Control	0 0 0 0 0	0 0 0 0 0	Treatment	0 0 0 0 0	0 0 0 0 0
	2605721147		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0
	2605721149		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0
72	2605721145	Control	0 0 0 0 0	0 0 0 0 0	Treatment	0 0 0 0 0	0 0 0 0 0
	2605721147		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0
	2605721149		0 0 0 0 0	0 0 0 0 0		0 0 0 0 0	0 0 0 0 0

[c] Control, cottonseed oil (five injection sites per animal)
[d] Treatment, test article oil extract (five injection sites per animal)

Appendix 3. Scoring System for Intracutaneous (Intradermal) Reaction

Skin Reaction	Grade
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 1 mm)	3
· Severe oedema (raised more than 1 mm and extending beyond exposure area)	4

Appendix 4. Test Article Information Sheet

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INFORMATION FOR
■TEST ARTICLE/□SAMPLE/SPECIMEN
□CONTROL ARTICLE SHEET

管制文件章 品保室(麥)

Medical device

Sponsor's company name	JIUNDAR INDUSTRIAL CO., LTD.
Sponsor's address	No. 9, Aly. 2, Ln. 252, Sanjun St., Shulin Dist., New Taipei City 238024, TAIWAN
Test article name	TPU / 70D Nylon Fabric
Package	■Bag □Tube □Box □Bottle □Other:
External features	□Irregular □Liquid □Powder ■Flat □Membrane □Tube □Other:
Color	Black
Major components	TPU / 70D Nylon Fabric
Storage condition	■Room temperature □Refrigerated □Frozen
Expiration date	■Labeled expiry date: 02/09/2028 □Minimum validity for testing: MM/DD/YYYY
Batch/Lot No.	J685-10-58-F / 70D
Surface area of test article	**Surface area per test article__-__cm²** **Thickness: 0.18 mm (Thickness < 0.5mm or ≧ 0.5mm)** *Please provide the surface area if applicable. (This area includes the combined area of all tissue contacting surfaces of the test article.)
Remark/Requirement	
Sponsor Signature	

Note:

1. Please indicate" - "where not applicable.
2. MDG is not responsible and liable for any test article properties. The test article information listed above is provided and confirmed by the sponsor. Sponsor is take fully responsibility on the test article chemical and physical characteristics, and it's related analyses information.
3. Target Regulatory Authority(ies) (multiple selections allowed):
   ■TFDA ■US FDA ■ CE Marking ■NMPA □Others:

Appendix 4. Test Article Information Sheet (Cont'd)