Title: *Tests for Local Effects after Implantation of Finished Products* *Report Form*

Customer Code: M0230030201007/01
Form Code: F02-P38

Identification

Applicant	Rasa Salamat Arvand		
Address	National Institute of Genetic Engineering and Biotechnology, Pajoohesh Blvd.		
Batch Number	02032331		
Product Name	Revaheal Sept		
Date of receipt	1403.02.01	**Test Duration**	110-120 Days
Date of Test	1403.02.03	**Number of received items**	9 Samples
Date of Report	1403.06.31	**Number of tested items**	3

Animal Management

Species	Rat	**Body Weight Range**	300-350 g
Strain/Type	Wistar	**Number of Treated Animals (right side)**	3
Sex	Male	**Number of Control Animals (left side)**	3

Sample Preparation

Administration Site	Based on the customer's request was implanted in the: Subcutaneous ☒ Muscle ☐ Bone ☐ Brain ☐
Sample application	Hemodialysis
Sample type	non degradable solid
Negative Control	PE (Polyethylene was selected as the negative control material in accordance with ISO 10993-6, since it is considered a biocompatible and inert polymer commonly used in implantation studies)
Positive Control	PVC
Implant size	2-3×5-10 mm

Animal Husbandry

Food	Standard pellet provided from the authorized supplier, and unlimited supply of drinking water
Housing	Healthy animals were acclimatized to the laboratory conditions before the treatment, and then they were housed in spatial cages identified by a card indicating the required data
Humidity	At least 30% and preferably not exceed 70%
Lighting	12 hours light, 12 hours dark
Temperature	22 ± 3^0C

❖ Healthy, adult and young rats (6-8 weeks old) were used. Before entering the test, the animals were examined for appearance (checking the health of the skin, hair, eyes and the absence of wounds or lesions), respiratory status and behavior (assessing activity level, response to stimulation and signs of stress or pain), and no signs of appearance or behavior disorders were observed.

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Description of product

Material composition: This Wound antiseptic solution provides effective disifection while promoting tissue regeneration and accelerating the healing process. It contains silver, Known for its strong antibacterial properties, and chitosan, which enhances wound healing and tissue repair.

Test Results

All animals appeared clinically **Normal** throughout the study. Histological Evaluation System - Cell Type/Response is shown at the Table.

	Animals					
	Treatments			Controls		
	1	2	3	1	2	3
A) Inflammation						
Polymorphonuclear	0	0	0	0	0	0
Lymphocytes	0	0	0	0	0	0
Plasma cells	0	0	0	0	0	0
Macrophages	0	0	0	0	0	0
Giant cells	0	0	0	0	0	0
Necrosis	0	0	0	0	0	0
Sub Total (× 2)	0	0	0	0	0	0
B) Neovascularization	0	0	0	0	0	0
Fibrosis	0	0	0	0	0	0
Fatty infiltrate	0	0	0	0	0	0
Sub Total (B)	0	0	0	0	0	0
Total (A+B)	0	0	0	0	0	0
Group Total	0			0		
Average	0			0		
Treatments –Controls	0					
Traumatic necrosis	Absent	Absent	Absent	Absent	Absent	Absent
Foreign debris	Absent	Absent	Absent	Absent	Absent	Absent
No. sites examined	Complete	Complete	Complete	Complete	Complete	Complete

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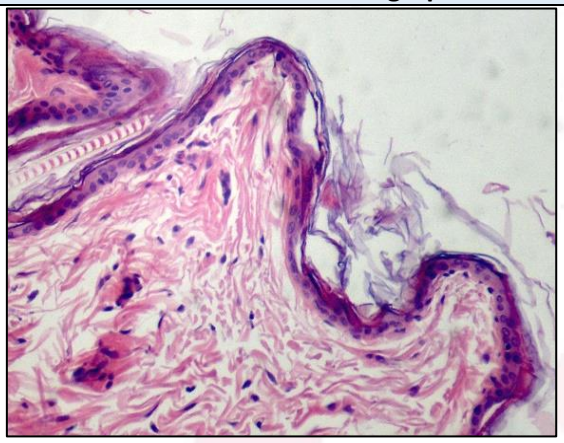
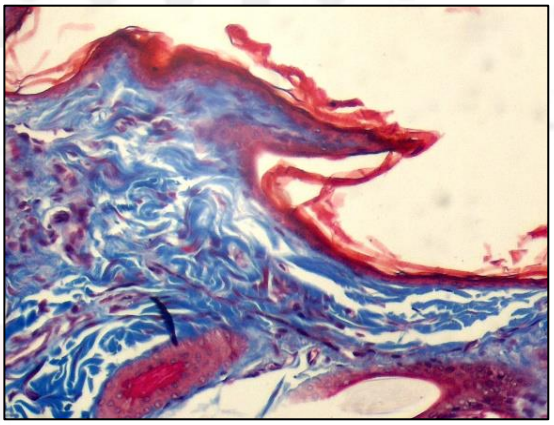
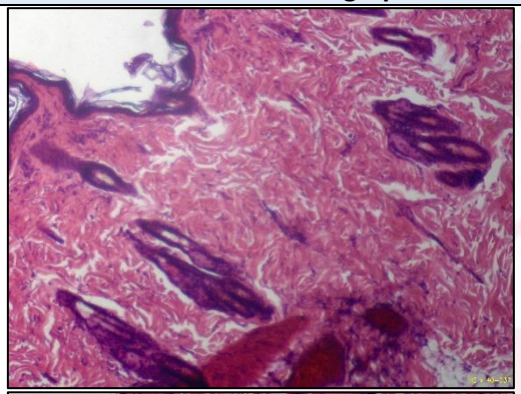
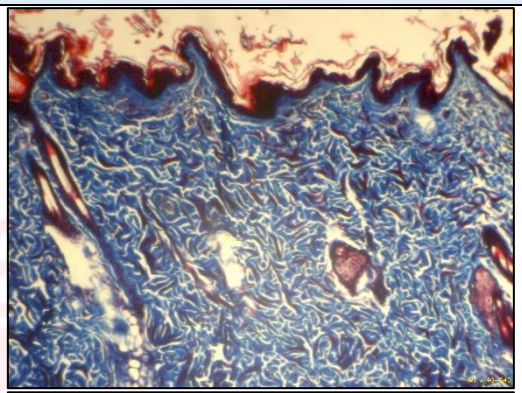
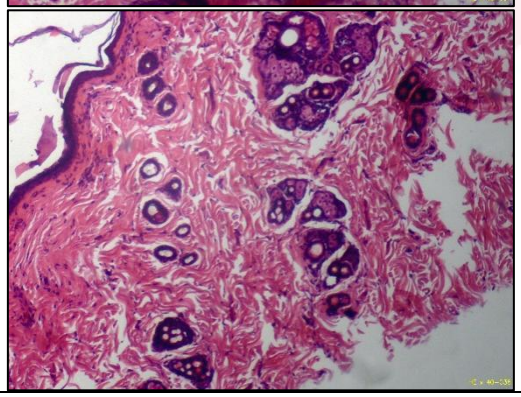
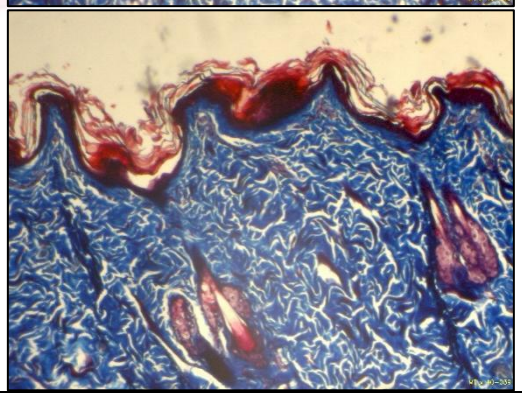
Photograph of the Animal Tissues – Controls	
	
H&E x 100: No pathologic changes.	Trichrome x 100: No pathologic changes.

Photograph of the Animal Tissues – Treatments	
	
	

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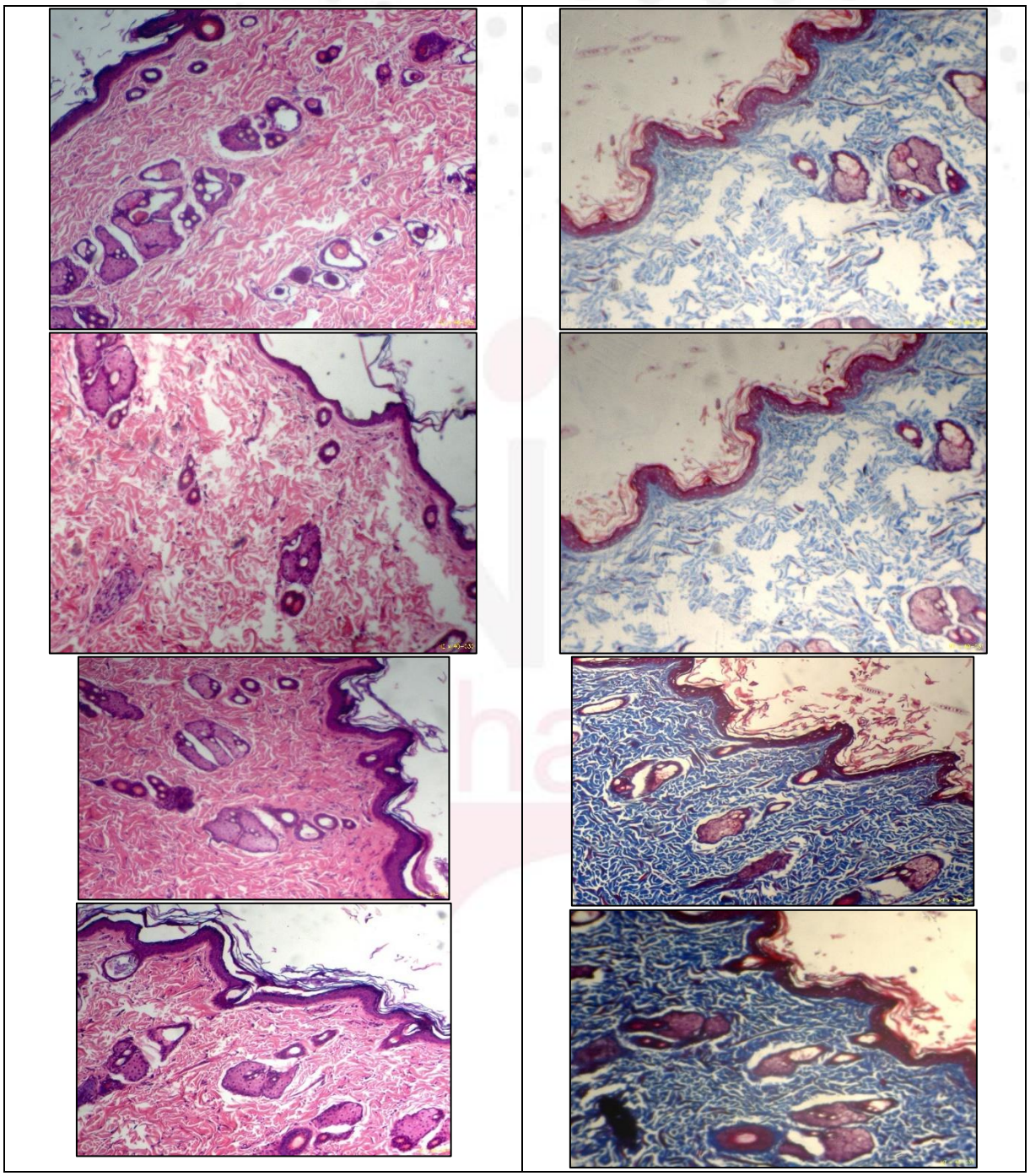

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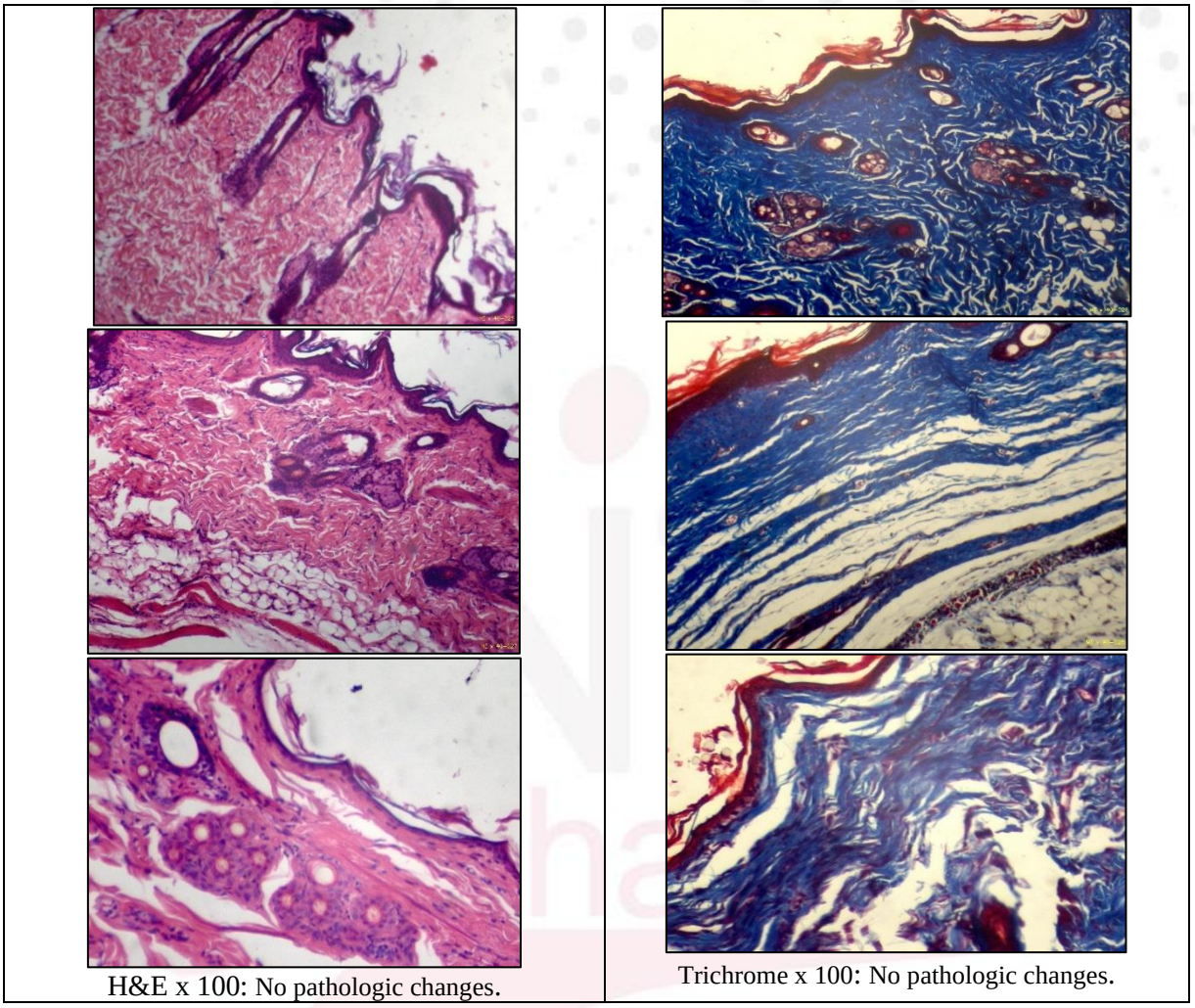

H&E x 100: No pathologic changes.

Trichrome x 100: No pathologic changes.

Conclusion

The mean score of the tissue reaction to the material after implantation was **0**, thus this provided evidence to support that the examined product was **non-irritant**.

Histopathological study of the submitted specimens (Skin) belonging to Rat that were categorized into two groups including Control and Treatment revealed the following items:

Group Control:

- No pathologic changes.

Group Treatment:

- No pathologic changes.

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Photograph of the Test Article

References

1. ISO 10993-6:2016, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
2. ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
3. ISO 10993-2:2022, Biological evaluation of medical devices - Part 2: Animal welfare requirements.

Description	Based on the customer request according to the F02-p12/05		
Test Performer: *Z. Sayyahi*	**Technical Manager:** *M. Daliri*	**CEO:** *M.Borjian*	**Nikopharmed laboratory sign**

- *Test results are only related to the tested products.*
- *Reproduction of test results without the permission of the laboratory is prohibited.*
- *Sampling has been done by the customer.*
- *This report is not valid without the seal and signature of the CEO.*
- *If the tests were performed by the contractor, the name of the contractor is given in the description section.*
- *Any objection to the issued results can be processed within 7 days after the date of issuance of the result.*
- *If the sample is stable, after the test, the sample will be stored in the laboratory for one month.*
- *Expanded uncertainty (CI: 95% , K=2) is calculated for quantitative tests and included upon customer request.*
- *Nikopharmed Arya Company, National Institute of Genetic Engineering and Biotechnology, Pajuhesh Boulevard, 17km Tehran-Karaj Highway, Tehran, Iran*

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