

Test Report

No: GZCPCH150601175

Date: 2015-07-06

Client name: Nano and Advanced Materials Institute Limited & Profit Royal Pharmaceutical Ltd.
Client address: Unit 517, Lakeside 1, No.8 Science Park West Ave. Hong Kong Science Park, Shatin, Hong Kong & RM 1211, 12/F., Sunbeam Centre, 27 Shing Yip Street, Kwun Tong, Kowloon.
Sample name: NASK Mask
No.: 40
Batch No.: S150408
Date: 2015 April 8th
Manufacturer: Profit Royal Pharmaceutical Ltd

The above sample information was submitted and identified by the clients.

SGS job No.: GZCPCH150601175
Date of receipt: 2015-06-18
Testing period: 2015-06-18~2015-07-06

TEST(S) REQUESTED:

Selected test(s) as requested by applicant:
Dermal Irritation Test*

TEST METHOD(S):

ISO 10993-10:2010(E) Biological evaluation of medical devices—Part10: Tests for irritation and skin sensitization.

TEST RESULT(S):

Please refer to next page(s).

CONCLUSION:

According to "Table 2-Primary or cumulative irritation index categories in a rabbit" in ISO 10993-10:2010(E), the irritation of the sample is negligible in rabbits' skins.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, and this document cannot be used for publicity without approval of the Company.

Signed for and on behalf of SGS


Authorized Signature
Queeny Chan

SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

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RAND: 6992410



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GZCPCH 008169

TEST METHOD(S):

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

Test environment: Rabbit room of conventional condition. Certificate No.SYXK 2013-0086, Guangdong; Room temperature 21~23°C,Relative humidity 60~65%.

Test animal: New Zealand white albino rabbits, each weight between 2.1- 2.3 kg, supplied by Guangdong Medical Experiment Animal Center (Certificate No. SCXK 2013-0002,Guangdong), animals certificate NO. 44411600001365.
No. of animals/sex: 3/♀:♂=1:2

Preparation of Sample: Prepared the sample to 2.5 cm×2.5 cm square piece, moistened with 0.9 % sodium chloride solution as test substance.

Observation period: 1,24,48 and 72 hours following removal the test substance, use only 24h,48h and 72h observations for calculations.

Test procedures: (1) Preparation of test animals. Selected three healthy young adult New Zealand white albino rabbits. Fur was shaved 24h before the test (approximately 10 cm×15 cm). (2) Procedures for testing: Applied the test substance on the test skin site as shown in Figure 1 of ISO 10993-10:2010(E) with a gauze patch. Applied the control patch of gauze(moistened with 0.5mL 0.9% sodium chloride solution) on the control site indicated in Figure 1 of ISO 10993-10:2010(E). Wrapped with non-irritating tape and bandage for 4 hours. At the end of the contact time, removed the dressings and marked the sites, Removed residual test material and washed with lukewarm water. Examined for signs of erythema and edema, recorded the dermal reactions at each observation period according to table 1 and table 2 of ISO 10993-10:2010(E).

TEST RESULT(S):

The Primary Irritation Index(PII) of the test substance is 0.

The scores of the test substance

Observation period	1 h								24 h											
	Skin reaction				Erythema-eschar				Edema				Erythema-eschar				Edema			
	Skin application site		Test Site		Control Site		Test Site		Control Site		Test Site		Control Site		Test Site		Control Site			
Rabbit Number	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R		
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	



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Observation period	48 h								72 h								
Skin reaction	Erythema-eschar				Edema				Erythema-eschar				Edema				
Skin application site	Test Site		Control Site		Test Site		Control Site		Test Site		Control Site		Test Site		Control Site		
	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R	
Rabbit Number																	
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Note: 1. L= Left, R = Right
 2. *Test was carried out by external laboratory assessed as competent.

Reference information:

ISO 10993-10:2010 Table2- Primary or cumulative irritation index categories in a rabbit

Mean score	Response category
0~0.4	Negligible
0.5~1.9	Slight
2~4.9	Moderate
5~8	Severe

SAMPLE DESCRIPTION: Blue flake material

Photo Appendix



*** End of Report***



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