



T.C.  
HACETTEPE ÜNİVERSİTESİ  
Eczacılık Fakültesi  
Eczacılık Meslek Bilimleri Bölümü  
Farmakoloji Anabilim Dalı

Sayı : B.30.2.HAC.0.03.00.00/  
Konu :

## RAPOR

### İRRİTASYON TESTİ

#### Numunenin tanıtılması:

Geldiği yer :Nanotego Nano Teknolojik ürünler Ar. Gel. Kimya San ve Tic. A.Ş.  
Cinsi ve adedi :Antimic QAC bazlı Genel Hijyen Maddesi  
Lot no :100915  
Evrak tarih/no :28.10.2010

#### Deney tarihi:

Numunenin geldiği tarih :28.10.2010  
Deneyin başlangıç tarihi :23.11.2010  
Deneyin bitiş tarihi :26.11.2010

#### Uygulanan standart

:TS EN ISO 10993-1  
TS EN ISO 10993-10  
TS EN ISO 10993-10/A1

#### Deney sonucu

: Numune irritasyona neden olmamaktadır.

#### Rapor tarihi:

: 03.12.2010

#### Onay :

Prof.Dr.S. Uma

Prof.Dr.İ. Erdemli

Prof.Dr.C. Pekiner



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## **IRRITATION TEST REPORT**

HACETTEPE ÜNİVERSİTESİ  
ECZACILIK FAKÜLTESİ  
FARMAKOLOJİ ANABİLİM DALI



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## 1.) PREFACE

### 1.1- General

**Supplier of the Sample**

Nanotego Nano Teknolojik Ürünler Ar. Gel.  
Kimya San. ve Tic. A.Ş.  
Atatürk Mah. Sedef Cad. Ata Plaza 3-4, D:171  
Ataşehir İSTANBUL

**Testing Facility**

Hacettepe University  
Faculty of Pharmacy  
Department of Pharmacology 06100 ANKARA

**Test Sample**

Antimic QAC-based General Hygiene Agent

**Test Name**

Irritation

### 1.2- Study Director

Professor Inci Erdemli

### 1.3- Schedule

**Arrival of the test sample**

:28.10.2010

**Start of Experiment**

: 23.11.2010

**End of Experiment**

: 26.11.2010

### 1.4- Signature:

Prof. Inci Erdemli



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### 1.5- Guidelines

This study followed the procedures indicated by the following internationally accepted guidelines:

|                    |   |
|--------------------|---|
| EN ISO 10993-1     | “Biological evaluation of medical devices”                |
| EN ISO 10993-10    | “ Test for irritation and delayed-type hypersensitivity”  |
| EN ISO 10993-10/A1 | “ Tests for irritation and delayed-type hypersensitivity” |

## 2.) MATERIALS AND METHODS

### 2.1- Characterisation of the Test Sample

|                   |   |
|-------------------|---|
| <b>Type</b>       | Antimic QAC-based General Hygiene Agent |
| <b>Lot Number</b> | 100915                                  |
| <b>Quantity</b>   | 3 x 500 cc                              |

### 2.2- Test animals

One healthy adult albino rabbit (male, 2300 g) was used.

### 2.3-Experimental Procedure

On the day before the test, the fur on the back of the animal was shaved. A sufficient distance was kept on both sides of the spine for the application and observation of all test sites. The test material and a sample of negative control were applied directly to the skin on each side of rabbit. 25 mm x 25 mm four-ply gauze patch was used as negative control sample. The application sites were covered with a 60 mm x 60 mm gauze patch and were wrapped with a semi-occlusive bandage for 4 h. At the end of the contact time the dressings were removed and the position of the sites were marked.



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## 2.4-Observation

For acute (single exposure) tests, each application site was observed for erythema and oedema at 24h, 48h, and 72 h following the removal of the patches.

## 3.) RESULT

No lesion was observed at 1 h, 24 h, 48 h and 72 h recordings for both test material samples and negative controls. Therefore, according to table 1 (EN ISO 10993-10; 2008), the score for irritation is 0 (zero) and according to table 2 (EN ISO 10993-10; 2008), response category is "negligible" for both the test material and the negative control . Irritation reaction was not observed.

| <u>Observation time</u> | <u>Criteria</u>        | <u>Negative Control</u> | <u>Test Sample 100915</u> |
|-------------------------|------------------------|-------------------------|---------------------------|
| 24 h                    | Erytheme<br><br>Oedema | Not existing            | Not existing              |
| 48 h                    |                        | Not existing            | Not existing              |
| 72 h                    |                        | Not existing            | Not existing              |