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 .....

HACETTEPE UNIVERSITY
FACULTY OF PHARMACY

DEPARTMENT OF PHARMACOLOGY
TR-06100 Sıhhiye-Ankara, Turkey
Telephone: +90 (312) 305 2131 • Fax: +90 (312) 305 2014
www.farma.hacettepe.edu.tr

Number: B.30.2.HAC.0.03.00.00/

IRRITATION TEST REPORT

HACETTEPE ÜNİVERSİTESİ
ECZACILIK FAKÜLTESİ
FARMAKOLOJİ ANABİLİM DALI

HACETTEPE UNIVERSITY
FACULTY OF PHARMACY

DEPARTMENT OF PHARMACOLOGY
TR-06100 Sıhhiye-Ankara, Turkey
Telephone: +90 (312) 305 2131 • Fax: +90 (312) 305 2014
www.farma.hacettepe.edu.tr

Number: B.30.2.HAC.0.03.00.00/

CONTENTS

HACETTEPE ÜNİVERSİTESİ
ECZACILIK FAKÜLTESİ
FARMAKOLOJİ ANABİLİM DALI

HACETTEPE UNIVERSITY
FACULTY OF PHARMACY

DEPARTMENT OF PHARMACOLOGY
TR-06100 Sıhhiye-Ankara, Turkey
Telephone: +90 (312) 305 2131 • Fax: +90 (312) 305 2014
www.farma.hacettepe.edu.tr

Number: B.30.2.HAC.0.03.00.00/

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 Hygene 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

HACETTEPE ÜNİVERSİTESİ
ECZ[illegible] FAKÜLTESİ
FARMAKOLOJİ ANABİLİM DALI

HACETTEPE UNIVERSITY
FACULTY OF PHARMACY

DEPARTMENT OF PHARMACOLOGY
TR-06100 Sıhhiye-Ankara, Turkey
Telephone: +90 (312) 305 2131 • Fax: +90 (312) 305 2014
www.farma.hacettepe.edu.tr

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

Type	Antimic QAC-based General Hygene Agent
Lot Number	100915
Quantity	3 x 500 cc

2.2- Test animals

One healty 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.

HACETTEPE ÜNİVERSİTESİ
ECZACILIK FAKÜLTESİ
FARMAKOLOJİ ANABİLİM DALI

HACETTEPE UNIVERSITY
FACULTY OF PHARMACY

DEPARTMENT OF PHARMACOLOGY
TR-06100 Sıhhiye-Ankara, Turkey
Telephone: +90 (312) 305 2131 • Fax: +90 (312) 305 2014
www.farma.hacettepe.edu.tr

Number: B.30.2.HAC.0.03.00.00/

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.

Observation time	Criteria	Negative Control	Test Sample 100915
24 h	Erytheme Oedema	Not existing	Not existing
48 h		Not existing	Not existing
72 h		Not existing	Not existing

HACETTEPE ÜNİVERSİTESİ
ECZ[illegible] FAKÜLTESİ
FARMAKOLOJİ ANABİLİM DALI