



THE SOUTH INDIA TEXTILE RESEARCH ASSOCIATION

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Centre of Excellence for Medical Textiles

Biotechnology Laboratory

XXVII/ *Aug 9* /16

Biotechnology laboratory
29/Jun /2016

TEST REPORT

To,
M/s. General Surgical Company (India) Pvt. Ltd,
Biologics Division, Old No. 73, New No 2, 'S' Block,
18th Street, Anna Nagar, Chennai – 600 040
REF No. : Nil
Date of performance: 23.06.16-27.06.16

Sample : Liquid
Received on : 27.04.16
No .of Samples : 1
Total No. of Pages : 2
Despatched no :

TEST RESULTS

Sample No.	BT 98
Sample Name	Disinfectant

Details of *in vitro* skin irritation

1. Cell culture

Source : SkinEthic laboratory , France

Justification : Normal human keratinocytes taken from healthy donor and culture for 17 days on an inert polycarbonate.

Culture medium : Maintenance medium (SMM) and Growth medium (SGM)

2. Test details

Assay method and Rationale : skin irritation - In vitro method

(As requested by the customer)
Test sample preparation



None

Contd 2..

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M/S. General surgical company dated on 27.04.16

3. Test procedure


An *in vitro* skin irritation test method was performed for the given test sample as per ISO 10993:10 (modified). The test sample is topically applied on the tissues for 42 mins at room temperature. After exposure, test samples were washed with PBS and transferred to fresh medium and incubated at 37° C for 42 h. Cell viability is assessed by incubating the skin sample in MTT (1 mg/ml) for 3 h. The precipitated formazan is then extracted by using isopropanol and quantified by spectrophotometry at 570nm.

4. Observation

Sample code	Sample Particulars	Cell viability (%)	Cytotoxic reactivity
BT 98	0.5% Disinfectant (2.5 µl)	> 50	No category
	0.5% Disinfectant (5.0 µl)	> 50	No category

5. Result

As per ISO 10993:10 (modified), the test sample Disinfectant is considered to be non-irritant to skin, as the cell viability after exposure and post incubation is > 50 %


Authorized Signatory
(Dr. E. Santhini, SSO)




(Head - CoE Medical Textiles)

IMPORTANT

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