



# TAMILNADU TEST HOUSE PRIVATE LIMITED

NABL ACCREDITED & DRUG CONTROL LICENSED

[www.tamilnadutesthouse.com](http://www.tamilnadutesthouse.com)

## CERTIFICATE OF ANALYSIS

Form 39 [See Rule 150 E (f)]

The Drugs and cosmetics Act, 1940 and the Rules there after

Approval Number: TN00004381

TEST REPORT NO: TNTH/M-1875/2020-21

DATE: 11.07.2020

### SAMPLE SUBMITTED BY CUSTOMER

CUSTOMER DETAILS	<b>M/s.Stedman Pharmaceuticals Pvt Ltd</b>
ADDRESS	C-4,Sidco Pharmaceuticals Complex, Alathur,Thiruporur-603110
SAMPLE DESCRIPTION	Dygerm ENA Gel
BATCH NUMBER	RD/MENG/0720/001
DATE OF MANUFACTURING	Jul-20
DATE OF EXPIRY	Jun-22
SAMPLE QUANTITY	100 ml
PACKING	In Plastic bottle
SAMPLE RECEIVED ON	08.07.2020
ANALYSIS STARTED ON	08.07.2020
ANALYSIS COMPLETED ON	11.07.2020

#### Terms and Conditions

This report in full or in part shall not be published, advertised, used for any legal action, unless prior permission has been secured. This test report pertains only for the sample tested and such samples are retained for 7 days (in case of perishable) and 15 days for all other samples. In case of Complaint received from customers sample will be kept for 30 days. The samples from regulatory bodies are to be retained as specified. This document cannot be reproduced except in full, without prior written approval of the company.

For Tamilnadu Test House Private Limited

Chief Executive Officer

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### SAMPLE SUBMITTED BY CUSTOMER

SAMPLE DESCRIPTION Dygerm ENA Gel

ANALYSIS STARTED ON 08.07.2020

ANALYSIS COMPLETED ON 11.07.2020

S. NO	TEST ORGANISM	Initial Microbial Count (CFU/ml)	Viability of Organisms/ Killing Inactivation at Different Contact Time			
			Efficacy ( %)			
			15 Secs	30 Secs	5 Mins	10 Mins
1	E.coli	1925687	99.99	99.99	99.99	99.99
2	Salmonella	1923578	99.99	99.99	99.99	99.99
3	Shigella flexneri	2012457	99.99	99.99	99.99	99.99
4	Pseudomonas aeruginosa	1956874	99.99	99.99	99.99	99.99
5	Staphylococcus aureus	2014587	99.99	99.99	99.99	99.99
6	Bacillus subtilis	2058674	99.99	99.99	99.99	99.99
7	Enterococcus faecalis	2056471	99.99	99.99	99.99	99.99
8	Micrococcus leuteus	2032564	99.99	99.99	99.99	99.99
9	Aspergillus niger	2012458	99.99	99.99	99.99	99.99
10	Vibrio cholerae	2014875	99.99	99.99	99.99	99.99

Remark : The Tested sample shows 99.99 % Efficacy w.r.t the Test method EN1276:2009

\*\*\*\*END OF REPORT\*\*\*\*

For Tamilnadu Test House Private Limited

Verified By

Authorised Signatory

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**SECTION 1: Product and Company Identification**

Product Code	:	DBG/DSG/DCG/ DLG/XDBG/XDSG/XDCG/XDLG
Product Name	:	DYGERM Gel (Isopropyl Alcohol Handrub Gel)
Chemical Family	:	Germicide Hand-rub
Product Use	:	Hand-rub, Gel Hand Sanitizer
Company Identification	:	STEDMAN PHARMACEUTICALS PVT. LTD.
Manufacturer	:	STEDMAN PHARMACEUTICALS PVT. LTD. C-4, SIDCO, Pharmaceutical Complex, Alathur, Thiruporur -603110, Tamilnadu
Contact details	:	3A, Adyar Bridge Road, Adyar, Chennai – 600020
Email	:	customercare@stedmanpharma.com

**SECTION 2: Hazards Identification**

Hazard classification	:	This product is Hazardous/Dangerous Goods Flammable Liquid
GHS label elements	:	  GHS02 GHS07
Signal word	:	<b>DANGER</b>
Hazard statement (s)	:	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness.

**SECTION 3: Composition/Information on Ingredients**

Component:	CAS No	Quantity/ Pack
Isopropyl Alcohol	67-63-0	70% v/v
Gel base q.s		

**SECTION 4: First-aid Measures**

Emergency and First Aid Procedures

EYES:

If this product comes in contact with the eyes:

- ▲ Wash out immediately with fresh running water.
- ▲ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.  
Seek medical attention without delay.

INGESTION:

If swallowed do NOT induce vomiting.

- ▲ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- ▲ Observe the patient carefully.
- ▲ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- ▲ Seek medical advice.

IF INHALED:

- ▲ If fumes or combustion products are inhaled remove from contaminated area.
- ▲ Lay patient down. Keep warm and rested.
- ▲ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- ▲ Transport to hospital, or doctor.

IF ON SKIN:

Flush with water. If signs / symptoms develop seek medical attention.

Note to Physician: No specific data available.

**SECTION 5: Fire-fighting Measures**

- |                            |  |
|----------------------------|--|
| <b>Flash Point</b>         | : CLOSED CUP: 18.3°C (64.9°F) - 24 deg. C (75 deg. F)  |
| <b>Explosive Limits</b>    | : The greatest known range is LOWER: 2%<br>UPPER: 12.7% (Isopropyl alcohol)  |
| <b>Extinguishing Media</b> | : Alcohol stable foam, carbon dioxide, dry chemical, BCF (where regulations permits) or water spray (large fires only) |

<b>Fire Fighting Instructions</b>	:	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>Flammable Properties and Hazards:</b>		Inflammable. Keep away from fire.
<b>Hazardous Combustion Products</b>	:	No hazardous combustion products known.

### **SECTION 6: Accidental Release Measures**

Steps to be taken in case material is released or spilled: Remove all source of ignition. Use appropriate tools to put the spilled material in a convenient waste disposal container.

Mop up material and place in a container suitable for chemical waste.

### **SECTION 7: Handling and Storage**

#### **Precautions to be taken in handling**

Limit all unnecessary personal contact.

Wear protective clothing when risk of exposure occurs.

Use in a well-ventilated area away from heat.

Avoid physical damage to containers.

Do not store above 30°C. Protect from heat and moisture.

**Precautions to be taken in storing:** Avoid storage with oxidisers.

#### **Other Precautions:**

Store in original containers in approved flame-proof area.

No smoking, naked lights, heat or ignition sources.

DO NOT store in pits, depressions, basements or areas where vapours may be trapped.

FOR EXTERNAL USE ONLY.

### **SECTION 8: Exposure Controls/Personal Protection**

Employers may need to use multiple types of controls to prevent employee overexposure.

For flammable liquids and flammable gases, local exhaust ventilation or a process enclosure ventilation system may be required. Ventilation equipment should be explosion-resistant.

**Personal Protection:**



**Eye & face Protection:**

Minimize exposure. Wash hands and arms thoroughly after handling. Use Safety glasses with side shields.

**Skin Protection:** Use of Protective gloves are recommended. The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Bare skin is cleaned with this material.

Application of hand cream / barrier cream after use is recommended.

**SECTION 9: Physical and Chemical Properties**

<b>Physical State</b>	:	[ ] Gas, [ ] Liquid, [X] Semi solid
<b>Appearance</b>	:	Bluish green coloured homogenous Viscous Gel (Blue Ice ) Pink coloured viscous gel with strawberry flavour. (Strawberry) Yellow orange coloured viscous gel with cucumber flavour. (Cucumber) Purple coloured viscous gel with lavender flavour. (Lavender)
<b>Boiling Point</b>	:	No data available
<b>Melting Point</b>	:	No data available
<b>Specific gravity</b>	:	0.870 – 0.890 at 25°C
<b>Density</b>	:	No data available
<b>Vapor Pressure at 20°C</b>	:	No data available
<b>Vapor Density at 20°C</b>	:	No data available
<b>Evaporation Rate</b>	:	No data available
<b>Solubility</b>	:	Miscible with water
<b>Percent Volatile</b>	:	No data available
<b>Saturated Vapor Concentration</b>	:	No data available
<b>Viscosity at 25°C</b>	:	2400 – 3600 cps
<b>pH</b>	:	6.0 – 7.5

**SECTION 10: Stability and Reactivity**

<b>Stability</b>	:	Product is considered stable.
<b>Incompatibility</b>	:	Keep away from heat, sparks and open Flame.
<b>Hazardous Decomposition or by products:</b>		None Known
<b>Hazardous Polymerization</b>	:	Will occur [ ] Will not occur [X]
<b>Conditions to avoid</b>	:	Heat

**SECTION 11: Toxicological Information**

Acute inhalation toxicity: LC50 (Rat): >20 mg / l

**Inhaled:** The vapour is discomforting. Inhalation hazard is increased at higher temperatures. Acute effects from inhalation of high concentrations of vapour are pulmonary irritation, including coughing, with nausea; central nervous system depression - characterised by headache and dizziness, increased reaction time, fatigue and loss of co-ordination.

Acute Oral Toxicity: LD50 Oral (Rat): >2.000 mg / kg

**Ingestion:** Accidental ingestion of the material may be damaging to the health of the individual.

Acute Dermal Toxicity: LD50 Dermal (Rabbit): >2.000 mg / kg

**Skin contact:** Not considered to cause discomfort through normal use. The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (non allergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis.

**Eye:** The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

**Carcinogenicity, Mutagenicity & Reproductive toxicity:** Based on available data, the classification criteria are not met.

**SECTION 12: Ecological Information**

No data available

**SECTION 13: Disposal considerations**

Disposal to be done as per local regulations.

**SECTION 14: Transport Information**

Flammable liquid, UN No. 1219 PG: II) ICAO / IATA class 3



**SECTION 15: Regulatory Information**

No information available

**SECTION 16: Other Information**

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