



TAMILNADU TEST HOUSE PRIVATE LIMITED

NABL ACCREDITED & DRUG CONTROL LICENSED

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-0101/2020-21

DATE: 24.04.2020

SAMPLE SUBMITTED BY CUSTOMER

CUSTOMER DETAILS	M/s.Stedman Pharmaceuticals Pvt Ltd
ADDRESS	C-4,Sidco Pharmaceuticals Complex, Alathur,Thiruporur-603110
SAMPLE DESCRIPTION	Hand Sanitizer - Dygerm Liquid
BATCH NUMBER	20-DYL-056
MANUFACTURED ON	Apr-20
EXPIRED ON	Sep-21
SAMPLE QUANTITY	100 ML
PACKING	In packed condition
SAMPLE RECEIVED ON	20.04.2020
ANALYSIS STARTED ON	20.04.2020
ANALYSIS COMPLETED ON	24.04.2020

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This report in full or in part shall not be published, advertised, used for any legal action, unless prior permission has been secured.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 **Hand Sanitizer - Dygerm Liquid**
BATCH NUMBER 20-DYL-056
ANALYSIS STARTED ON 20.04.2020
ANALYSIS COMPLETED ON 24.04.2020

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	2378560	91.23	99.99	99.99	99.99
2	Salmonella	2124580	92.56	99.99	99.99	99.99
3	Shigella flexneri	2015875	93.21	99.99	99.99	99.99
4	Pseudomonas aeruginosa	1956782	95.56	99.99	99.99	99.99
5	Staphylococcus aureus	2012482	92.78	99.99	99.99	99.99
6	Bacillus subtilis	2124578	93.56	99.99	99.99	99.99
7	Enterococcus faecalis	2014852	97.23	99.99	99.99	99.99
8	Micrococcus leuteus	1987563	95.12	99.99	99.99	99.99
9	Aspergillus niger	2012458	90.25	99.99	99.99	99.99
10	Vibrio cholerae	2125368	92.25	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 : DYL/XDYL
 Product Name : DYGERM
 (Isopropyl Rubbing Alcohol IP / USP)
 Chemical Family : Germicide Hand-rub
 Product Use : Hand-rub, Liquid 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 : **DANGER**

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
Purified Water	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

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

Fire Fighting Instructions	:	Use standard firefighting procedures and consider the hazards of other involved materials.
Flammable Properties and Hazards:		Inflammable. Keep away from fire.
Hazardous Combustion Products	:	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.

Store below 30°C. Protect from light. Do not freeze.

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

Physical State	:	<input type="checkbox"/> Gas, <input checked="" type="checkbox"/> Liquid, <input type="checkbox"/> Solid
Appearance	:	Yellowish orange coloured clear flavoured liquid.
Boiling Point	:	No data available
Melting Point	:	No data available
Specific gravity	:	0.872 – 0.883 at 25°C
Density	:	No data available
Vapor Pressure at 20°C	:	No data available
Vapor Density at 20°C	:	No data available
Evaporation Rate	:	No data available
Solubility	:	Miscible with water
Percent Volatile	:	No data available
Saturated Vapor Concentration	:	No data available
Viscosity	:	No data available

SECTION 10: Stability and Reactivity

Stability	:	Product is considered stable.
Incompatibility	:	Keep away from heat, sparks and open Flame.
Hazardous Decomposition or by products:		None Known
Hazardous Polymerization	:	Will occur <input type="checkbox"/> Will not occur <input checked="" type="checkbox"/>
Conditions to avoid	:	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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