

# HEALTHCARE PRODUCTS

Manufactured by;  
**OPROMA COSMETICS (PVT)LTD**

## WHO ARE WE?

Oproma Cosmetics is a Healthcare and Cosmetic Manufacturing Company in Asia, manufacturing 100% quality products to the customer by assuring the quality and safety of each and every product, managing human and other resources to give best products and services to customers.

## WHAT WE DO

We use Sri Lankan Herbal Heritage and Modern Cosmetology to achieve our products excellence with maximum commitment. Our effort is to offer the best Natural /Herbal products for the benefit of our customers. Develop more Healthcare and Cosmetic products which are currently needful and create product lines that are wellpositioned within the current market.

## CONTACT DETAILS

NO. 223/1, BATAHENAROAD,  
KIRIKITHTHA, WELIWERIYA.  
OFFICE : +94114938817  
FACTORY : +94332254449  
HOTLINE : +94703030420  
E-MAIL : INFO@OPROMACOSMETICS.COM  
WEB : WWW.OPROMACOSMETICS.COM



# INTRODUCING HEALTHCARE PRODUCT RANGE



**OPLEE**  
Luxury Herbal Products



## INSTANT HAND SANITIZER

KILLS MORE THAN 99.99% OF GERMS

**WHO**   
**Formulation**  
EN1500 Standard



Registered in NMRA, Sri Lanka

Follows International Standards and Guidelines



# HAND SANITIZER PRODUCT VARIETIES & SIZES



## PRODUCT PORTFOLIO

Hand sanitizer gel and liquid varieties



Instant Hand Sanitizer



Cinnamon



Lavender



Lemon



Mint



Aloe Vera (gel)



OPLEE HAND  
SANITIZER

COMPANY &  
PRODUCT  
CERTIFICATIONS


GMP, BAMBER & BRUCE, NMRA, EN-1500  
CERTIFICATIONS



INSTANT HAND SANITIZER



# GMP CERTIFICATE

தொலைபேசி Telephone 0112658896/7 0112659173		எனது எண் My No. NMRA/GMP/P37/2019
ஃபாக்ஸ் Fax 0112658704	<p align="center"><b>ජාතික ඖෂධ නියාමන අධිකාරිය</b>  <b>தேசிய மருந்துகள் ஒழுங்குமுறைத் துறை சபை</b>  <b>National Medicines Regulatory Authority</b></p>	எனது வருட எண் Year No. 05/04/2019

National Medicines Regulatory Authority, No: 120, Norris Canal Road, Colombo 10.  
 NMRA 120, Norris Canal Road, Colombo 10, Sri Lanka

Mr. Pradeep Mapalagama,  
 Managing Director,  
 Oproma Cosmetics (Pvt) Ltd  
 223/1,  
 Batahena Road,  
 Kirikiththa,  
 Weliveriya.

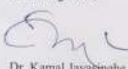
**Inspection Report of Oproma Cosmetics (Pvt) Ltd**

This refers to the GMP inspection of the above-mentioned Cosmetic Manufacturing plant which was carried out by the officials of the National Medicines Regulatory Authority (NMRA) on 29<sup>th</sup> March 2019.

I would like to inform you that the inspection team has satisfied with the current GMP followed by your company.

The copy of GMP report is attached herewith.

Thanking You,

  
 Dr. Kamal Jayasinghe,  
 CEO,  
 National Medicines Regulatory Authority.

**Dr. Kamal Jayasinghe**  
 MSc, DPM, MSc-Med Adm, MSA, DIPPCA  
 Chief Executive Officer  
 National Medicines Regulatory Authority  
 120, Norris Canal Road, Colombo 10.

National Medicines Regulatory Authority  
 Sri Lanka

**Routine Site Inspection Report**

Inspected Site : Oproma Cosmetics (Pvt) Ltd  
 223/1, Batahena Road, Kirikiththa, Weliveriya.  
 Phone- 0773132204, 0114938817, 0332254449  
 E mail- bloominglk@gmail.com

Activities Carried Out : Manufacture of Skin Care Products (Face Wash, Cleansers, Scrubs, Toners, Face Packs, Lotion, Cream, Soap) & Hair Care (Shampoo, Conditioner, Oil)

Inspection Date : 29<sup>th</sup> March 2019

Inspectors : Ms. R. P. Dimuda (Regulatory Pharmacist/ Team Leader)  
 Ms. Harshani Ilangakoon (Regulatory Pharmacist)

Reference : Site Master File No: SMF/COS/029

Introduction : Oproma Cosmetics (Pvt) Ltd is a Cosmetic Manufacturing Company located in the above address in Gampaha district. The plant and ancillary are in 5000 square feet of land. There is a one-story building for manufacturing. Inside that building there are separate areas to carry out each function.

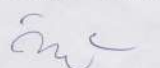
**Brief report of the inspection activities undertaken**

Scope of Inspection : Routine

Inspected areas : Raw material storing area  
 Production area  
 Packing and Labelling area  
 Finish product storing area  
 Water treatment system

Personnel met during the Inspection : Key personnel (not all inclusive)

Mr. Pradeep Mapalagama - Managing Director  
 Mr. A. W. Sunil - Factory Manager  
 Ms. Rasika Tissera - Management Representative  
 Ms. M. T. Seetha Nandani - Personal Secretary- MD/HR



**Inspectors team's Findings and Observations**

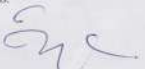
Personnel : The company has adequate number of experienced employees to perform and supervise the production processes.

Premises and Equipment : Premises was in a satisfactory condition and kept clean and tidy.  
 Adequately secured to prevent unauthorized access for the manufacturing site  
 Well maintained daily cleaning system and checking system were available.  
 There were adequate building and free space in the factory site.  
 Satisfactory Water treatment system was available.  
 Separate area for Raw material storage including Quarantine area, Approved raw material area, Sampling area, Day storage area, Packing material storage area and Bulk storage area were available. It should be avoid raw materials directly open when opening door. It is needed to install temperature and humidity controllers in these areas. Separate lock and key area should be maintained for rejected raw materials.  
 Separate area for Finish product storage was available. It should be avoid Finish products directly open when opening door. It is needed to install temperature and humidity controllers in this area.  
 Separate changing rooms for staff and visitors are available.  
 There was adequate equipment in the premises to carry out each function.  
 Pest control system was available.

Documentation : Documentation was in a satisfactory level. SOPs for cleaning should be developed. Cleaning and machine operating procedures should be displayed in a lay language on the wall near the each machine.  
 Training schedules and Medical checkups for employers should be maintained.

Production : Production area was clean and tidy.  
 Employers wear gowns, caps, masks, shoes and gloves.

Quality control : Satisfactory quality control laboratory was available.  
 Water quality checking should be installed after cleaning the equipment to assure the cleaning process.



Finish product stability checking (Real time and Accelerated) should be installed.

Complaints and product Recall : Complaint handling procedure should be installed.  
 Batch numbering traceability was available.

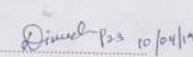
**List of deficiencies**


Critical deficiencies were not observed.


- Temperature and Humidity controllers should be installed at Raw material storing area and Finish product storing area
- Separate, Raw materials and Finish products when opening the doors.
- Need to be installed lock and key area for rejected raw materials.
- SOPs for cleaning should be developed.
- Equipment handling and washing procedures should be display in a lay language on wall.
- Water quality checking should be installed after cleaning the equipment to assure the cleaning process.
- Finish product stability checking (Real time and Accelerated) should be installed.
- Complaint handling procedure should be installed.

**Conclusion**

According to the inspection of Oproma Cosmetics (Pvt) Ltd, 223/1, Batahena Road, Kirikiththa, Weliveriya, Sri Lanka is considered to be operating at an acceptable level of GMP compliance. Commercial production can be continuing.  
 However, above mentioned improvements to be done before next routine inspection.

  
 R. P. Dimuda Rajapaksha  
 10/04/2019

  
 I.P. Harshani Ilangakoon



**Dr. Kamal Jayasinghe**  
 MSc, DPM, MSc-Med Adm, MSA, DIPPCA  
 Chief Executive Officer  
 National Medicines Regulatory Authority  
 120, Norris Canal Road, Colombo 10.

# ISO 9001:2015 CERTIFICATE



## Certificate of Conformity

This is to certify that the  
**Quality Management System**  
of

**OPROMA COSMETICS (PVT) LTD**

NO. 223/1, BATAHENA ROAD, WELIWERIYA

is in compliance with the  
requirements of ISO 9001:2015

**Scope of certification** : *Activities pertaining to manufacturing of face creams, face mask, face scrub, face wash, lotions, shampoo, conditioner, hair oil, body gel, nail polish remover, foot cream, soap and sanitizers*

**Certificate no.** : **QMS 0069**

This certificate awarded on **2020-09-07** is valid until **2023-09-06**

**Date of initial certification** : **2020-09-07**

First Surveillance Audit	2021-07-07
Second Surveillance Audit	2022-07-07
Recertification Audit	2023-06-07

**Ind-Expo Certification Limited**

Apt. No. 20, 1st Floor, Galle Face Court 2,  
Colombo 03,  
Sri Lanka

Email: info@indexpo.lk  
Tel: +94 11 2423452 Fax: +94 11 2423453  
Web: www.indexpo.lk

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Director



# MICROBIOLOGICAL ANALYSIS REPORT



## BAMBER & BRUCE (PVT) LTD

Established in 1880 / Company Reg. No.: PV 7078

No.29/1, Idama Avenue, Vijaya Kumarathunga Mawatha, Polhengoda, Colombo 05, Sri Lanka.  
Telephone: 011-2514254, 011-5738843, 011-2514105 Fax: 011-2514813  
E-mail: info@bamber-bruce.lk

17<sup>th</sup> March 2020  
Our Ref 73/Mar/20

### MICROBIOLOGICAL ANALYSIS REPORT

#### EXAMINATION OF A SAMPLES OF HAND SANITIZER

**CUSTOMER :** Oproma Cosmetics (Pvt) Ltd;  
No. 223/1, Batahena Road, Kirikiththa, Weliweriya.

Ref. Customer's letter dated on 11<sup>th</sup> March 2020.

**SAMPLE :** A sample of Hand Sanitizer submitted by the customer on 11<sup>th</sup> March 2020.

**MARKS :** Product : Hand Sanitizer

#### ANALYSIS RESULTS:

Type of microorganisms	Initial count	After adding the Hand Sanitizer	Efficiency of germs killings
Total Bacterial Count /ml	$6.2 \times 10^7$	4	99.9%
<i>Pseudomonas aeruginosa</i> /ml	$4.7 \times 10^7$	6	99.9%
<i>Staphylococcus aureus</i> /ml	$1.0 \times 10^8$	$8.4 \times 10$	99.9%

**Test Method :** AOAC 960.09

Dates of performance : From 11<sup>th</sup> March 2020 to 17<sup>th</sup> March 2020.

THIS REPORT REFERS SPECIFICALLY TO THE SAMPLE ANALYZED.  
THIS REPORT SHALL NOT BE REPRODUCED EXCEPT IN FULL, WITHOUT THE WRITTEN APPROVAL  
OF BAMBER & BRUCE LTD.

"Samples (except water) will be retained for 30 days from the date received. Water samples will be retained for 14 days from the date received."

DG/HT

Page 1 of 1

  
HASIKA THILAKARATNE  
Authorized Signatory  
BAMBER & BRUCE (PVT) LTD  




INSTANT HAND  
SANITIZER

# NMRA CERTIFICATE

Form A

Regulation 5 (2)

065069



Sri Lanka

No. COS-005436-PR

SCHEDULE III

## CERTIFICATE OF REGISTRATION - COSMETICS

*The Following cosmetics is hereby registered under the Cosmetics, Devices and Drug Act: No. 27 of 1980*

Name of Cosmetics : Oplee Hand Sanitiser

Type of Cosmetics : Hand Sanitiser

Name & Address of Manufacture : Onroma Cosmetics (Pvt) Limited, 223/1, Batahena Rd, Kirikiththa, Welhwariya

Country of Manufacture : Sri Lanka

Name & Address of Importer : \_\_\_\_\_

Registration Type : Provisional Period of Validity : From 08.04.2020 To 07.04.2021

Previous Registration No : \_\_\_\_\_

Provisional Registration shall be valid for the period stipulated.

National Medicines Regulatory Authority

Date of issue : 09.04.2020

Receipt No : 082009

Date : 09.04.2020

REF : COS / 6376/L

8

**Chief Executive Officer**  
**National Medicines Regulatory Authority**  
**No.120, Norris Canal Road,**  
**Colombo 10**

Note : This licence is issued based on the cabinet decision dated 10th of October 2017 as a transitional Provisions under subsection (d) of section 145 of the NMRA act No.05 of 2015 by the National Medicines Regulatory Authority.

National Medicines Regulatory Authority, No. 120, Norris Canal Road, Colombo 10, Sri Lanka



**BUREAU  
VERITAS**

# TEST REPORT

Report No: (7420)094-0064

Apr 08, 2020

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17	5.10	4.10	-1.00
18	5.16	4.14	-1.01
19	5.19	4.16	-1.02
20	5.13	4.13	-1.00

Acceptance Criteria According to EN 1500:2013

- Complete set of results from 20 volunteers available (Hence , more than the minimum of 18)
- Mean of lg pre values for PR = & for PP= (Hence both greater than 5)
- All acceptance criteria are fulfilled

## CONCLUSION

The Testing Results revealed that this tested product (Oplee Hand Sanitizer) comply with EN 1500:2013.

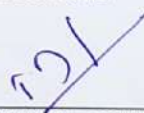
Contact information for this report (Technical and General Inquiries and Feedback)

<b>GENERAL INQUIRIES:</b>		
IROSHA UDUGAMPALA	TEL: +94 768 229 528	E-MAIL: Irosha.Udugampala@lk.bureauveritas.com
<b>TECHNICAL INQUIRIES:</b>		
RUWINI AMARASINGHE	TEL: +94 768 229 457	E-MAIL: ruwani.amarasinghe@lk.bureauveritas.com
<b>FEED BACK:</b>		
KUMUDINI RATHNAYAKE	TEL: +94 768 229 455	E-MAIL: kumudinie.rathnayake@lk.bureauveritas.com

REVIEWED BY: RUWINI AMARASINGHE

BUREAU VERITAS CONSUMER PRODUCTS SERVICES LANKA (PVT) LTD.  
AUTHORIZED SIGNATORY

APPROVED BY:

  
 \_\_\_\_\_  
 RUWANI AMARASINGHE  
 SENIOR EXECUTIVE -  
 MICROBIOLOGY LABORATORY



INSTANT HAND  
SANITIZER

# EN1500 CERTIFICATE

EN 1500  
CERTIFIED



BUREAU  
VERITAS

## TEST REPORT

Report No: (7420)094-0064

Apr 08, 2020

Page 1 of 7

Attn: Mr.Pradeep Maplagama

**Customer:** Oproma Cosmetics (pvt)Ltd.  
**Address :** No.223/1,Batahena Road, Kirikiththa,Weliweriya Sri Lanka  
**Date of Sample Test performed:** March 10, 2020  
**Date of Testing Started:** Apr 03, 2020  
**Date of Testing Completed:** Apr 08, 2020  
**Sample Description:** Oplee Hand Sanitizer  
ML : 50ml/100ml/300ml/500ml

Sample Drawn By BVCPS YES

### Photo of the Tested Sample



Report Number  
(7420)094-0064

**Bureau Veritas Consumer  
Products Services Lanka (Pvt)  
Ltd.**

No. 570, Galle Road, Katubedda, Moratuwa, Sri Lanka  
Tel: (9411) 2350111-115 (dedicated lines), Fax: (9411)  
112622198 & 199  
Email: bvcps.lanka@lk.bureauveritas.com

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# HAND SANITIZER

# SAMPLE



# HAND WASH



# SOAP

