CENTRE FOR CRUELTY – FREE TESTING (CCFT)

(ISO 9001:2015; 14001:2015, OECD Compliant)

SPONSOR

BOMBAY TEST HOUSE PVT LTD

CLINICAL RESEARCH ORGANIZATION

MITTAL GLOBAL CLINICAL TRIAL SERVICES (MGCTS)

Report Number CCFT/CT/2026/1898

STUDY TITLE: "A Clinical Study to Evaluate the Skin Irritation Potential of Lubu Baby Nourishing Bar and Lubu Skin Brightening Bar on Healthy Human Volunteers."

LAB Address: Dermalab, CCFT Laboratories, Mittal Group Building, 121-B, Mansarovar Industrial Estate, Panchli, Baghpat Road, Meerut-250005.
Tel: +91-9258535734 (INDIA)
www.centreforcrueltyfreetesting.com

Clinical Study Report

Title Page

Study Title: "A Clinical Study to Evaluate the Skin Irritation Potential of Lubu Baby Nourishing Bar and Lubu Skin Brightening Bar on Healthy Human Volunteers."

Protocol No.	CCFT1898
Version Number and Date	1.0 DATED 25 Jun 2026
Investigational Product	1. Lubu Baby Nourishing Bar (BTHBOMRND2606200001) 2. Lubu Skin Brightening Bar (BTHBOMRND2606200002)
Name & Address of Sponsor	Bombay Test House Pvt Ltd Fourth Floor, Unit No. 1, Banking Complex II, Plot No 9 & 10, Sector 19-A, Nr. APMC Market 2, Vashi, Navi Mumbai 400 703. India
Marketed By	Vigo Distribution Private Limited
Name & Affiliation of the Investigator (s)	Name: Dr. Robin Chugh (MD- Dermatology) Designation: Principal Investigator
Date of First subject in the Study	27 June 2026
Date of Last subject follow up	05 July 2026
No. of subjects	24
Report Number	CCFT/CT/2026/1898
Date of the draft report	06 July 2026

Confidential

The information in this document is confidential and is to be used only in connection with matters authorized by Bombay Test House Pvt Ltd and no part of it is to be disclosed to the others without prior written permission from Bombay Test House Pvt Ltd. This study was performed in accordance with ICH E6 R2, Schedule-Y (2017) and Ethical Principles as per the Declaration of Helsinki (2013) including archiving of all the essential documents.

INVESTIGATOR(S) SIGNATURE(S)

"A Clinical Study to Evaluate the Skin Irritation Potential of Lubu Baby Nourishing Bar and Lubu Skin Brightening Bar on Healthy Human Volunteers."

I have read this report and confirm that to the best of my knowledge it accurately describes conduct and result of the study.

Dr. Robin Chugh **CCFT Laboratories,** **Mittal Group Building, 121-B,** **Mansarovar Industrial Estate, Panchli,** **Baghpat Road, Meerut-250005, U.P,** **India**	 06 July 2026 **SIGNATURE & DATE**

STATEMENT OF COMPLIANCE

"A Clinical Study to Evaluate the Skin Irritation Potential of Lubu Baby Nourishing Bar and Lubu Skin Brightening Bar on Healthy Human Volunteers."

This study was conducted in compliance with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

Name	Designation & Address	Signature	Date (DDMMM YYYY)
PUNEET MITTAL	**Director- Clinical Research, CCFT Laboratories, Mittal Group Building, 121-B, Mansarovar Industrial Estate, Panchli, Baghpat Road, Meerut- 250005, U.P, India**	MITTAL GLOBAL CLINICAL TRIAL SERVICES MGCTS.ORG	06 July 2026

STATEMENT OF COMPLIANCE

(DATASAFETY MONITORINGBOARD)

"A Clinical Study to Evaluate the Skin Irritation Potential of Lubu Baby Nourishing Bar and Lubu Skin Brightening Bar on Healthy Human Volunteers."

This study was verified and reviewed independently according with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

S. No	Name and Designation	Signature	Date (DD MMM YYYY)
1	**NIDHI DIXIT** **Study Director** **CCFT Laboratories, Meerut**		06 July 2026
2	**SHEETAL** **Data Manager** **CCFT Laboratories, Meerut**		06 July 2026

REPORT SUMMARY:

Title of the Study	A Clinical Study to Evaluate the Skin Irritation Potential of Lubu Baby Nourishing Bar and Lubu Skin Brightening Bar on Healthy Human Volunteers.
Rationale of Investigational product	1. Lubu Baby Nourishing Bar (BTHBOMRND2606200001) 2. Lubu Skin Brightening Bar (BTHBOMRND2606200002)
Name of Sponsor	Bombay Test House Pvt Ltd
SITE	CCFT Laboratories, Mittal Group Building, 121-B, Mansarovar Industrial Estate, Panchli, Baghpat Road, Meerut-250005, U.P, India
Investigator (s)	Dr Robin Chugh
Study Objective	**Primary objective:** To evaluate the irritation potential of Lubu Baby Nourishing Bar and Lubu Skin Brightening Bar on healthy human subjects by Single application patch test method. (Primary Irritation Patch Test).
Study Phase	NA
Study Design	Each trial participant will be assigned to a regimen of investigational products and advised to take general precautions as needed. Patients will be assigned to an investigational product for 24 Hours, Starting on day 1st, followed by 2nd day. A follow up visit would be done after 1 week of patch removal.
Number of subjects	24
Subject disposition	Single Arm Study- all subjects would be assigned to patches with all Products.

Study Inclusion Criteria	Subjects were included based on the following criteria. 1. Voluntary man/women between 18 and 65 years. 2. Phototype III to V. 3. Having apparently healthy skin on test area. 4. For whom the investigator considers that the compliance will be correct. 5. Cooperating, informed of the need and duration of the examinations and ready to comply with protocol procedures. 6. Having signed a Consent Form 7. Willingness to avoid intense UV exposure on test site (sun or artificial UV), during the course of the study. 8. Willingness to avoid excessive water contact (for example swimming) or activity which causes excessive sweating (that is exercise, sauna), during the course of the study. 9. Having valid proof of identity and age

Test Product/ Study Product	1. Lubu Baby Nourishing Bar (BTHBOMRND2606200001) 2. Lubu Skin Brightening Bar (BTHBOMRND2606200002)
Study Methodology	8 Days [3 days and T8 (T+1 week after 0 hour of patch removal) visit was scheduled to monitor follow up reactions]. Screening & T0 (before patch application) T1 (0 hour after the patch removal) T2 (24 hours after the patch removal) T8 (T+1 week after of patch removal)
Clinical assessment	Erythema & Oedema Scoring on 5-point Severity Scale [0-4], where 0 is no irritation & 4 being the highest. Scoring to be taken at below time points. T2 (24 hours after the patch removal) T8 (T+1 week after of patch removal)
Primary Outcome	Change in Skin Irritation Score- erythema and oedema.
Statistical Analysis	**Statistical Considerations** Data listings and summary tables will be provided. Listings will include all data captured on the case report form (CRF) unless specified otherwise. Calculated (derived) variables will be listed as appropriate. Summary tables will be provided for select variables. Assessment would be done on Erythema & Oedema data received from CRF for visit T2 and T8.
Ethical Conduct of the study	The study was initiated after written approval from the hospital's Committee. The trial was conducted as per ICH E6 R2 Guidelines, Schedule Y (2017), Declaration of Helsinki (Brazil, 2013) and in Accordance with other applicable guidelines.
Efficacy and SafetyResults	Out of 24 subjects screened, none were found screen failures, none were dropouts. 24 subjects underwent the Trial. The mean age of the subjects was 34 years. The mean height of the subjects was 154 cm. The mean weights of the subjects were 58.2 kg.

	Data from all 24 subjects who completed the study were analyzed. The primary end point change in the Erythema & Oedema Score was calculated as total irritation score was measured at 24 hours after the patch removal. Patch 1 product - Lubu Baby Nourishing Bar showed/was found non-Irritant to the skin. Patch 2 product - Lubu Skin Brightening Bar showed/was found non-Irritant to the skin. Patch 3 product - (Negative Control) - 0.9% Isotonic Saline Solution showed/was found non-Irritant to the skin. Patch 4 product (Positive Control) - 1% Sodium Lauryl Sulphate showed/was found Irritant to the skin. There were no subjects lost to follow up. There was no subject who withdrawn the consent.
Conclusion	In conclusion, Lubu Baby Nourishing Bar and Lubu Skin Brightening Bar were tested dermatologically as per BIS standard IS 4011:2018 by the Dermatologist and were found non-irritant with 24-hour Primary Irritation Patch Test.
Date of Report	06 July 2026