



CLINICAL STUDY REPORT

refreshing baby wash

Keeps baby's skin cool and fresh

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DOCTORS

Clinical Credentials

HRIPT (Human Repeat Insult Patch Test)*

Number of subjects: 200

Age group: 18 years-65 years

Clinical study outcome: The test product was found to be hypoallergenic in the test population with no indicative allergenic response in the Challenge phase. It was found to be 'Mild and Gentle' on the skin of the test population.

In-Use Clinical Efficacy Study

Number of subjects: 40

Age group: 0 years-4 years

Clinical study outcome:

- **Effectiveness of cleansing:** By the end of the study, 85% of mothers were very pleased with the cleansing activity.
- **Fragrance:** By the end of the study, 80% of mothers were very pleased with the fragrance.
- **Tears while bathing:** None of the babies had tears while bathing, as reported by their mothers.
- **Skin texture:** By the end of the study, 100% of babies had smooth skin according to the parents.
- **Rinsing:** At the end of the study, 75% of parents remained convinced with the perspective of easy to rinse.

* The Study conducted as per:

- BIS 4011: 2018 guidelines
- CDSCO (Central Drug Standard Control Organization) guidelines
- ICH-GCP (Good Clinical Practice) guidelines
- Principles stated in the "Declaration of Helsinki"

refreshing baby wash Himalaya

HRIPT (Human Repeat Insult Patch Test):

Evaluation of skin sensitization potential of an investigational product by Human Repeat Insult Patch Test (HRIPT).

The objective of this study was to determine sensitization potential of each product and to determine the cumulative irritation potential of the test product by 9 occlusive applications under occlusion. This was a single-center, evaluator-blinded, sensitization study in healthy adult human subjects (18 to 65 years of age) using repeat insult patch testing conducted at independent CRO in the year 2020. Qualified subjects finished all three phases of the study (i.e. Induction, Rest, and Challenge).

Each test material was applied three (3) times a week for a total of nine (9) applications following a two (2) week Rest period, a minimum of 12 days and a maximum of twenty-four (24) days. After the Rest period, a 48-hour Challenge application of each material was made.

The study was initiated after the Ethics Committee's approval; study protocol and other study documents were submitted to the Independent Ethics Committee and the study was approved on February 4, 2020. Subjects were enrolled in the study after voluntarily signing the informed consent

form. 200 subjects completed the study. All subjects received the test product along with Negative Control as per the guidelines.

Occluded patches were used in the study (i.e. Finn Chambers measuring about 1 cm diameter). 1 cm diameter filter paper was placed on the Finn chamber disc. Then the test product was applied to the filter paper. The area beneath the patch was only considered for the irritation observation, whereas any sign of irritation due to tape was ignored. There was no tape irritation observed in this study.

Investigational Product: Refreshing Baby Wash Himalaya

Number of subjects: 200

Number of Patches: Each test material was to be applied three (3) times a week for a total of nine (9) applications followed by a two (2) week Rest period, a minimum of 12 days and a maximum of twenty-four (24) days. After the Rest period, a forty-eight (48) hour Challenge application of each material was to be made.

Study Methodology: The study was conducted for approximately 6 weeks for each subject to confirm that the test substances would not produce evidence of delayed contact sensitization following external contact with the skin using a repeated patch application procedure. The

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study was conducted on male and female subjects, 18 to 65 years of age. This study was comprised of 3 phases:

Induction Phase: A volume of 40 µl of the test product (diluted or pure, according to the type of product) was applied after loading on the occlusive chambers under occlusion for 3 weeks at the frequency of 3 applications per week. A negative control with 0.9% normal saline was applied along with the test product on every patch application visit. The product was applied to the upper back of subjects after ensuring that the skin was free from any active diseases. The other site where no patch was applied served as non-treated control. The patch applied was required to stay in place for twenty-four (24) hours and was reapplied each time on the same site after evaluation by the dermatologist. The days of patch application were on visits 2, 3, 4, 5, 6, 7, 8, 9, and 10. The evaluation was done twenty-four (24) hours postpatch removal and the fresh patch was applied immediately after evaluation.

Rest Phase: During the 2 weeks of Rest phase, no patch was applied. The previous reaction seen in test sites (product sites) should have completely subsided in the Rest phase. The Rest phase was of minimum 12 days and a maximum of 24 days.

Challenge Phase: During the Challenge

phase, the test product was reapplied in a patch following the same procedure at a new contralateral naive test site, as used in the Induction phase. The applied patches were taken off twenty-four (24) hours after application, and a series of clinical readings were carried out at 24 hours, 48 hours, and 72 hours.

Re-challenge Phase (only those products which show a positive response in Challenge phase): Subjects, indicative of allergic dermatitis, as per the reactions observed in Challenge phase were to be patched with the indicated product on the original site and another site on the back to affirm the nature of the reaction. As none of the subjects showed an indicative allergenic response, the Re-challenge phase (confirmatory patch application) was not done.

Executive Result: The test product was found to be hypoallergenic in the test population with no indicative allergenic response in the Challenge phase. The test product was found to be 'Mild and Gentle' on the skin of the test population. Hence, it can be inferred that Refreshing Baby Wash Himalaya will not show any allergenic reactions in the majority of the population. *Individual response may vary due to pre-existing sensitization/allergy with any of the ingredients.*



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In-Use Clinical Efficacy Study:

Once safety is established by HRIPT study in healthy adult volunteers, the test product will be tested on the target population. This kind of study is called an in-use study or claim substantiation study. This study is conducted to support all the claims on the pack for that product. The study was conducted at Dhanvantari Ayurveda College Hospital & Research Centre under the supervision of Dr. Roopa Bhat in the year 2017.

The study was initiated after the Ethics Committee's approval; study protocol and other study documents were submitted to the Independent Ethics Committee for review and approval. Subjects were enrolled in the study after voluntarily signing the informed consent form by the babies' mothers/ caretakers. All enrolled subjects underwent assessment as per the protocol, and 40 subjects completed the study.

Name of Product: Refreshing Baby Wash Himalaya

Title of Study: A monocentric, single-arm, efficacy, safety, and quality of life study for Refreshing Baby Wash Himalaya in imparting refreshness in babies between 0 to 4 years.

Study Center: Dhanvantari Ayurveda College Hospital & Research Centre Siddapur (N.K)- 581355, Karnataka

Objectives:

Primary Objective: The trial aims at evaluating the efficacy of Refreshing Baby Wash Himalaya in skin moisture, effective cleansing activity, fragrance, skin texture, rinsing activity, no tears, and overall satisfaction when used once daily.

Secondary Objective: Safety of the Refreshing Baby Wash Himalaya.

Number of subjects: 40

Inclusion Criteria:

- Healthy babies in the age group of 0 to 48 months
- Ability to comply with study procedures
- Signed informed consent form

Exclusion Criteria:

- Any apparent skin pathology
- Participating or participated in similar studies within 6 weeks

Efficacy and Safety Evaluation:

The efficacy of Refreshing Baby Wash Himalaya was measured using a nonparametric scale. Skin moisture, the effectiveness of cleaning, fragrance, skin texture, after bath rinsing, tears while bathing, and overall satisfaction were assessed at screening. This measurement served as the baseline for the Treatment phase of the study. The criteria for

refreshing baby wash Himalaya

evaluation were measured in the following visit schedule:

1. Visit 0 (Screening/Baseline)
2. Visit 1 (after 3 days)
3. Visit 2 (after 7 days)
4. Visit 3 (after 14 days)
5. Visit 4 (after 28 days)

Clinical Examination: During each visit, the investigator performed a thorough clinical examination for any adverse events and recorded them in the CRF.

Safety: During each visit, the investigator performed a complete skin examination and noted any abnormality or adverse events. Subjects were instructed to inform the investigator if they experience any untoward events during the study.

Discussion and Overall Conclusion:

The efficacy and safety of Refreshing Baby Wash Himalaya was planned to be conducted in 40 subjects. All the subjects completed the study at the time of report preparation. Primary endpoints being studied for evaluation of Refreshing Baby Wash Himalaya were:

- **Effectiveness of cleansing:** At entry 58% of mothers were satisfied, and 43% of mothers of subjects were very pleased with the cleansing activity. By the end of the study, 85% of mothers were very

pleased with the cleansing activity of Refreshing Baby Wash Himalaya.

- **Fragrance:** The fragrance was assessed as per the mothers' opinion; 55% of mothers liked the fragrance of Refreshing Baby Wash Himalaya at the entry, wherein by the end of the study, 80% of mothers were very pleased with the fragrance.
- **Tears while bathing:** None of the subjects had tears during bathing with Refreshing Baby Wash Himalaya as reported by mothers.
- **Skin texture:** 56.25% of parents of the subjects found that their baby's skin was smooth after the first application, whereas 34.38% of parents felt their baby's skin was slightly dry after the first application. By the end of the study, 100% of babies had smooth skin according to the parents.
- **Rinsing:** 93.75% of subjects' mothers found it easy to rinse after the first application. Later, 21.88% of mothers had an opinion that the product takes more water to rinse, and 75% remained with the perspective of easy to rinse.
- By the end of day 28, an average of 38% of parents of the subjects were satisfied with Refreshing Baby Wash Himalaya, and 63% were very pleased with it.

refreshing baby wash **Himalaya**

Keeps baby's skin cool and fresh

Watermelon



Known for its hydrating and cooling properties

Lemon



Helps cool and refresh baby's skin

Neem



Well-known for its antibacterial and anti-inflammatory properties

Champaca



Known to possess hydrating and cooling properties

Cleanses and refreshes baby's skin

pH-balanced formulation

Has cooling and refreshing actions

Contains herbal ingredients that possess antibacterial and anti-inflammatory properties to help protect baby's skin

Helps maintain soft and supple skin



Available in 200 ml & 400 ml

FREE FROM

Parabens
SLS/SLES*
Synthetic Colors



*SLS - Sodium Lauryl Sulfate; SLES - Sodium Lauryl Ether Sulfate

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Helps cool and refresh baby's skin

Neem



Well-known for its antibacterial and anti-inflammatory properties

Champaca



Known to possess hydrating and cooling properties

Usage

Ideal for use in summer

Directions for use

- Pour onto a wet sponge or hands and apply to the baby's skin
- Gently work up a lather and rinse



FREE FROM

Parabens
SLS/SLES*
Synthetic Colors



*SLS - Sodium Lauryl Sulfate; SLES - Sodium Lauryl Ether Sulfate



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