

Original Research Article

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Post marketing studies for safety, tolerability, and effectiveness of Himalaya's comprehensive range of baby care products

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ABSTRACT

Background: The baby care product market has seen a substantial growth in the recent years which has resulted in an increased concern about the safety and tolerability of these products for babies aged 0-36 months. Due to their delicate skin, the infants are highly sensitive to the potential undesirable effects of chemicals present in such products. This study is conducted with Himalaya's range of baby care products. To assess safety, tolerability and effectiveness of natural baby care products for newborns, infants and toddlers.

Methods: These post marketing observational studies (PMOS) were conducted among 9000 babies (approx. 500 babies were allocated to each of the 18 products), enrolled at 25 different medical centres across India. Safety, tolerability and efficacy of Himalaya's range of baby products were assessed after 15 days of usage. Mildness and gentleness of the products on babies' skin was assessed through dermatological assessment by a pediatrician on the scale of 0-4 (0=No change and 4=excellent). The safety was assessed by continuous monitoring of any signs or symptoms of local intolerance, undesirable effects, and adverse events. Subjective assessments from parents/caretakers were also recorded to know the tolerability and overall suitability of the test products.

Results: The study ensured the ability to evaluate both the improvement of symptoms from the initial baseline and the potential reappearance of symptoms throughout the research period. The products showed, statistically significant improvement (p value of <0.05) in the softness and smoothness of baby's skin along with keeping the skin moisturized. No product related local intolerance, undesirable effect or adverse events were observed or reported during the study.

Conclusions: Himalaya's range of baby care products are well-tolerated and found to be safe, effective, and suitable for regular use in babies aged 0 to 36 months.

Keywords: Baby care products, Gentle, Mild, Moisturization, Smoothness, Softness

INTRODUCTION

Parenting is a process of nurturing and supporting the physical, emotional, and social development of a baby. The right care for children ensures that the child grows well and reaches full potential.¹⁻³ The developing state of infant's skin is highly susceptible to dryness, irritation, rash, and redness from external elements such as extremes of temperature, air pollutants and also from harmful chemicals in the baby care products. Hence, it is essential that any baby care products such as oil, cream, soap, shampoo, etc. be well tolerated and not have any negative impact on the new-born's skin.⁴

Newborns and toddlers are routinely exposed to many external elements. It is crucial to safeguard the baby's skin barrier to maintain its effective functioning with the aid of safe and well tolerated natural baby care products.

Perhaps this explains why consumers and healthcare professionals are increasingly looking for products with natural ingredients. Using natural oils like mustard oil, coconut oil on infant skin offers several advantages, including natural protection against injuries and skin infections. These oils also play a role in regulation of temperature of the skin by minimizing water evaporation through the outer skin layer (epidermis) and absorbing important lipid components.⁵ Himalaya's range of baby care products have been formulated by using upto 99% natural origin ingredients.

The European regulation (EU) No. 1223/2009 requires safety assessment of all the ingredients used in formulations to ensure the safety of finished product in babies prior to marketing. The safety assessment for all ingredients used in each product was performed using the literature-based weight-of-evidence (WoE) with respect to the reported use concentration for the product category (leave on or rinse off), and primary irritation patch test (PIPT)/ human repeat insult patch test (HRIPT) studies. In addition, exposure-based risk assessment (Toxicological profile) on the basis of the following: frequency of use (/day), estimated daily exposure (g/day) and relative daily exposure (mg/kg bw/day) based on the body weight for infants (6 months-1 year), toddlers (1-3 years) and children (3-10 years) was conducted to obtain the margin of safety (MoS) of cosmetic ingredient. MoS >100 was ensured which indicated that the cosmetic ingredient can be considered safe for use.⁶ Two-tiered approach of literature-based WoE and exposure-based risk assessment (Toxicological profile) confirmed the product safety to protect the target consumers. As a standard development process of topical products, all the test products were evaluated through HRIPT on 200 adults (male/female) healthy volunteers to confirm non-allergenic potential through scientifically robust and statistically reliable data (BIS 4011:2018 guidelines).⁷ This PMOS was conducted to further confirm the usefulness in terms of safety, tolerability and effectiveness in larger target population.

This article presents the outcome of PMOS conducted with Himalaya's range of baby care products assessing the safety, effectiveness and tolerance on new-borns, infants and toddlers.

METHODS

Study design

Open label, multicentric, post-marketing observational clinical studies were conducted to assess the tolerability, safety, and effectiveness of Himalaya's range of baby care products after use for 15 days period. The study included approximately 500 subjects (n) for each of the 18 products (two products namely baby diapers and gentle baby wipes had two variants each). Parents were instructed to use the test products as per the frequency and directions of use (details given in Table 1). A total of approximately 9000 babies were enrolled at 25 different medical centres across India ensuring a broad geographic distribution while minimizing potential biases.

The studies were carried out at out-patient clinics/hospitals and assessed by investigators. The choice of conducting the studies in target babies allowed for observations under routine conditions, including potentially suboptimal environments.

Study participants

Healthy, full-term newborns, infants and toddlers of age 0-36 months were considered eligible for the studies. Participants were required to be in overall good health, as confirmed through pediatricians by recent medical history and physical examination. The subjects' mother had to mandatorily provide voluntary written informed consent and also required to adhere to the study's established protocol and follow up visits. Participants with a documented history of allergies requiring medical intervention, with a history of allergy to any of the components of the test products or those currently experiencing allergic conditions, as well as individuals with chronic illnesses were excluded from the study. Additionally, subjects whose parents or guardians were unwilling to halt the application of concomitant similar products throughout the study, were also excluded.

Intervention/ study products

This study included 18 ranges of Himalaya's baby care products (hair oil, body oil, soap, powder, wipes, cream, lotion, shampoo, body wash, etc). The detailed description of the study products and their directions of use is given in Table 1. The parents or caretakers of the babies were instructed to use the test product consistently for 15 days. Products were to be stored in a cool and dry place after each successive use or application. The studies included two separate visits, the baseline visit (Visit 1) on day 1 and end of study (EOS) visit (Visit 2) on day 15 for final assessment.

Ethical conduct of the study

The studies adhered to ethical principles based on the declaration of Helsinki and international council for harmonisation of technical requirements for pharmaceuticals for human use (ICH), guideline for good clinical practice (GCP).⁸ Before commencing the study, study protocol and documents were reviewed and approved by competent ethics committee (The Raneshwar multispecialty hospital ethics committee; reg. no. ECR/1232/Inst/GJ/2019, approved on 20/08/2022). These studies were prospectively registered in clinical trial registry of India (CTRI). Table 2 provides details about study sites, study duration, and CTRI Registration number for each product.

Efficacy assessments

Efficacy assessments of these studies were carried out by pediatricians and through feedback from subject's Parent/LAR. The mildness and gentleness of the product on baby's skin or scalp was assessed by pediatricians in every study visit. During visit 1 (baseline/day 1) and visit 2 (EOS/day 15), subjective assessment by parents were recorded to evaluate the overall suitability of the test products with respect to keeping the baby's skin soft, smooth, moisturized and keeping baby's hair untangled, shining and soft. Additionally, symptom assessment questionnaire was filled by subject's parent/LAR at visit 1 (baseline/ day 1) and visit 2 (EOS/ day 15) for 3 products: baby massage oil-mustard, diaper rash cream and prickly heat baby powder. Purpose was to assess

effect of products in resolving symptoms (rashes, itchiness etc.,) that were present at baseline. Furthermore, at visit 2 (EOS/day 15) subjective feedback questionnaire was used to capture parents' experiences with test products. Details about assessments are given in Table 3.

Safety assessments

Safety was assessed through local intolerance such as dryness, erythema, edema, scaling, itching, rashes, and burning sensation by pediatricians. Any undesirable event was monitored and recorded in line with the principles of COLIPA guidelines given in Table 3.⁹ Safety and tolerability of the test products were closely monitored by recording and assessing any adverse events (AE) and serious adverse events (SAE).

Statistical analysis

Demographic details of subjects were analysed using descriptive statistics. Frequencies and percentages were reported for qualitative variables. Central tendencies like means, medians and measures of dispersion like standard deviations, minimum and maximum values were used to summarize quantitative variables. To assess the significance of continuous variables, Wilcoxon matched pairs signed rank test was utilized, level of significance was fixed at a level of 0.05. Statistical analyses were conducted on the subjects who completed the entire study by statistical analysis system (SAS) software version 9.4. Data collections were compliant with 21 CFR part 11 electronic data capture system.

Table 1: Description of the products.

Product name	Product code	Main ingredients	Indication/direction of use
Baby massage oil-mustard	HKMO-031738	Country mallow, winter cherry, vetiver, aloe vera, olive oil	Gently massage oil all over baby's body including hands and legs
Baby massage oil	HNBO-091901	Olive oil, country mallow, aloe vera, vetiver	Gently massage oil all over baby's body including hands and legs
Baby massage oil-coconut	HKMO-031738 (CO)	Coconut, country mallow, winter cherry, vetiver, aloe vera, olive oil	Gently massage oil all over baby's body including hands and legs
Baby hair oil	HBHO-011711	Indian gooseberry, false daisy, asiatic pennywort, fenugreek seed	Gently massage hair oil over scalp.
Baby cream	HBYC-091904	Olive oil, licorice	Apply cream after bath to baby's body and areas like face, face, knees, and elbows. Avoid the area around the eyes.
Baby lotion	HBLT-091905	Country mallow, licorice, olive oil, almond oil	Apply the lotion all over the baby's body (use twice daily or as directed by your doctor).
Baby diapers	HNBD-071601	Aloe vera, super absorbent polymer layer	Clean the diaper area, position diaper under baby, adjust below navel, secure relockable tapes for a comfortable fit, and fasten relockable hook-on loop for added comfort.
Total care baby pants	HTCP-091910	Aloe vera, super absorbent polymer layer	Pull the diaper up like pants and ensure that the waist area is not folded over.
Diaper rash cream	HDRC-061817	Aloe vera, almond, Indian madder	Apply the cream on rashes and on the area where the edges of the diaper rub against baby's skin.

Continued.

Product name	Product code	Main ingredients	Indication/direction of use
Extra moisturizing baby soap	HEBS-091541	Almond and olive oils, aloe vera, milk	Wet the baby's body and face with water, apply the soap generously, work up lather and rinse with water
Nourishing baby soap	HNBS-091912	Honey, milk, castor oil, sunflower extracts	Wet the baby's body and face with water, apply soap generously, work up lather and rinse with water.
Extra moisturizing baby wash	HEMW-091902	Aloe vera, olive oil, almond oil	Pour baby wash into a wet sponge and apply directly to baby's skin and rinse well.
Gentle baby shampoo	HGSH-091903	Hibiscus extract, chickpea, vetiver	Pour baby shampoo on wet sponge and apply directly to baby's skin and rinse well.
Gentle baby bath	HGBB-061818	Chickpea, green gram	Pour baby bath on wet sponge and apply directly to baby's skin and rinse well.
Prickly heat baby powder	HPHB-091908	Indian beech, neem, vetiver	Sprinkle baby powder on to your palms and apply on baby's skin after bath, nappy changes and before bedtime.
Baby powder	HBYP-091907	Olive oil, almond oil, vetiver	Sprinkle baby powder on to your palms and apply on baby's skin after bath, nappy changes and before bedtime.
Gentle baby wipes	HGBW-101506	Aloe vera, Indian lotus	Pull out wipes and gently clean the baby, carefully reseal the pack flap to keep wipes fresh and moist for future.
Extra-large baby wipes	HGBW-101506XL	Aloe vera, Indian lotus extracts	Pull out wipes and gently clean the baby, carefully reseal the pack flap to keep wipes fresh and moist for future.
Gentle baby soap	HGBS-101507	Almond oil, olive oil, vitamin e	Wet the baby's body and face with water, apply the soap generously, work up lather and rinse with water.
Refreshing baby soap	HRBS-091911	Watermelon, vetiver oil, neem	Wet the baby's body and face with water, apply the soap generously, work up lather and rinse with water.

Table 2: Study details.

Product name	N	No. of study sites	Study period	Ctri. registration no.	Reg. date
Baby massage oil-mustard	500	22	28-May-2022 to 14-Jul-2022	CTRI/2022/05/042590	17/05/2022
Baby massage oil	500	25	15-Oct-2021 to 05-Feb-2022	CTRI/2021/10/037101	05/10/2021
Baby massage oil-coconut	500	24	17-May-2022 to 21-July-2022	CTRI/2022/05/042584	17/05/2022
Baby hair oil	500	24	26-Oct-2021 to 05-Feb-2022	CTRI/2021/09/036987	30/09/2021
Baby cream	500	25	25-Oct-2021 to 05-Feb-2022	CTRI/2021/10/037103	05/10/2021
Baby lotion	500	24	18-Oct-2021 to 01-Feb-2022	CTRI/2021/10/037290	13/10/2021
Baby diapers	252	25	28-Jan-2022 to 29-May-2022	CTRI/2021/10/037294	13/10/2021
Total care baby pants	248	26	28-Jan-2022 to 29-May-2022	CTRI/2021/10/037294	13/10/2021
Diaper rash cream	492	23	29-Jan-2022 to 28-Jun-2022	CTRI/2021/10/037472	22/10/2021
Extra moisturizing baby soap	500	24	27-Jan-2022 to 04-May-2022	CTRI/2021/10/037295	13/10/2021
Nourishing baby soap	500	25	29-Jan-2022 to 16-May-2022	CTRI/2021/10/037555	25/10/2021
Extra moisturizing baby wash	498	24	26-Jan-2022 to 02-May-2022	CTRI/2021/10/037296	13/10/2021
Gentle baby shampoo	500	24	19-Apr-2022 to 01-Jun-2022	CTRI/2021/10/037297	13/10/2021
Gentle baby bath	500	24	19-Apr-2022 to 07-Jul-2022	CTRI/2021/10/037298	13/10/2021
Prickly heat baby powder	500	24	19-Apr-2022 to 12-Jul-2022	CTRI/2021/10/037163	07/10/2021
Baby powder	500	25	25-Oct-2021 to 05-Feb-2022	CTRI/2021/10/037102	05/10/2021
Gentle baby wipes	251	24	20-Oct-2021 to 05-Feb-2022	CTRI/2021/09/036991	30/09/2021
Extra large baby wipes	249	24	20-Oct-2021 to 05-Feb-2022	CTRI/2021/09/036991	30/09/2021
Gentle baby soap	500	25	27-Jan-2022 to 25-May-2022	CTRI/2021/10/037322	14/10/2021
Refreshing baby soap	500	24	19-Apr-2022 to 02-Jul-2022	CTRI/2021/10/037485	22/10/2021

*N: No. of subjects included in each study product, CTRI: Clinical trials registry-India.

Table 3: Effectiveness and safety assessments.

S. no.	Assessment	Scale
Effectiveness assessment		
1	Dermatology assessment for mildness and gentleness on baby's skin was assessed by the pediatricians	0=Nil; 1=Fair; 2=Good; 3=Very good; and 4=Excellent
2	Subjective feedback questionnaire assessment of the test product on the following areas: Overall suitability of the test product on the applied body part (skin, scalp, diaper area etc.) Overall sensory perception of the product (coolness, softness, good smell, etc.) Overall improvement of the baseline conditions after using the test products	1=Strongly disagree 2=Disagree 3=Neither agree nor disagree 4=Agree 5=Strongly agree
3	Symptom assessment questionnaire was used to assess, itchiness (Q1), redness (Q2), rashes (Q3), burning sensation (Q4), boils/blisters (Q5) using a rating scale-where applicable. Duration of recovery of symptoms (in days)-where applicable	Q1: 0=Very itchy skin to 10=No itching, Q2: 0=Severe red patches to 10=No red patches Q3: 0=Severe rashes to 10=No rashes Q4: 0=Severe burning to 10=No burning Q5: 0=Many boils/blisters to 10=No boils/blister
4	Subjective questionnaire assessment for softness (Q1), smoothness (Q2) and moisturization (Q3) of the baby's skin assessed	Q1: 0=Not soft to 10= Very soft Q2:0=Very rough to 10=Very smooth Q3:0=Very dry to 10=Very moisturized
Safety assessment		
5	Local intolerance assessment for dryness, erythema, oedema, scaling, itching, rashes, burning sensation	0=None, 1=Mild, 2=Moderate, 3=Severe
6	Undesirable event: As per COLIPA guidelines (Cosmetics guidelines from Europe) on the management of undesirable effects	

*COLIPA Guidelines: The European cosmetic and perfumery association.

RESULTS

Demographic distribution of subjects

Demographic characteristics such as gender, age for all subjects included in studies shown in Table 4. Research encompassed children with distinct age categories: 0 day to \leq 1 month, >1 month to \leq 12 months, and >12 months to 36 months and representative day 1 babies.

Effectiveness assessments

Dermatological assessment

Dermatological assessment for mildness and gentleness indicated that the test products were mild and gentle for babies' skin; in more than 90% of subjects, the test products were found to be good, very good or excellent in mildness and gentleness. Details are given in Figure 1.

Subjective assessment questionnaire

For all studies, parents completed subjective assessment questionnaires at the baseline and at the end of study (EOS) (Details given in Table 5 and 6). The study outcome demonstrated notable clinical validation, confirming the overall softness, smoothness, and hydrating properties of the baby products. Statistically

significant improvements were seen in hair softness, shine, reduction of tangles, in management of dandruff and cradle cap in baby hair, in maintaining baby skin's softness, suppleness, moisturization, as well as providing a cooling and fresh sensation post-bath.

Symptom assessment questionnaire

Symptom assessment questionnaire was used to assess the effect of the products in resolving the symptoms (rashes, itchiness) after use of baby massage oil-mustard, diaper rash cream and prickly heat baby powder. There was a significant improvement in rash and itchiness at EOS when compared to baseline. The highest resolution rate was for diaper rashes with diaper rash cream at 95.1%. Skin itchiness and skin rashes treated with baby massage oil- mustard showed 81.4% and 73.5% resolution, while prickly heat powder resolved prickly heat rash in 68.6% of subjects (Figure 2). Results indicated that 70-90% of subjects had their symptoms resolved in 7 to 10 days (Figure 3).

Safety assessments

Adverse events and local intolerance

There were no significant test product related adverse events or serious adverse events observed or reported throughout the study. Throughout the study few sporadic

incidences of mild to moderate local intolerance (i.e., erythema, rashes and burning sensation) were observed (<1%) and the details are mentioned in Table 7. During the study one subjects out of 500 (0.2%) experienced mild rashes in each of the following study products: baby lotion, baby bath and moisturizing baby soap, gentle baby soap, baby massage mustard oil. Further two subjects out

of 500 (0.4%) experienced mild rashes in refreshing baby soap and baby massage oil. Around 3 subjects out of 252 (1.2%) experienced mild and moderate rashes for baby diaper. Overall, it can be concluded that products safe to use without any significant local intolerance or any product related adverse events/serious adverse events.

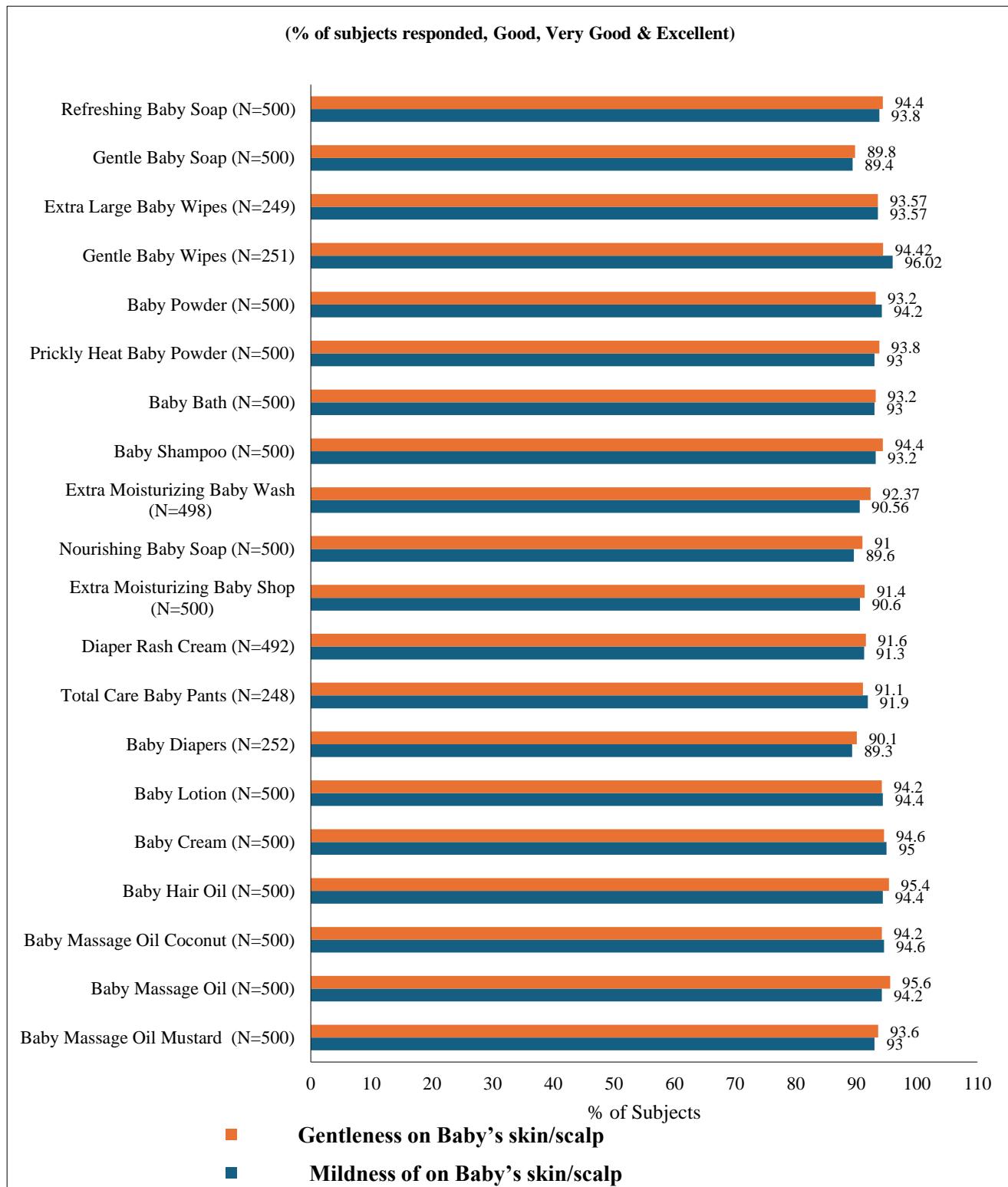


Figure 1: Summary of dermatological assessment mildness and gentleness of the products.

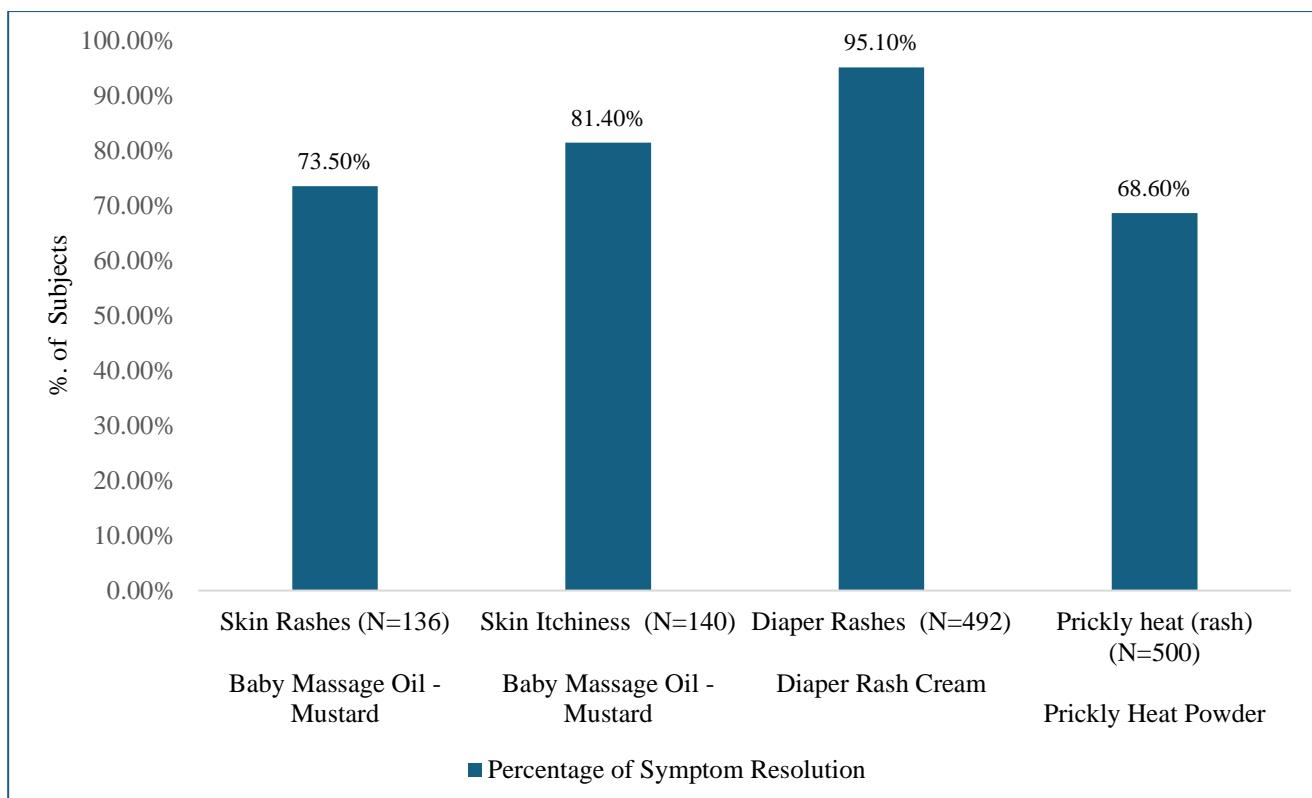


Figure 2: Percentage of subjects showing symptom resolution.

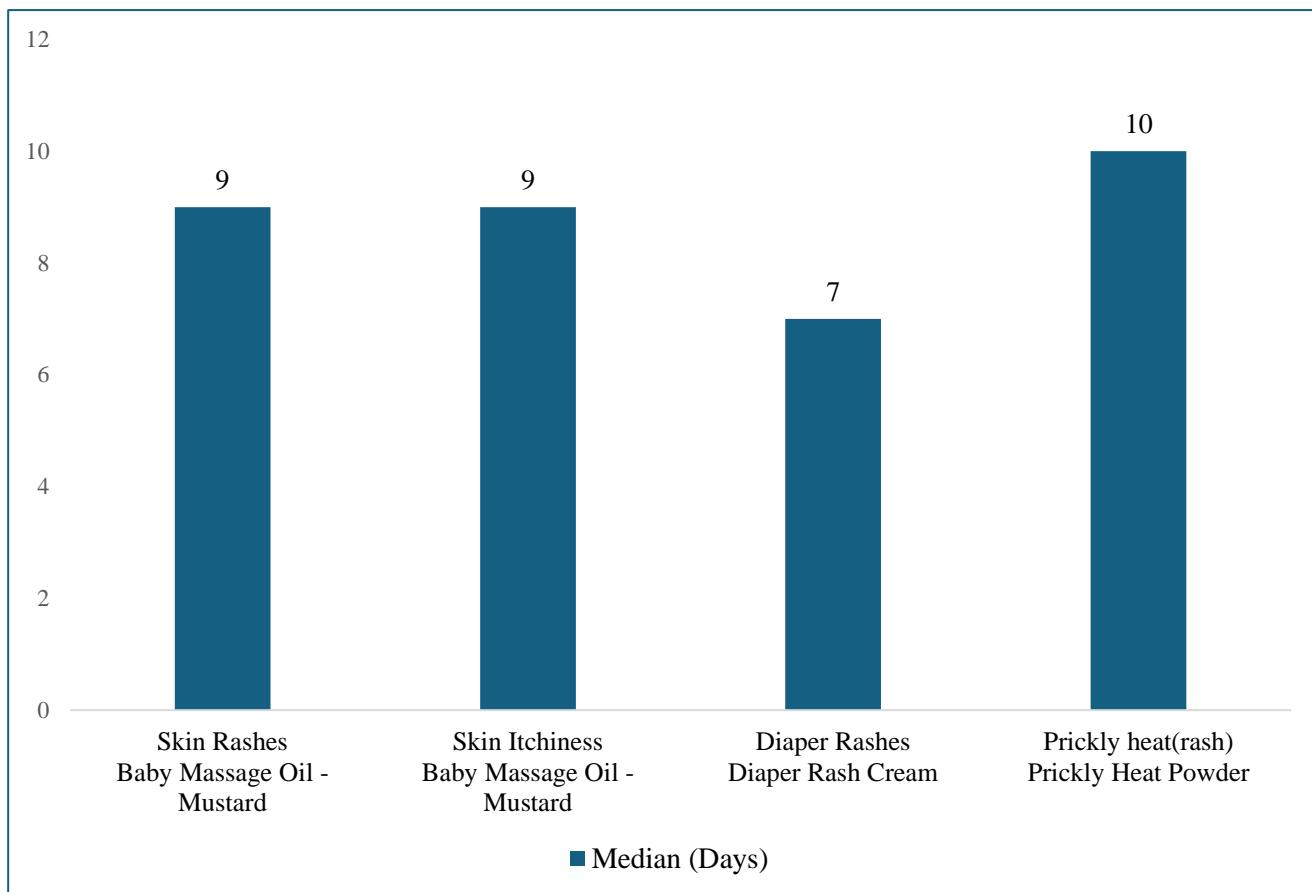


Figure 3: Median days of resolution of symptoms.

Table 4: Demographics.

Name of the products	Completed subjects (N)	Age distribution (%)			Statistics			Gender distribution (%)	
		0 day to \leq 1 month	>1 month to \leq 12 months	>12 months to 36 months	Mean \pm SD (months)	Median (months)	Min, max (months)	Female	Male
Baby massage oil-mustard	500	12.8	46	41.2	12.5 \pm 10.5	9.9	0, 36	47.4	52.6
Baby massage oil	500	7.8	49	43.2	12.54 \pm 10.14	10.50	0, 35	43	57
Baby massage oil-coconut	500	15.4	43.8	40.8	11.68 \pm 9.94	9	0.35	46.4	53.6
Baby hair oil	500	3.8	37.4	58.8	15.55 \pm 10.21	14	0, 36	49.6	50.4
Baby cream	500	5.8	39.2	55	15.36 \pm 10.58	14	0, 35	51.2	48.8
Baby lotion	500	8.2	35.2	56.6	15.23 \pm 10.77	14	0, 35	46.4	53.6
Baby diapers	252	6.7	71.0	22.2	7.6 \pm 6.9	5.3	0, 36	47.2	52.8
Total care baby pants	248	0.8	50.4	48.8	13.8 \pm 9.8	12.2	0.36	44.8	55.2
Diaper rash cream	492	5.5	47.6	47	12.9 \pm 9.8	11.6	0, 36	51.0	49.0
Extra moisturizing baby soap	500	8	44.6	47.4	13.06 \pm 9.95	11	0, 36	47.2	52.8
Nourishing baby soap	500	4.4	42.2	53.4	14.6 \pm 10.5	13.2	0, 36	56.4	43.6
Extra moisturizing baby wash	498	15.7	42.2	42.2	11.32 \pm 10.63	8	0, 36	48.8	51.2
Gentle baby shampoo	500	4.8	46.8	48.8	14.6 \pm 10.3	12	0, 36	47.4	52.6
Gentle baby bath	500	14.4	44.4	41.2	11.8 \pm 9.2	10.1	0, 36	47.2	52.8
Prickly heat baby powder	500	5.4	43.2	51.4	14.7 \pm 9.8	12.9	0, 35	52.4	47.6
Baby powder	500	8.2	35.2	56.6	14.99 \pm 10.19	14	0, 35	51.4	48.6
Gentle baby wipes	251	12.4	51.8	35.9	10.91 \pm 10.29	8	0, 35	46.22	53.78
Extra-large baby wipes	249	10.8	50.2	39	11.24 \pm 9.98	8	0, 35	43.77	56.22
Gentle baby soap	500	3.8	48	48.2	14.2 \pm 10.2	12	0, 36	47.4	52.6
Refreshing baby soap	500	8.2	48	43.8	12.7 \pm 9.9	10.8	0, 36	48	52

*N: No. of subjects included in each study products, the values are expressed as numbers (%), and median (range), SD: Standard deviation, including 1 transgender subject.

Table 5: Subjective assessment questionnaire A.

Products name	Completed subjects (N)	Q1. How moisturized is your baby's skin/baby's hair?*			Q2. How soft is your baby's skin or scalp?*			Q3. How smooth/shine is your baby's skin/ hair?*		
		Baseline (Mean±SD)	EOS (Mean±SD)	CFB (%)	Baseline (Mean±SD)	EOS (Mean±SD)	CFB (%)	Baseline (Mean±SD)	EOS (Mean±SD)	CFB (%)
Baby massage oil mustard	500	5.7±1.1	7.8±1.17	39.1	5.8±1.2	7.8±1.3	36.4	5.8±1.2	7.8±1.35	38.2
Baby massage oil	500	4.64±1.15	7.42±1.39	69.45	4.76±1.21	7.49±1.53	65.46	4.72±1.2	7.48±1.48	68.1
Baby massage oil coconut	500	5.39±1.25	7.57±1.3	45.5	5.51±1.28	7.59±1.31	42.4	5.53±1.25	7.66±1.35	43.18
Baby hair oil	500	4.57±1.13	7.34±1.5	69.9	4.78±1.16	7.47±1.35	64.72	4.74±1.13	7.34±1.5	69.49
Baby cream	500	4.7±1.2	7.4±1.4	69.7	4.78±1.16	7.47±1.2	70.1	4.8±1.2	7.6±1.5	70.5
Baby lotion	500	4.71±1.27	7.34±1.41	65.35	4.76±1.2	7.38±1.4	63.47	4.78±1.27	7.47±1.48	65.84
Baby diapers	252	5.1±1.48	7.3±1.29	54.5	5.1±1.57	7.2±1.48	53.2	5.1±1.6	7.3±1.59	55.3
Total care baby pants	248	4.9±1.53	7.1±1.38	56	4.9±1.49	7.2±1.49	55.5	4.8±1.58	7.1±1.56	58.9
Diaper rash cream	492	5.2±1.48	7.4±1.4	49.8	5.2±1.51	7.3±1.5	47.9	5.1±1.54	7.2±1.65	50.3
Extra moisturizing baby soap	500	4.43±1.33	6.76±1.38	66.41	4.34±1.35	6.7±1.5	67.08	4.31±1.35	6.79±1.64	70.47
Nourishing baby soap	500	4.9±1.37	7.1±1.43	55.1	4.9±1.31	7.2±1.41	55.2	4.9±1.36	7.1±1.5	56.1
Extra moisturizing baby wash	498	4.52±1.38	6.9±1.37	66.87	4.51±1.40	6.8±1.49	65.3	4.47±1.42	6.93±1.58	70.18
Prickly heat baby powder	500	NA	NA	NA	5.6±1.41	7.7±1.11	46.6	5.7±1.29	7.7±1.2	40.7
Baby powder	500	NA	NA	NA	4.82±1.24	7.31±1.39	60.81	4.87±1.29	7.41±1.46	61.34
Gentle baby wipes	251	4.9±1.39	7.37±1.44	58.98	4.93±1.39	7.42±1.45	60.69	4.89±1.41	7.53±1.45	65.17
Extra-large baby wipes	249	4.79±1.17	7.29±1.41	59.48	4.79±1.26	7.27±1.55	60.13	4.84±1.27	7.33±1.57	60.58
Gentle baby soap	500	4.8±1.34	7.1±1.45	56.3	4.9±1.36	7.2±1.42	56.9	4.8±1.36	7.1±1.46	56.5
Refreshing baby soap	500	5.2±1.44	7.5±1.33	57	5.2±1.32	7.5±1.28	52.4	5.3±1.55	7.6±1.44	54.4

*Assessment was carried out on 0 to 10 point scale, Q1: 0=Very dry 10=Very moisturised, Q2: 0=Not soft 10=Very soft, Q3: 0=Very rough 10=Very smooth, N: No. of subjects included in each study products, EOS: End of study, CFB: Change from baseline, All EOS values were found to be statistically significant with $p<0.0001$.

Table 6: Subjective assessment questionnaire B.

Products name	Gentle baby shampoo			Gentle baby bath		
	Baseline (Mean±SD)	EOS (Mean±SD)	CFB (%)	Baseline (Mean±SD)	EOS (Mean±SD)	CFB (%)
Questionnaire*						
How soft and shine is your baby's hair?	5.8±1.39	8±1.2	43.5	NA	NA	NA
How tangled are your baby's hair?	6.4±1.84	8.4±1.19	40.1	NA	NA	NA
Does your baby have dandruff?	6.3±1.97	8.9±1.29	53.6	NA	NA	NA
Does your baby have cradle cap?	9.3±1.58	9.9±0.57	10.8	NA	NA	NA
How soft and supple is your baby(s) skin?	NA	NA	NA	5.1±1.4	7.4±0.27	55.8
How moisturized is your baby(s) skin?	NA	NA	NA	5.1±1.36	7.5±0.33	57.1
Is your baby's skin cool and fresh after bath?	NA	NA	NA	5.3±1.55	7.6±0.41	55.1

*Assessment was carried out on 0-to-10-point scale, Q1: 0=Not soft and shiny 10=Very soft and shiny, Q2: 0=Tangled soft 10=Not Tangled, Q3: 0=Dandruff 10=No Dandruff, Q4: 0=Severe cradle cap 10= No cradle cap, Q5: 0=Not Soft and supple 10=Very soft and supple, Q6: 0=Very dry 10=Very moisturised, Q7: 0=Not fresh 10=Very fresh, EOS: End of study, CFB: Change from baseline, All EOS values were found to be statistically significant with $p<0.0001$.

Table 7: Adverse events-local intolerance assessment.

Products	N	Dryness	Erythema	Edema	Scaling	Itching	Rashes		Burning sensation
							Mild	Moderate	
Massage oil mustard	500	Nil	Nil	Nil	Nil	Nil	0.2	Nil	Nil
Baby massage oil	500	Nil	0.4	Nil	Nil	Nil	0.4	Nil	Nil
Baby massage oil coconut	500	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Baby hair oil	500	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Baby cream	500	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Baby lotion	500	Nil	Nil	Nil	Nil	Nil	0.2	Nil	Nil
Baby diapers	252	Nil	Nil	Nil	Nil	Nil	0.79	0.39	Nil
Total care baby pants	248	Nil	Nil	Nil	Nil	Nil	0.4	Nil	Nil
Diaper rash cream	492	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Moisturizing baby soap	500	Nil	Nil	Nil	Nil	Nil	0.2	Nil	Nil
Nourishing baby soap	500	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Extra moisturizing baby wash	498	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Baby shampoo	500	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Baby bath	500	Nil	Nil	Nil	Nil	Nil	0.2	Nil	Nil
Prickly heat baby powder	500	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Baby powder	500	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Gentle baby wipes	251	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Extra large baby wipes	249	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Gentle baby soap	500	Nil	0.2	Nil	Nil	Nil	0.2	0.2	Nil
Refreshing baby soap	500	Nil	Nil	Nil	Nil	Nil	0.4	Nil	Nil

*N: No. of subjects included in each study product.

DISCUSSION

The baby's skin is designed to provide a crucial skin-barrier which maintains optimum functioning while preventing potential infections and irritants from penetrating the skin.¹⁰

In these clinical studies, the entire eighteen Himalaya's baby care products were found to be mild, gentle, and well-tolerated for children aged 0 to 36 months. Each of these products were used by approximately 500 babies aged less than three years, encompassing a diverse population of total 9,000 babies from 25 medical centres across India. The study subjects represented three age groups (less than one month, one month to \leq 12 months, and $>$ 12 months to 36 months), aligning with the product's intended users. Equitable proportions of male and female infants were recruited, mitigating potential gender-based variations in outcomes. The robustness of comprehensive approach ensured the study's transparency, ethical integrity in assessing the safety and effectiveness of the products across diverse age categories, enhancing the validity and applicability of its outcome.

The safety of all products was assessed in concurrence with the global guidelines. Each product was tested for duration of two weeks, to allow adequate exposure to the study products for evaluating safety and in-use tolerability in infants and toddlers. In a previous study conducted by Coret et al it was found that a majority exceeding 90% of mothers or caregivers believed the baby skin care products to be mild and gentle for their babies aged 0-36 months under typical usage conditions.¹¹ Similarly, in our studies, investigator assessment found the baby skin care products to be good, very good or excellent in mildness and gentleness for $>$ 90% babies aged 0-36 months. The outcome of the study validated the effectiveness of the product in relieving the symptoms like skin irritation, diaper rashes; prickly heat etc in babies after use of the product for two weeks. The study ensured the ability to evaluate both the improvement of symptoms from the initial baseline and the potential reappearance of symptoms throughout the research period. Clinical observation was verified through dermatological assessment, subjective assessment questionnaire. The findings from our studies address the shared concern of both healthcare provider and consumers regarding the tolerability of natural baby care products, when applied to toddlers or infants.

The study involved twenty-five pediatric centers across 25 cities in India involving both subjects and investigators from diverse geography and ensuring the safety of the products in varied weather and living condition. Large population of 500 subjects were enrolled in each product which provided adequate data to establish the safety of the products. The study involved standard dermatology scales evaluated by pediatricians and

questionnaires in 5-point scale for mothers' feedback about the product.

The subjects were enrolled at the site, and mothers were instructed to use the product continuously at home for period of two weeks which represented a natural setting of intended use of the products to provide a real-world experience on the product safety and effectiveness. This approach allowed for observations under real conditions, including potentially suboptimal environments (e. g., exposure to the bacteria), giving valuable insights into the product's resilience and effectiveness.

In addition of following robust research standards, the studies had two main limitations, which was kept in mind while interpreting the results of this research. Firstly, two weeks of study duration is short and not adequate to assess long-term tolerability or effectiveness of the test products. Secondly, some of the assessments were subjective in nature due to the potential subjective bias by mothers. In future studies, objective assessments through instruments can be contemplated which would further provide more accurate, impartial, and quantifiable results. There is also an opportunity for further research to explore the tolerability and effectiveness of the test products on babies with dry or sensitive skin.

CONCLUSION

The present clinical study shows that Himalaya's baby care range products have been consistently validated for their safety, tolerability, and suitability for newborns and infants and confirmed the mild and gentle nature of these products. Mothers noted their effectiveness in maintaining baby skin as soft, moisturized, smooth and hair as tangle-free, shinier, and dandruff-free. Himalaya's extensive lines of natural baby care products ensure full care to the baby throughout all environmental conditions.

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