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Design And Assessment Of Baby Wet Wipes To Provide Non-Irritating Antifungal And Antibacterial Effect

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ABSTRACT:

Wet baby wipes are pre-moistened cloths commonly used for cleaning and hygienic purposes, particularly for infants. These wipes are designed to provide an efficient, convenient solution for cleaning babies' delicate skin, offering an alternative to traditional methods like water and soap. Typically made from a combination of non-woven fabrics and various soothing ingredients, such as terminalia Arjuna, papaya seed powder and vitamins, wet baby wipes are formulated to be gentle and safe for sensitive skin. The wipes are soaked in a mild cleaning solution containing water, surfactants, preservatives, and moisturizing agents to cleanse, hydrate, and protect the skin. They offer a practical solution for on-the-go diaper changes, quick clean-ups, and even in cases where water access is limited. The widespread use of wet baby wipes has raised concerns about their environmental impact, particularly in relation to their disposal, as many contain non-biodegradable materials. Consequently, the industry is increasingly focusing on developing more sustainable alternatives, such as biodegradable wipes, to address these concerns while maintaining their practical benefits.

KEYWORDS: *Baby hygiene, Pre-moistened wipes, Sensitive skin, Gentle wipes*

1. INTRODUCTION:

Using diapers can be beneficial for babies' hygiene and comfort, but it also comes with potential risks. One common issue is skin irritation and rashes, which can occur when babies' skin is exposed to moisture, urine, or stool for extended periods. This can lead to redness, soreness, and discomfort. Some disposable diapers may contain harsh chemicals like chlorine, dyes, and fragrances that can irritate sensitive skin or trigger allergic reactions. When choosing baby wipes, it's essential to consider factors like safety, effectiveness, and comfort. Baby wipes are designed to be gentle and safe for infants' delicate skin. The science behind their composition and function is based on skin care principles, microbiology, and chemistry. Diaper dermatitis is a common issue in infancy, peaking at 9-12 months. Skin irritation can worsen this condition, increasing discomfort and suffering. Using skin-safe products and keeping the diaper region dry and clean will help reduce the baby's chance of developing dermatitis while also making them more comfortable.

MERITS OF USING BABY WET WIPE:

· They can be used anywhere

· They are easily transported

. No water is needed

·They are effective at cleaning

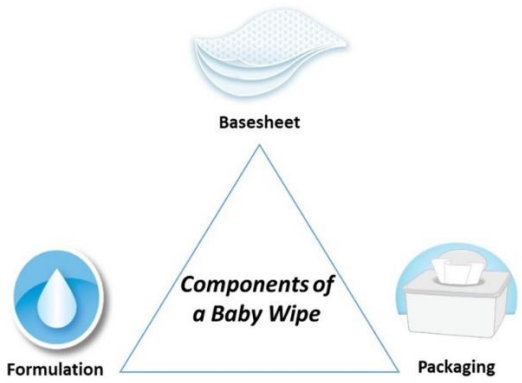
·They are available for a wide range of uses and to suit different Preferences.

2. A BABY WIPE'S NATURE:

Three essential parts make up a disposable baby wipe: the liquid composition, the base material, and the container. The three variants of the base material, which is the visible cloth-like portion of the wipe, varies in composition, which in turn affects thickness, absorbency, and tactile softness. Although the materials utilized, such as wood pulp, polyester, and polypropylene, are somewhat common, these variations may affect how well a cleaning is done. With an emphasis on eliminating potentially irritating substances, baby wipes have seen tremendous developments in recent years. Clinical investigations have shown that contemporary baby wipes are preferable to the conventional water and cloth approaches for cleansing diapered skin. According to expert recommendations, such as those published by the European Roundtable Meeting on Best Practice Healthy Infant Skin Care, baby wipes should preserve the pH balance of the skin, stay away from any irritants, and use mild preservatives to guarantee the best possible skin health.

3. FORMULATION OF BABY WIPES:

Creating a baby wipe that is gentle, safe, and effective is a complex task. The formulation must adhere to strict regulatory, safety, and performance standards while also being visually appealing. Ideally, baby wipes should have a highwater content. However, water alone is insufficient for removing stubborn residue and maintaining skin health. To address this, baby wipes typically contain a mild cleansing agent to facilitate cleaning, a preservation system to prevent microbial growth, and a pH balancing system to maintain a skin-friendly pH. The spray method for baby wet wipes involves using a spray bottle to apply a gentle cleansing solution onto a wipe or directly onto the baby's skin, rather than using pre-moistened wipes. This method allows for better control over the moisture level of the wipe, preventing it from being too wet or dry. It also enables the use of homemade solutions, potentially offering a more tailored and cost-effective approach.



FORMULATION OF BABY WIPES

3.1 DEVELOPMENT

Formulation Procedure of Baby Wet Wipes: Four distinct formulations (F1–F4) were created using the solvent spraying technique, with varying percentages of polymer, as indicated in Table 7.1. Every wipe, with an approximate surface area of 15 cm², contained a dosage of 10 mg *Carica papaya* seed extract and 8.5 mg *Terminalia Arjuna Bark*. The polymeric solution was prepared by dispersing the appropriate quantity of wet wipes forming polymer in 15 ml of distilled water and subjected to continuous stirring using a

magnetic stirrer for 2 hours to achieve a homogeneous mixture.

Ingredient	F1	F2	F3	F4
Terminalia Arjuna Bark	*8.5*	*8.5*	*8.5*	*8.5*
Carica papaya seed extract	*10*	*10*	*10*	*10*
Aloe Vera Gel	*8*	*6*	*8*	*6*
Lavender Oil	*4*	*2*	*2*	*4*
Ethanol	*q.s*	*q.s*	*q.s*	*q.s*
Distilled Water	*q.s*	*q.s*	*q.s*	*q.s*

Table no. 3 .1: Formulation table for *Terminalia Arjuna Bark* and *C. papaya* seed extract for Baby Wet Wipes

4. OVERVIEW OF FUNGAL SKIN INFECTIONS:

Fungi typically inhabit moist areas such as the vaginal region, beneath the breasts, and the area between the toes where the skin surfaces touch. Fungal skin infections are often caused by dermatophytes (like Epidermophyton) or yeasts (like Candida or Malassezia furfur). Many of these fungi are found exclusively in the stratum corneum, the outermost layer of the epidermis. Because they have more skinfolds than typical, obese people are more prone to these conditions, particularly if the skin inside a skinfold deteriorates and becomes inflammatory (intertrigo). Fungal infections are also more common in people with diabetes. It's odd that rashes on healthy portions of the body can result from fungal infections in other areas.

Symptoms:

1) Alterations in the skin may manifest as redness, along with potential cracking or peeling.

2) Itching Causes of fungi skin infection:

Imbalance of bacteria is due to following reasons:

➤ excessive use of antibiotics

➤ Hormonal changes/imbalance

➤ loss of appetite

Diagnosis-:

1. **Visual inspection:** Examination of the affected skin area for characteristic signs such as redness, itching, and scaling.
2. **Medical history:** Assessment of the patient's medical history, including previous fungal infections, allergies, and medications.

3. Treatment -:

Antifungal drugs

Fungal infections are generally managed with antifungal medications. These medications are often administered topically to the infected region, utilizing forms such as creams, gels, lotions, solutions, or shampoos. In certain instances, antifungal agents may be prescribed for oral consumption. Alongside pharmacological treatment, maintaining dryness in the affected area through the use of powders or opting for open-toed footwear can prove beneficial.[13]

Antifungal wet wipes: Antifungal agents are offered in various topical formulations on the market, including creams, ointments, and powders designed for dermatological treatment.

Concept of Antifungal wet wipes:

Antifungal wet wipes are topical preparations that inhibit fungal growth, treating fungal skin infections like Tinea pedis, ring root, and Moniliasis. They: -

Relieve symptoms like itching, burning, and redness - Prevent recurrence by creating an environment unfavourable to fungal growth.

- Contain active ingredients like Terminalia Arjuna bark, Carica Papaya Seed Extract, alovera, and lavender oil that inhibit fungal cell membrane synthesis or function.[12]

5. LIST OF MATERIAL'S

Table No. 5.1 Material Used in The Experimental Work.

Sr. No	Ingredients	Name of Suppliers	Functional Categories
1	*Terminalia Arjuna Bark*	Zyrex Ayurveda	API
2	*Carica papaya* seed	Zyrex Ayurveda	API
3	Aloe Vera	Fine chem industries, Mumbai.	Skin-smoothing Agent
4	Lavender Extract	Fine chem industries, Mumbai.	Calming properties, Perfume
5	Ethanol	Fine chem industries, Mumbai.	Co-solvent, Preservative
6	Dist. Water	-	Co-solvent

6. PRE-FORMULATION STUDIES

The initial stage on the logical development of pharmacological dosage formulations is pre-formulation research. Initial investigation is the process of improving drug delivery by identifying new substances physicochemical characteristics that may have an impact on the efficacy of medications and the creation of effective, reliable, and secure dosage forms. It offers the data required to ascertain the properties of the pharmaceuticals and serves as a framework for the dosage form's incorporation of the drugs and pharmaceutical excipients. As a result, preformulating experiments for compatibility and identification were conducted on the drug samples that were acquired.

6.1 CHARACTERIZATION OF DRUG

(a) Organoleptic properties

An analysis was conducted on the *terminalia arjuna bark* and *Carica papaya* seed extract sample to assess its organoleptic characteristics, including odor, color, and appearance.

(b) Solubility

The solubility of *Terminalia Arjuna Bark and Carica papaya* seed extract was checked in different solvent like water, methanol, ethanol, acetone, isopropyl alcohol and 6.8 phosphate buffer.

(c) Melting point [16]

Terminalia Arjuna Bark and Carica Papaya Seed extract melting point were determined using a melting point device, and the obtained value was compared to the value that had been reported.

7. SAFETY TESTING OF BABY WIPES:

Both the product as a whole and its individual constituents should be listed in baby wipe safety profiles. Both allergic and irritating responses can occur in the skin. It's important to consider the possibility of eye discomfort because baby wipes are frequently used around the face as well. Animal test models, non-animal in vitro test models, and clinical human subject testing are currently available methods for doing safety testing. When suitable, the latter two choices have become more popular. Testing on human subjects happens when the formulation is evaluated and it is concluded that there are no potential safety hazards. To show tolerance and validate their alleged usage, tests of this kind are often conducted under the supervision of Good Clinical Practices (GCPs). It should be emphasized that human subject testing is done to verify the safety of cosmetic products, not to identify potential risks. Since baby wipes are used to clean the skin, eye irritation, dermal irritation, and allergic responses are the main concerns. Participants with sensitive skin may be enrolled in products made for sensitive skin.The scientific literature served as the foundation for the design of these tests, even though the testing labs and study sponsors will specify the protocols. The participants used for the studies might change depending on the goals and design of the research because they are tests on human people.[14]

8. SELECTION OF A DRUG CANDIDATE:

The drug candidate is selected on the basis of solubility, antibacterial activity, availability, side effect, economy, and positive aspect with herbal medicine, ecological environment, and patient tolerability. In our work focusing on baby wet wipes formulation, selecting a drug candidate such as *Terminalia Arjuna* Barks extract and *Carica Papaya* Seed extract offers several advantages and opportunities for research. The formulation of *Terminalia Arjuna* and *Carica Papaya seed extract*-loaded BWW could enhance its therapeutic efficacy, bioavailability.

9. SELECTION OF POLYMER AND EXCIPIENTS:

The required excipients are selected on the basis of compatibility, inertness, purity, availability and economy. Selection of wipes forming polymer, solvents for preparation of solution, Distilled Water, Glycerin, lavender extract, Aloe Vera, Perfume on the basis of their properties required for wet wipes.

10. PREFORMULATION STUDIES OF *TERMINALIA ARJUNA BARK* AND *CARICA PAPAYA SEED* EXTRACT.

To comprehend physicochemical characteristics and compatibility of the API & polymers, pre-formulation studies were performed. It includes.

10.1 Characterization of Drug:

a. Organoleptic properties of drug

b. Solubility determination

c. Ultra-violet spectroscopy

10.2 Drug Excipient Compatibility Studies

- Physical compatibility study.
- Chemical compatibility study by Fourier Transform Infra-Red Spectroscopy

a. Fourier Transform Infrared Spectroscopy (FTIR)

10.3 FORMULATION OF BABY WET WIPES

Formulation of *Terminalia Arjuna bark* and *Carica papaya* seed extract baby wet wipes with different concentration of natural and synthetic polymers by spraying method.

10.4 EVALUATION OF BABY WET WIPES

Evaluation parameters for Baby Wet Wipes

a. Thickness:

To ensure that the medication contents are consistent, the wipes thickness is measured using a micrometre, also known as a screw gauge and A digital vernier calliper is utilized. The precision of the drug dosage is dependent on the consistency of the wipes thickness. Wipes thicknesses were measured from the centre of each Wipes as well as from its four corners, and average values were recorded

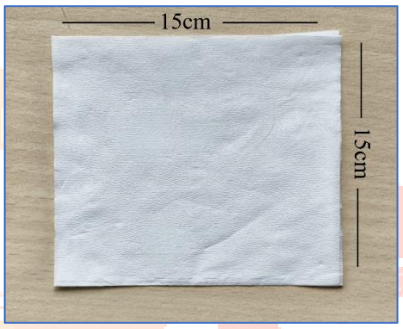
b. Weight:

To accurately measure the weight of wet wipes, use a balance or scale with a resolution of at least 1-3 grams. You can either weigh the entire package of wipes or individual wipes. If weighing individual wipes, it's helpful to remove the wipes from the packaging to ensure accurate measurements. For

basis weight calculations, you'll also need to measure the area of the wipe.

c. Size:

To measure the size of wet wipes, use a ruler to determine the length and width of the wipe in millimetres (mm) or centimetres (cm). For a more precise area calculation, you can then calculate the area of the wipe in square millimetres (mm^2) or square centimetres (cm^2).



d. Texture:

To physically measure the texture of wet wipes, you can assess their softness, thickness, and surface feel through touch and visual inspection. You can also use tools to measure physical characteristics like width, length, and thickness, as well as tensile properties like tensile strength.

e. pH Level [15]

The easiest way to test the pH of wet wipes for newborn is to use pH test paper. Put on a clean plastic glove, soak the test paper with liquid, and then compare the color of the test paper to determine the pH of the infant wipes. Generally, weakly acidic yoboo alcohol-free wet wipes are relatively more beneficial to babies. The testing method for the quality of wet wipes for newborn can be carried out by testing the three aspects of wear resistance, moisturizing degree and PH value. We hope all mothers can understand the testing skills.

f. Moisture Content:[17]

Moisture content by **LOSS ON DRYNING**

1) Clean the Petri plates with dry paper.
2) Take the weight of empty Petri - plate Consider it as (W1).
3) Weigh sufficient amount of sample i.e. piece sample of wipes add with petri-plate & weigh both a balance. (W2)
4) place the (w2) petri plate with sample in hot air oven at specific temperature given in Indian pharmacopoeia (w3)
5) Calculate % moisture using below formula.

$$\textbf{\% Moisture content} = \frac{(W2-W3)}{(W2-W1)} \times 100$$

Where,
W1= weight of an empty plate.
W2 = weight of weighing plate with Sample (Before drying)
W3 = weight of weighing plate with sample (After drying)

g. Cleaning Efficacy: [16]

1. Sensitivity Test: Apply baby wipe: Applied a small piece of baby wipe to the skin.
2. Allow to remain: Allowed the baby wipe to remain on the skin for 24 hours.
3. Observe test area: Observed the test area for signs of irritation.
4. Remove baby wipe: Removed the baby wipe from the test area.

11. RESULT AND DISSCUTION:

The baby wipes demonstrated satisfactory physical characteristics, performance, and sterility, making them suitable for use on sensitive skin. The results inform product development, quality assurance.

A. Physical Evaluation:

THICKNESS	1.5mm – 1.6mm
SIZE	15 X15 cm
WEIGHT	1 -3 grams
TEXTURE	Softness, smoothness

B. Chemical Evaluation:

a) pH Analysis:

BATCH (1)	BATCH (2)	BATCH (3)
5.8	6.1	6.7

b) Moisture Content:

BATCH (1)	BATCH (2)
63 %	68 %

c) Cleaning Efficacy:

REDNESS	ITCHING	SWELLING
NO REDNESS	NO ITCHING	NO SWELLING

C. Chemical Compatibility

(a) Fourier Transform Infrared Spectroscopy

An analytical method for determining the chemical interactions between drugs is infrared spectroscopy and polymer during storage. Therefore, infrared spectroscopy utilizes to examine the chemical interactions of *Terminalia Arjuna Bark* and *Carica papaya* seed extract and other ingredients incorporated in the formulation.

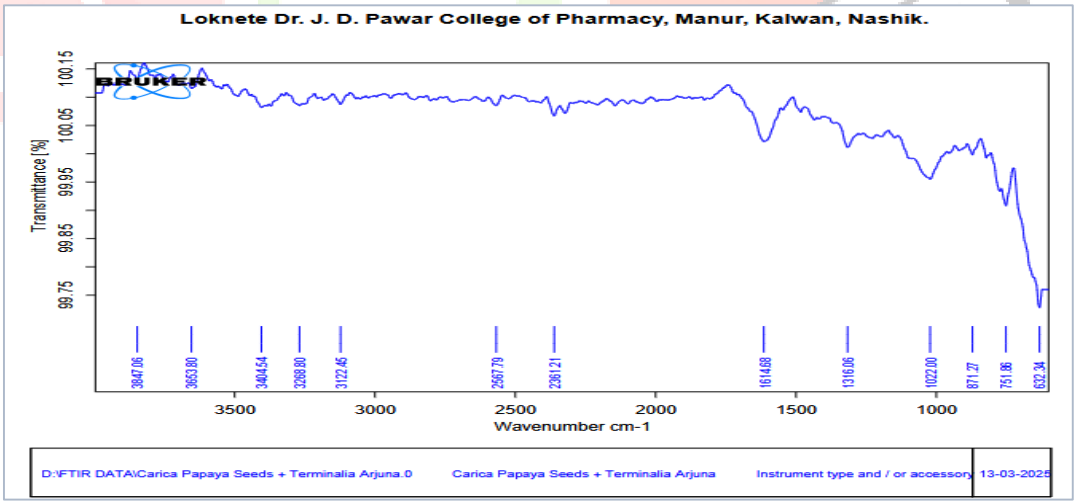


Fig No. 1: FTIR Spectrum of Carica papaya Seeds & T. Arjuna Bark

(b) Standard Calibration curve of Terminalia Arjuna Bark in Distilled Water:

Accurately weighed quantity of Terminalia Arjuna (10 mg) was dissolved in little quantity of water and volume was made up to 100ml with the same (100 µg/ml). Then withdraw 0.5, 1, 1.5, 2, 2.5ml from the above solution in to separate 10 ml volumetric flasks and made up the volume to 10ml to produce 5, 10, 15, 20, 25µg/ml respectively. And the absorbances were taken at 245 nm. This procedure was performed in triplicate to validate the calibration curve.

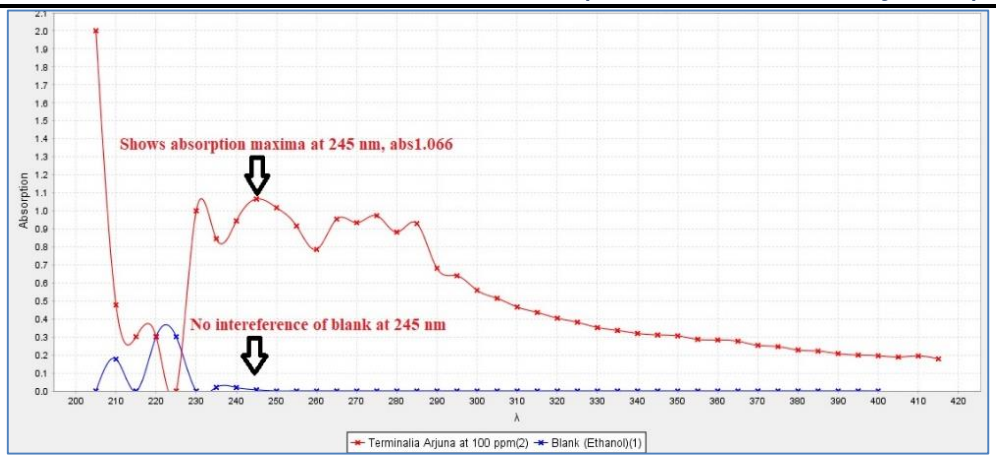


Fig No. 2: UV- Spectrum of Terminalia Arjuna Bark in Ethanol

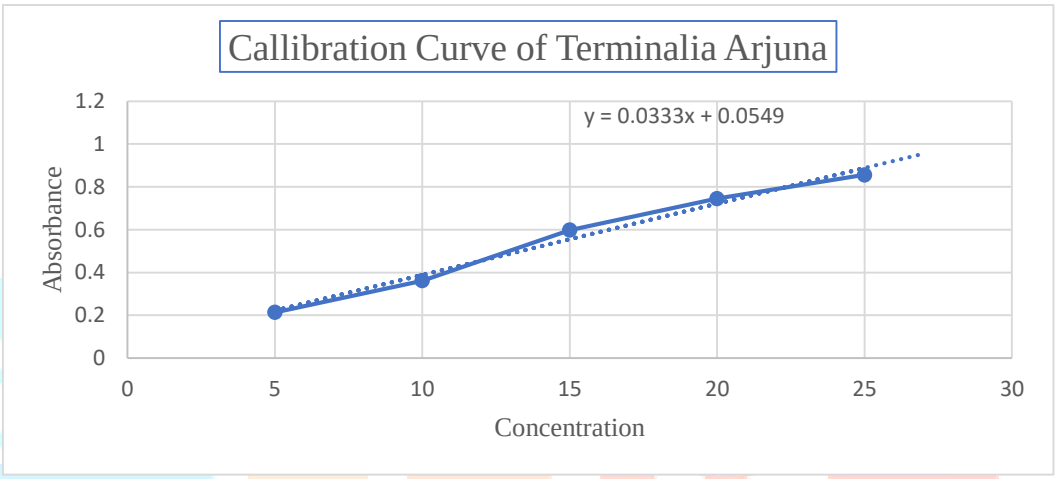


Fig No. 3: Calibration Curve of Terminalia Arjuna Bark in Ethanol

12. CONCLUSION:

Baby wet wipes have become as essential hygiene product for due to their convenience, effectiveness and ease of use. Their formulation has evolved over the years, incorporating safer ingredient, hypoallergenic properties, and skin-friendly additive to minimize irritation and allergies. However, concern remain regarding the presence of certain preservatives, fragrance and chemicals that may cause skin reaction in sensitive infant. While biodegradable and eco-friendly options are gaining popularity, their overall environmental impact remains a challenge due to disposal concerns. Present are encouraged to choose dermatologically tested, fragrance-free and alcohol-free wipes to ensure the safety of their baby's delicate skin. Future advancements in baby wipes should focus on sustainability, improved biodegradability and the eliminations of potentially harmful ingredients while maintaining their effectiveness. Further research on their long-term effects and alternative formulations will help create safer and more environmentally responsible options.

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