

FORMULATION AND EVALUATION OF NOVEL DRUG DELIVERY SYSTEMS AS COSMECEUTICAL CREAM VITAMIN C FOR STRETCH MARKS

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ABSTRACT

The objective of the present study to formulate an effective cream for the treatment of stretch marks using a blend of natural oils and vitamins. Essential ingredients such as Vitamins C for their roles in promoting collagen production and improving skin elasticity also caffeine for improving blood flow, and a blend of natural oils were selected for their moisturizing and nourishing properties. The cream was formulated using advanced cosmetic techniques and evaluated through stability tests, microbial tests. Additionally, the tests confirmed that the cream is safe for use, causing no irritation or side effects. The study concludes that this oil- and vitamin-based cream offers a promising solution for stretch mark treatment. It was concluded that the optimized cream formulation is the best formulation among all cream formulations NDDS. Formulation scientist from his experience and knowledge have to significantly in the preformulation

study stage and is an important factor in the NDDS (Novel Drug Delivery Systems) product development process.

KEYWORDS: Vitamin C (Ascorbic acid), NDDS, Development, Formulation, Creams, Stretch marks, Cosmeceutical.

INTRODUCTION

Stretch Marks^[1,22]

Stretch marks, also known as striae distensae (SD), are visible linear scars that form in areas of dermal damage as a result of stretching of the skin. Stretch marks do not represent a serious health issue, but they can have a profound psychological impact on patients, especially on young, healthy women who are frequently affected by this problem. The breasts, upper arms, abdomen, buttocks, and thighs are the area's most frequently affected by this condition.

For the treatment of SD, numerous techniques have been tried that work to stimulate the formation of collagen. These include topical creams, chemical peels, microdermabrasion, pulse dye laser, diode laser, ablative and nonablative lasers, intense pulse light, micro-needling, fractionated microneedle radiofrequency, dermal filler injections, and others. None is advised as standard therapy due to inadequate skin color improvement or persistent skin atrophy.

Types of Stretch Marks

Striae atrophicans (thinned skin), striae gravidarum (following pregnancy), striae rubrae (red), striae albae (white), striae nigra (black) and striae caerulea (dark blue). Striae are a form of dermal scarring associated with stretching of the dermis. They often result from a rapid change in weight (gain and loss) or are associated with endogenous or exogenous corticosteroids. Proposed mechanisms relate to hormones, physical stretch, and structural alterations of dermal collagen and elastic tissue. Adrenocorticotrophic hormones promote fibroblast activity and increase protein catabolism. Pregnancy-related hormones may also contribute. Serum relaxin has been described to be lower in women with striae distensae. Deficiency of fibrillin has also been proposed.

Striae distensae occur in pregnancy (43% to 88%), puberty (6% to 86%) and obesity (43%). Striae atrophicans follow medical conditions, particularly Cushing syndrome/disease, and treatments, usually exogenous topical or systemic corticosteroids, or surgery. Other associated diseases are Marfan syndrome, anorexia nervosa, various febrile illnesses, and chronic liver disease. Medications associated with striae also include chemotherapy, prolonged antibiotic therapy, contraceptives and neuroleptics.

Striae are more common in females than in males and may be more common in certain races. They can appear more prominent in dark-skinned individuals. A positive family history is a risk factor for striae. During pregnancy, striae are more common in younger women than in older women.

Pathophysiology is thought to involve elastases released from mast cells and macrophage activity. Elastolysis of the mid-dermis is followed by a reorganization of collagen and fibrillin. Histopathology of striae rubrae reveals excessive fine elastic fibers in the papillary dermis with thicker tortuous fibers in the periphery, with perivascular lymphocytes, dilated dermal vessels and edema. There are reduction and reorganization of elastin and fibrillin fibers, and structural changes in collagen fibers, which are thicker and densely packed in parallel rows. Histopathology of striae albae shows epidermal atrophy, loss of rete ridges, less vascularity, and densely packed, thin and scar-like horizontal collagen bundles. They appear similar to mature atrophic scars.

Pharmaceutical Research Paths^[23,80]

Pharmaceutical research is characterized by having both a natural source and synthetic source for primary active raw materials and excipients, each source is mainly prepared to the effectiveness and safety of the drug.

The development of pharmaceutical dosage forms is the basis for delivering the drug to the body. The development of drug delivery systems makes the drug the fastest to arrive, most effective, accurate. and in fast time. Some systems were need to prolong the effect, so they operate with controlled delay system.

All of this development through the various methods of administrating medicine to the body requires developing the medicine, starting from natural and synthetic sources of raw materials for the active ingredients and excipients that are used in formulating medicines in their various dosage forms. The research related to this path is research in drug design or drug extraction, preformulation studies, formulations, evaluation research and stability studies. Clinical studies are important in the development of pharmaceutical dosage forms, and pharmacovigilance follow-up services the safety of medicines. Studying Pharmacoeconomics saves the cost of drug manufacturing, industrial pharmaceutical research and development of production lines, which makes pharmaceutical dosage forms in continues development.

Pharmaceutical care and treatments depend mainly on prescribing medications, taking into account the most important factor, which is drug delivery systems. Research and studies on the effectiveness and use of medicines, their mechanism of action, and safety are all relevant to the manufacture of pharmaceutical dosage forms. Pharmacokinetics and pharmacodynamics research is considered the most important factor in developing novel drug delivery systems NDDS. The continuous development in the pharmaceutical industry is accelerating in the development of drug delivery systems that serve to improve human healthcare.

Dosage Forms and Novel Drug Delivery Systems^[81-154]

The drug is defined as a substance recognized by official pharmacopoeia / In house (IH) which, is intended for its use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Rarely drug is given in its pure chemical form. To ease the drug administration by a human being, it is essential to convert it into physical form in which drug is dispensed known as dosage form. The dosage form is a package of Active Pharmaceutical Ingredient (API) along with selective non medicinal compounds known as excipients.

Dosage Forms Pharmaceutical dosage forms, including oral, injectable, topical, and others, are essential in the therapeutic use of medications. These formulations generally consist of the active pharmaceutical ingredient along with excipients and other non-consumable components like packaging or delivery mechanisms. The term “dosage form” may sometimes only refer to the chemical composition of the drug, excluding the delivery method or container.

A dosage form refers to the specific physical formulation through which a medicinal substance is administered to achieve therapeutic effects. Dosage forms act as delivery systems that transport active pharmaceutical ingredients (APIs) to their intended sites of action within the body, enhancing therapeutic outcomes while reducing potential adverse effects. The selection of an appropriate dosage form depends on factors such as the drug's physicochemical characteristics, the desired route of administration, the patient's clinical condition, and considerations related to age and ease of use. Pharmaceutical dosage forms are composed of two essential components:

Active Pharmaceutical Ingredient (API)

The pharmacologically active compound responsible for producing the desired therapeutic effect.

Pharmaceutical Excipients

Inactive substances incorporated into the formulation to ensure stability, enhance bioavailability, improve patient acceptability, or facilitate the manufacturing process. Common excipients include colorants, sweeteners, flavoring agents, surfactants, solubilizers, antioxidants, preservatives, thickening agents, suspending agents, binders, solvents, lubricants, and lipid-based materials.

The major biopharmaceutical considerations include: Pharmacodynamic Considerations, therapeutic objective, toxic effect, adverse reactions of candidate drug molecule. Drug Consideration: Physicochemical characterization of the candidate drug molecules. Drug Product Consideration: Bioavailability of candidate drug molecule, pharmacokinetics of candidate drug molecule, desired drug dosage form, route of administration for the candidate drug molecule, and desired dose of the candidate drug molecule. Patient Consideration: Compliance and acceptability of the final drug product. Manufacturing Considerations: Cost, availability of pharmaceutical raw materials, stability and quality.

Formulation and Development

This stage involves the actual combination of candidate drug molecule with various excipients and also optimizing the concentration at which each excipient is used. The choice of excipients depends on the properties of the drug molecule and the nature of the intended drug product.

Classification of Dosage Forms

Pharmaceutical dosage forms can be classified in multiple ways, depending on their physical nature, route of administration, site of application, or intended therapeutic use and related data as shown in Tables (1 to 5).

No.	Table 1: Dosage Form Classifications Based on Physical Form State.	
1	Solid Dosage Forms	Powders, Tablets, Effervescent tablets, Capsules, Soft Gelatin Capsule (SGC), Hard Gelatin Capsule (HGC) Lozenges/Troches, Granules, Effervescent Granules, Chewable, Pills, Insufflation, Cachets, snuffs, Spansules, Hypodermic Tablets, Tablet Triturates, Dental Cones, Pastilles, Pessaries, Vaginal Rings, Transdermal Patches, Suppositories, Implants, Ocular Inserts, Film coated tablet, Orodispersible Tablets, Enteric-Coated Tablets, Dispensing Tablets, Tablet Triturates, Lollipops, Chewing Gum.
2	Semi Solid Dosage	Creams, Ointments, Pastes, Gels, Poultices, Suppositories, Hair colors, Shampoos, Lipsticks, Avaleha.

	Forms	
3	Liquid Dosage Forms	Syrups, Mixtures, Linctuses, Elixirs, Gargles, Mouthwashes, Lotions, Oral Drops, Nasal Drops, Ear Drops, Suspensions, Emulsions, Eye Washes, Liniments, Enemas, Irrigations, Draughts, Eye Drops, Douches, Drops, Tinctures, Spirits, Injections, Collodion, Paints, Throat Paints, Oxymels, Aromatic Waters. Extracts, Inhalants.
4	Gaseous Dosage Forms	Pressurized dispensers, Inhalers, Aerosols, Nebulizers, Sprays, Metered Dose Inhalers (MDIs), Dry Powder Inhalers (DPIs).
5	Special Drug Delivery System	Ocular Inserts, Progestaserts, Intra –Uterine, Liposomes, Prodrugs, Transdermal Patches.

No.	Table 2: Dosage Form Classifications Based on Route of Administration.	
1	Oral Dosage Forms	Powders, Granules, Tablets, Capsules, Suspension, Gels, Pills, Elixirs, Syrups, Emulsion.
2	Parenteral Dosage Forms	Solutions, Suspensions, Emulsions.
3	Trans dermal Dosage Forms	Ointments, Powders, Creams, Lotions, Pastes.
4	Intra ocular Dosage Forms	Solutions, Suspension, Ointments, Gels.
5	Conjunctival Dosage Forms	Ointments
6	Vaginal Dosage Forms	Solutions, Tablets, Ointments, Creams, Suppositories, Douches.
7	Sublingual Dosage Forms	Tablets, Lozenges.
8	Intra-Nasal Dosage Forms	Solutions, Sprays, Inhalations, Gels.
9	Rectal Dosage Forms	Ointments, Suppositories, Enemas.
10	Pulmonary Dosage Forms	Aerosols
11	Urethral Dosage Forms	Suppositories.
12	Intra-Otic Dosage Forms	Solutions, Suspension, Douches, Ear Powders.

No.	Table 3: Dosage Form Classifications Based on Site of Application.	
1	Skin	Powders, Emulsion, Gels, Ointments, Creams, Pastes, Lotion, Suspension, Solutions, Shampoos, Lipsticks, Liniments, Douches.
2	Eye	Ointments, Gels, Eye Drops, Eye Wash, Eye Lotion, Eye Packs, Contact Lenses.
3	Tooth	Powders, Pastes, Spray, Dental cone, Dentrifices.
4	Hand	Powder, Emulsion, Gels, Suspension, Ointments, Creams, Paste, Lotions.
5	Foot	Powder, Emulsions, Gels, Ointments, Creams, Lotions.
6	Hair	Gels, Creams, Hair serums, Hair oils, Hair Sprays, Hair colours.
7	Nose	Aerosols, Insufflations, Snuffs, Gels.

8	Ear	Ear Drops, Douches, Ear Powders.
9	Vaginal	Solutions, Tablets, Ointments, Creams, Suppositories, Douches.
10	Rectal	Ointments, Suppositories, Enemas.

Table 4: Dosage Form Classifications Based on Use.

Internal	Powders, Tablets, Capsules, Emulsion, Syrups, Elixirs, Gels, Pills, Suspension, Avaleha, Pessaries, Suppositories.
External	Aerosols, Ointments, Creams, Powders, Pastes, Lotions, Sprays, Inhalations, Liniments, Throat Paints, Plasters, Jellies, Aerosols, Pellets, Trans dermal Patches.

Table 5: Routes, Dosage Forms, and Uses.

Dosage Form	Route of Administration	Purpose/Use
Tablets/Capsules	Oral	Purpose/Use Convenient systemic delivery
Solutions/Suspensions	Oral/Topical	Rapid action, suitable for children
Injections/Infusions	Parenteral	Fast action, emergency use
Inhalers/Nebulizers	Inhalation	Respiratory therapy
Ointments/Creams/Gels	Topical	Local skin or mucosal treatment
Suppositories/Enemas	Rectal/Vaginal	Local/systemic when oral not possible
Transdermal Patches	Skin	Long-term controlled systemic effect
Modified/Controlled Forms	Varies	Targeted or sustained drug delivery

The term dosage forms refer to the means by which drug molecules/APIs are delivered to sites of action within the body to produce optimum desired effects with minimum adverse effects.

The word cosmetic is derived from the Greek word 'cosmetics' meaning decorates. Cosmetics are used to enhance the appearance. Cosmetics is actually derived from its use in ancient era. They produced by female slaves known as the 'cosmetic' derived from 'cosmetics'. The increased cosmetics using peoples stay young and attractive creams are topical preparation to be applied on the skin. Cosmetics are available in the form of creams, lipstick etc. Cosmetic creams such as sunscreens protects the skin from sun rays. Medicated creams are used for wound healing. The ginger extract is used in the treatment of antifungal infection. The creams are easy to applying the skin.

Topical preparation that will be applied to the skin are called creams. Liquid or semisolid viscous emulsions with varying consistency depending on the oil and water. Creams are used for a range of cosmetic functions, as well as cleansing, beautifying, improving, aesthetics,

protection and therapeutic functions. Creams are classified as healthy products because they are created using strategies developed within the pharmaceutical industry each nonmedicated cream is generally used to treat a spread of skin conditions or dermatoses. Developed creams are Ayurvedic, herbal or medically assisted and people use them to treat their skin problems. They are created from one or more of the drug substances dispersed in a suitable phase. Penetration enhancer of cream in skin layers depend on important factors such as formulation factors, biological factors of skin, and physiochemical of drug natural and synthetic sources.

Cosmetics like creams, gels, and colognes are used on a daily basis by both women and men. Creams act as a cleanser for the face in many circumstances. More recently antiaging creams have been manufactured which can retain younger looking skin for many years. The best cleansing agents are cleansing cream, soap and water. Cosmetic creams serve as a skin food for hard, dry and chapped skin.

Pharmaceutical Creams

Pharmaceutical creams are white semisolid preparations intended for external application to the skin and mucous membranes containing one more medicinal agent dissolved or dispersed in either a W/O emulsion or an O/W emulsion or in another type of water-washable base.

Creams are more fluid compared to other semisolid dosage forms, such as ointments and pastes, since the bases used in creams are generally o/w emulsions.

Creams have a whitish with creamy appearance and the use of creams as drug delivery systems is associated with good patient acceptance.

Advantages of Topical Drug Delivery

Avoids complications related to injections and oral administration (e.g., enzymatic degradation, pH variation), provides localized action with a smaller dose, minimizing systemic exposure, allows for easy termination of therapy if adverse effects occur, avoids gastrointestinal irritation, enhances patient compliance and enables self-medication and suitable for drugs with short half-lives or narrow therapeutic windows.

Limitations of Topical Drug Delivery

Topical therapy may not be suitable for all drugs, ideal candidates should be low in molecular weight, lipophilic, and effective at low doses and additionally, penetration enhancers used to improve absorption might cause skin irritation.

Rational Use of Topical Formulations

Topical products serve various functions: Protection: Sunscreens shield skin from UV damage; antibacterial agents prevent infections. Therapy: Direct application of drugs like anesthetics and anti-inflammatory agents targets affected tissues. Cosmetic Use: Products like exfoliants and depilatories are used for personal care. Systemic Therapy: Transdermal patches deliver medications systemically for conditions like hypertension and motion sickness.

Classification of Creams

Classification of Creams, types, common excipients natural, synthetic and related data as shown in Tables (6 to 9).

Properties of Creams

Easy to apply and remove, spread evenly on the skin, should melt at body temperature, help cleanse skin pores, leave a protective, emollient layer, prevent skin dryness unlike soap, aid in removing makeup and impurities, soften and hydrate the skin and remove oil, dirt, and dead skin cells.

Key Characteristics of Creams

Should liquefy at body temperature, must penetrate the epidermis, low viscosity for easy spreading, non-toxic and non-irritating and should not cause inflammation.

Uses of Creams

Cleansing creams: Remove dead skin, dirt, and oil. Vanishing creams: Useful in humid environments to reduce facial sweat. Protective barrier: Prevents moisture loss. Soothing effect: Reduces irritation and supports healing. Medical use: Treats conditions like eczema, dermatitis, rashes, itching, insect bites, and allergies. Can be used on mucosal surfaces.

No.	Table 6: Herbs Commonly Used in Herbal Creams.	
	Uses	Common Herbs
1	Anti-fungal/Bacterial	Neem, Tea Tree, Turmeric, Basil.
2	Anti-aging	Green Tea, Ginseng, Liquorice, Rosehip, Gotu Kola.
3	Dry/Sensitive Skin	Calendula, Chamomile, Aloe Vera, Coconut, Shea Butter.
4	Eczema & Psoriasis	Liquorice, Turmeric, Chamomile, Oat, Manjistha.
5	Wound Healing	Aloe Vera, Calendula, Comfrey, Honey.
6	Pain Relief	Arnica, Capsaicin, Ginger, Turmeric, Menthol.
7	Skin Brightening	Liquorice, Saffron, Mulberry, Turmeric, Rose Water
8	Acne & Pimples	Neem, Tea Tree, Tulasi, Aloe Vera, Turmeric.

No.	Table 7: Some of Excipients Used in Formulation of Creams.	
	Excipients	Examples
1	Vehicle	Water
2	Wetting Agents	Sulfonated Oils, Glycerin
3	Oils	Liquid Paraffin, olive oil
4	Fats	Almond Oil, fatty acid
5	Waxes	Bees Wax, Paraffin wax
6	Lanolin	Hydrous Lanolin
7	Glycol	Propylene glycol, Ethylene glycol
8	Colors	Saffron, Curcumin
9	Emollients	Squalene, Lanolin
10	Emulsifying agents	Bentonite, Colloidal Kaolin
11	Gums	Gum tragacanth, Gelatin
12	Perfumes	White blossoms, orange blossom
13	Humectants	Honey, Aloe vera

Table 8: Types of Creams.	
Based on Phase	Oil-in-Water (O/W)
	Water-in-Oil (W/O)
Based on the Function	Make-Up Creams
	Vanishing Creams
	Foundation Creams
	Cleansing Creams
	Winter Creams
	General Creams and All-Purpose Creams
	Night Creams and Massage Creams
	Skin Protection Creams
	Hand Creams and Body Creams
	Cold Creams

Table 9: Classification of Creams.			
No.	Category	Types of Creams	Description
1	Based on Emulsion Type	Oil-in-Water (O/W) Creams	Water is the continuous phase; non-greasy, easily washable.
		Water-in-Oil (W/O) Creams	Oil is the continuous phase; greasy, more occlusive.
2	Based on Site of Application	Topical Creams	Applied on the skin surface for local effects.
		Transdermal Creams	Designed for systemic absorption through the skin.
		Mucosal Creams	Used on mucous membranes.
3	Based on Therapeutic Purpose	Antibacterial Creams	Treat bacterial infections.
		Antifungal Creams	Treat fungal infections.
		Anti-inflammatory Creams	Reduce inflammation.
		Analgesic Creams	Provide pain relief.
		Antiviral Creams	Treat viral infections.

		Wound Healing Creams	Promote tissue repair.
4	Based on Compositions and Consistency	Vanishing Creams	Non-greasy, leave little to no residue after application.
		Cold Creams	Emollient, greasy, used for dry skin.
		Hydrophilic Creams	Water-attracting, suitable for aqueous drug bases.
		Hydrophobic Creams	Oil-based, repel water, suitable for lipid-soluble drugs.
5	Based on Drug Release	Conventional Creams	Immediate release of active ingredient.
		Controlled Release Creams	Slow and sustained drug release over time.

In the present study, it was proposed to Formulated of Vitamin C as Cream Cosmeceutical studies of the safety, efficacy, quality and stability of a formulation are major concepts of any API development process. In API development process, a detailed characterization of the API and other formulation components is usually carried out with commonly different excipients using for formulation development of Vitamin C as Cream Cosmeceutical NDDS to Stretch Marks topical application.

MATERIALS AND METHODS

Vitamin C, and all raw materials used in the formulation including active pharmaceutical ingredients (APIs), excipients, and analytical reagents were obtained as a gift sample from (Shaphaco Pharma Pharmaceutical Industry Company - Yemen), (Yedco Pharma Pharmaceutical Industry Company - Yemen) and from local market.

As shown in Table 10.

Table 10: List of Materials Used.

No.	Name of Materials
1	Turmeric powder (<i>Local market</i>), (Yemen)
2	Aloe vera Oil (<i>Hemani</i>), (Pakistan)
3	Chamomile Oil (<i>Hemani</i>), (Pakistan)
4	Coconut Oil (<i>Hemani</i>), (Pakistan)
5	Vitamin C (<i>Shaphaco</i>), (Yemen)
6	Caffeine (<i>Shaphaco</i>), (Yemen)
7	Liquid Paraffin (<i>Shaphaco</i>), (Yemen)
8	Ceto stearyl Alcohol (<i>Shaphaco</i>), (Yemen)
9	Cremophor A25 (<i>Shaphaco</i>), (Yemen)
10	Methyl paraben (<i>Shaphaco</i>), (Yemen)
11	Propyl paraben (<i>Shaphaco</i>), (Yemen)
12	Propylene glycol (<i>Shaphaco</i>), (Yemen)

13	Zinc oxide (<i>Shaphaco</i>), (Yemen)
14	Cetyl alcohol (<i>Shaphaco</i>), (Yemen)
15	Stearic acid (<i>Shaphaco</i>), (Yemen)
16	Isopropyl myristate (<i>Shaphaco</i>), (Yemen)
17	Dimethicone (<i>Shaphaco</i>), (Yemen)
18	Glycerin (<i>Shaphaco</i>), (Yemen)
19	Menthol (<i>Shaphaco</i>), (Yemen)
20	Lanolin (<i>Shaphaco</i>), (Yemen)
21	Hexylene glycol (<i>Yedco</i>), (Yemen)
22	Phenyl trimethicone (<i>Yedco</i>), (Yemen)
23	Titanium dioxide (<i>Yedco</i>), (Yemen)
24	Triethanolamine (<i>Shaphaco</i>), (Yemen)
25	Sodium dihydrogen phosphate (<i>Shaphaco</i>), (Yemen)
26	Peppermint oil (<i>Shaphaco</i>), (Yemen)
27	Lime fragrance (<i>Shaphaco</i>), (Yemen)

Equipment

All equipment used are listed in Table Error! No text of specified style in document.

Table Error! No text of specified style in document.: List of Instruments.

No.	Instruments
1	pH Meter
2	Viscometer
3	Magnetic Stirrer
4	Electronic Balance
5	Digital Thermostatic Water Bath

Formulation and Evaluation of Creams^{[21-23] [81-192]}

Optimization and Development of Cream Formulations

Preparation of Oil Phase

The oil phase was prepared by adding liquid paraffin as the main base. Ceto stearyl alcohol and Cremophor A25 were incorporated and melted together using a water bath. Subsequently, lipophilic components such as dimethicone, stearic acid, isopropyl myristate, lanolin, and cetyl alcohol were added sequentially and dissolved completely. A predetermined quantity of selected oils was then introduced to the mixture. The entire oil phase was maintained at a temperature of approximately 70°C to ensure complete solubilization and homogenization. In F1, F2, F3 curcumin powder added as active ingredient, but problems with stability appeared.

Preparation of Aqueous Phase

In a separate beaker, the aqueous phase was prepared by dissolving glycerin in a specific amount of water, followed by heating to 70°C. Active ingredients (caffeine and vitamin C)

were dissolved separately in water to preserve their efficacy and added gradually to the final mixture in small portions to avoid phase separation.

Additionally, some components were pre-dissolved in suitable solvents before incorporation. For instance, the preservatives methyl paraben and ethyl paraben were dissolved in propylene glycol to ensure complete solubilization. Zinc oxide was then added to this mixture and stirred until partially or fully dispersed. This prepared mixture was added to the oil phase.

Emulsification Formulation

The aqueous phase was added to the oil phase with continuous stirring under high-shear mixing using an electric homogenizer at 70°C. Once the temperature of the emulsion dropped to 40°C or below, the active ingredients (Caffeine, Vitamin C) and volatile substances such as menthol were added and mixed thoroughly. Now, once the transfer was completed it was allowed to come at room temperature, all the while being stirred. Perfume (1%) was added at last just before the finished product was transferred to suitable container. Then cream was evaluated for various physical parameters.

Final System Optimization

To adjust the final pH of the formulation, two substances used disodium hydrogen phosphate which dissolved in hot water and added to the cream during the final mixing stage and triethanolamine which added to the cold stage at 40°C. as shown in Table 12.

Table 12: Composition of Cream Formulations.

No.	Ingredients	F1	F2	F3	F4	F5	F6	F7
1	Aloe Vera Oil	10	1.5	2	3	3	1	1
2	Coconut Oil	8	1.5	1.5	2	2	1	1
3	Chamomile Oil	--	--	2	2	2	1	0.5
4	Vitamin C	3	3	3	3	3	3	3
5	Caffeine	1.5	1.5	1.5	1.5	1.5	1.5	1.5
6	Turmeric Powder	1	0.5	0.5	0.5	--	--	--
7	Liquid Paraffin	12	12	12	12	12	12	12
8	Ceto stearyl Alcohol	7	7	7	7	7	7	7
9	Cremophor A25	3	3	3	3	3	3	3
10	Menthol	--	0.05	0.05	0.05	0.05	0.05	0.05
11	Methyl Paraben	0.2	0.2	0.2	0.2	0.2	0.2	0.2
12	Propyl Paraben	0.02	0.02	0.02	0.02	0.02	0.02	0.02
13	Propylene Glycol	2	4	4	4	4	5	5
14	Cetyl alcohol	2	1	1	1	1	1	1
15	Stearic Acid	--	2	--	--	--	--	2
16	Isopropyl myristate	--	1	1	--	1	1	3

17	Phenyl trimethicone	--	--	2	2	--	--	--
18	Hexylene glycol	--	--	2	2	--	--	--
19	Peppermint Oil	0.1	0.1	0.1	0.1	0.1	0.1	0.1
20	Dimethicone	--	--	--	2	2	1	1
21	Glycerin	10	6	2	5	5	4	4
22	Lanolin	--	--	--	--	2	2	2
23	Titanium Dioxide	--	--	--	1	1	--	--
24	Zinc Oxide	--	--	--	1	1	1	1
25	Triethanolamine	--	0.6	0.6	0.6	0.6	0.6	0.6
26	Lime Fragrance	0.5	0.5	0.5	1	1	1	1
27	Purified Water	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s

Evaluation of Cream Formulations

Macroscopic Evaluation of Formulations

General Appearance

Physical appearance of drug was examined by various organoleptic properties. The general appearance of cream, its visual identity and overall elegance is essential for consumer acceptance. The control of general appearance involves: color, presence or absence of odor, Homogeneity, Phase separation.

The Assessment Focused on the Following Aspects

Color

The formulation was visually inspected to ensure it exhibited a consistent and uniform color throughout the formulation. Any discoloration or uneven shading could indicate instability or improper mixing of components.

Odor

The formulation was checked for any undesirable or strong odor. A pleasant or neutral scent is important to enhance patient compliance, especially for topical applications. The absence of any foul or medicinal odor was confirmed.

HOMOGENEITY

The formulation was examined for uniformity in texture and composition. A homogeneous formulation should not contain any lumps, grittiness, or particulate matter, and should have a smooth, consistent feel when applied to the skin.

Phase Separation

The formulation was checked for any signs of phase separation, such as the separation of oil and aqueous layers. A stable cream should appear as a single, well-blended phase with no visible separation over time.

Viscosity Test

The cream is inserted into the beaker glass container then the mounted spindle is lowered so that the spindle boundary is dipped into the cream. The speed of the tool mounted at 20 rpm is then read and scaled. When the red needle is moving it has stabilized. Viscosity value (η) is expressed in centipoise (cps).

pH Determination Test

The pH of the cream can be measured on a standard digital pH meter at room temperature by taking adequate amount of the formulation diluted with a suitable solvent.

Skin Irritation Test

The study was conducted on healthy adult volunteers. The preparation is applied on the forearm, then left for 48 hours and seen any change in the form of redness and swelling of the skin.

Spreadability Test

A fixed quantity of each test formulation was uniformly placed on a clean glass slide, a second glass slide was carefully placed on top to sandwich the formulation between the two slides. A standardized weight (50 g) was placed on the upper slide for a fixed duration (1 minute) to ensure even distribution and adhesion of the formulation. The weight was removed, and the time taken for the upper slide to detach completely from the lower slide due to the formulation's viscous flow was recorded in seconds (s) and saw if spread smooth and easily the results evaluated in terms: good, very good, excellent spreadability ensures uniform application over the skin.

Microbial Test

To ensure the microbiological safety of the prepared cream formulations, samples with optimal physical and sensory properties were submitted to a certified local laboratory for evaluation. The testing focused on detecting any microbial contamination that could affect product stability or safety. The presence or absence of viable microorganisms was assessed,

and the formulations were classified accordingly as either passing or failing based on standard microbiological criteria.

Stability Studies for optimized Formulation

A stability study was conducted to evaluate the physical and chemical stability of the optimized formulation under accelerated conditions. The optimized formulation was stored for 3 months in an accelerated stability chamber at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $75\% \pm 5\%$ relative humidity. This study aimed to ensure that the formulation maintained their intended physical and chemical characteristics throughout the testing period without undergoing undesirable changes. The evaluation focused on monitoring key physical parameters such as changes in color, odor, clarity, phase separation, and overall appearance of the formulation. As shown in Table 13.

Table 13: Stability Study Parameters.

Stability Study	Temperature ($^{\circ}\text{C}$)	Humidity (%RH)	Time Period
Accelerated Stability Study	$40^{\circ}\text{C} \pm 2^{\circ}\text{C}$	$75\% \pm 5\%$ RH	3 Months

RESULTS AND DISCUSSION

Evaluation Parameters of the Cream Formulations

Macroscopic Evaluation of Formulations

All cream formulations (F1-F7) exhibited uniform off white creamy coloration and characteristic lime fragrance odor when evaluated 24 hours post-preparation. All cream formulations showed smooth homogeneous texture except formulation (F1). No separation occurs except in formulations (F1, F2, F3).

Viscosity Test

Viscosity measurements revealed significant variation among the formulations. Formulation F7 exhibited the viscosity at 16001CP within 50 rpm as shown in Table 14.

Table 14: Viscosity of Selected Cream Formulation.

The Optimized Formulation	
R.P.M	Viscosity (cP)
20	40216
50	16001
100	3897

pH Determination Test

All results of the optimized formulation demonstrated physiologically acceptable pH values ranging from 4.50 to 5.60 as shown in Table 15.

Table 15: pH Results of The Optimized Cream Formulation.

Substances	Initial	After 3 months
pH Using Triethanolamine	4.50	4.71
pH Using Sodium Dihydrogen Phosphate	4.50	5.60

Skin Irritation Test

The prepared cream formulation was applied on the skin of forearm and affected area, by watching the healthy volunteers, all results exhibited excellent tolerance to formulation without irritation.

Spreadability Test

The spreadability by applying the cream and all results exhibited very good spreadability of formulation.

Microbial Test

All of cream formulation samples submitted for microbiological contamination testing met the predefined sterility criteria. No viable microorganisms were detected in any sample, and the formulation was classified as “pass” according to the standard microbiological acceptance limits. The result for aerobic bacteria and total fungi is < 10, as shown in Figure 4.



Fig. 4: Microbial Test of the Optimized Formulation.

Stability Study of Optimized Formulation

The evaluation focused on monitoring key physical parameters such as changes in color, odor, clarity, phase separation, and overall appearance (**Error! Reference source not found.**). After the 3 months period, no noticeable changes in appearance, odor, or pH were observed, confirming the robustness and stability of the formulation.

Table 16: Stability Study Results of the Optimized Cream Formulation.

Evaluated Parameter	Initial	After 3 Months
Appearance	Off White Viscous Creamy with Lime Fragrance	Off white Viscous Creamy, Odor Lime
pH	4.50	4.71

CONCLUSION

This study demonstrated the efficacy and safety of a new cream for treating stretch marks, which contains Vitamin C, caffeine, and a blend of natural oils. We developed and evaluated seven different formulations of the cream, each with varying concentrations of ingredients. After conducting thorough evaluations parameters, it was concluded that the optimized cream formulation is the best formulation among all cream formulations NDDS. Formulation scientist from his experience and knowledge have to significantly in the preformulation study stage and is an important factor in the NDDS (Novel Drug Delivery Systems) product development process.

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