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FORMULATION AND EVALUATION OF ATORVASTATIN CREAM FOR ENHANCED DIABETIC WOUND HEALING AS NOVEL DRUG DELIVERY SYSTEMS

Abdalwali Ahmed Saif[1], Mahmoud Mahyoob Alburyhi[1*], Maged Alwan Noman[1]

[1]Professor, Dr. of Pharmaceutics and Industrial Pharmacy, Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.

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***Corresponding Author**

Mahmoud Mahyoob Alburyhi

Professor Dr. of Pharmaceutics and Industrial Pharmacy, Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.

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ABSTRACT

Background: Atorvastatin, a widely prescribed member of the statin class of drugs, is primarily known for its efficacy in lowering cholesterol levels by inhibiting HMG-CoA reductase. The topical application of Atorvastatin has demonstrated its potential to accelerate tissue repair and modulate key healing pathways. In the present study that the developed a novel topical cream of Atorvastatin (AT) to leverage their complementary actions. **Methods:** The cream was formulated via melt-emulsification and optimized for physicochemical properties (pH, viscosity, spreadability, homogeneity). Compatibility and microbiological sterility were confirmed. **Results:** The optimized cream exhibited desirable properties: a skin compatible pH (5.1–6.0), low viscosity with excellent spreadability, homogeneous texture, and no microbial contamination. **Conclusion:** It was concluded that the best Cream Formulation of the Atorvastatin Cream NDDS was found to be optimized formulation possessed excellent evaluated parameters among the Cream Formulations NDDS. These formulations favorable properties and efficacy indicate it as a promising strategy for improving outcomes in infected diabetic wounds. 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: Atorvastatin, NDDS, Development, Formulation, Cream, Infected Diabetic Wounds.

INTRODUCTION

Background[1,47]

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by hyperglycemia due to insulin deficiency or resistance. Affecting 589 million adults globally, with projections reaching 853 million by 2050, with an estimated 44.7% of cases remaining undiagnosed. Chronic hyperglycemia is a primary driver of systemic complications, including neuropathy, retinopathy, and cardiovascular disease. Among these, impaired wound healing is a devastating consequence, affecting an estimated 19% to 34% of diabetic patients and contributing to prolonged recovery, and mortality. This compromised healing capacity is further exacerbated by a markedly increased risk of infection; diabetic patients are 1.5 to 4 times more likely to develop infections compared to their non-diabetic counterparts, with the extremities being particularly vulnerable.

Mechanistically, hyperglycemia induces oxidative stress and advanced glycation end-products (AGEs), which impair collagen synthesis, angiogenesis, and macrophage function. These systemic defects create a microenvironment resistant to repair, prolonging inflammation and elevating infection risks, with *Staphylococcus aureus* being the most commonly isolated pathogen in chronic diabetic wounds. Delayed healing culminates in severe complications: over 60% of non-traumatic lower-limb amputations are diabetes-related, with a 5-year mortality rate exceeding 50% and 70% post-amputation.

Current clinical treatments for diabetic wounds inadequately address the multifactorial pathology of delayed healing. Topical antibiotics, such as silver sulfadiazine, reduce bacterial load but impair epithelialization and exacerbate oxidative stress, prolonging recovery. Growth factor-based therapies, including recombinant platelet-derived growth factor (PDGF-BB), enhance angiogenesis but lack antimicrobial activity, leaving wounds vulnerable to infection. Hydrogel dressings, though widely used for moisture retention, fail to resolve hyperglycemia-driven collagen degradation or chronic inflammation, even advanced modalities like negative pressure wound therapy (NPWT) struggle with biofilm persistence and high recurrence rates. These therapies target isolated aspects of healing, neglecting the dual challenges of infection and impaired tissue repair. Consequently, 50% of chronic diabetic wounds fail to heal within 12 weeks, often progressing to amputations.

Atorvastatin, a widely prescribed member of the statin class of drugs, is primarily known for its efficacy in lowering cholesterol levels by inhibiting HMG-CoA reductase. However, a growing body of evidence has illuminated a range of pharmacological actions, termed pleiotropic effects, that extend beyond its lipid-modulating capabilities and hold considerable promise for tissue repair and regeneration. These effects, which are independent of cholesterol reduction, include potent anti-inflammatory, antioxidant, and pro-angiogenic activities—all of which are highly pertinent to addressing the dysregulated processes in diabetic wounds. Preclinical studies investigating the topical application of Atorvastatin has demonstrated its potential to accelerate tissue repair and modulate key healing pathways. This exploration of Atorvastatin for wound healing exemplifies a drug repurposing strategy, wherein the "off-target" or secondary pharmacological properties of an established drug are harnessed for a novel therapeutic indication, offering a potentially accelerated path to new treatment options.

Pharmaceutical Research Paths[48-105]

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[106,152]

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 are the means by which drug molecules are delivered to sites of action within the body. The need for dosage forms: Accurate dose, protection e.g. coated tablets, sealed ampules, protection from gastric juice, masking taste and odor, placement of drugs within body tissues, sustained release medication, controlled release medication, optimal drug action, insertion of drugs into body cavities and use of desired vehicle for insoluble drugs**.**

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

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 8).

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: 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 7: 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 8: 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 Atorvastatin 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 formulation stage, with commonly different excipients using for formulation development of Atorvastatin Cream NDDS for topical application. These formulations favorable properties and efficacy indicate it as a promising strategy for improving outcomes in infected diabetic wounds.

MATERIALS AND METHODS

All raw materials, including active pharmaceutical ingredient (API), excipients, and analytical reagents, were kindly provided by Modern Pharma Industry (Sana'a, Yemen). Atorvastatin calcium (AT) was used as API. Excipients employed in the formulations include oil phase components: cetostearyl alcohol, stearic acid, Vaseline (petroleum jelly), liquid paraffin, antioxidant: butylated hydroxyanisole (BHA), preservative: chlorocresol, aqueous phase components: propylene glycol, and emulsifier: Tween 80. Reagents for analytical procedures and buffer preparation, including methanol (HPLC grade), hydrochloric acid (HCl), sodium hydroxide (NaOH), potassium dihydrogen phosphate (KH_2PO_4), and glacial acetic acid, were of analytical grade.

Equipment and Instruments

Major analytical instruments included a Varian 50 Conc. UV-Visible Spectrophotometer (Varian, USA). A Stuart SMP1 melting point apparatus (Stuart Scientifics, UK) was used for MP assessment. Formulation characterization was performed using a Brookfield DV2T viscometer (AMETEK Brookfield, Middleboro, MA, USA), a Metrohm 914

pH/Conductometer (Metrohm AG, Herisau, Switzerland), and ScichemTech SCT-SONIC-6 ultrasonic bath (Scientific Chemical technologies).

Formulation and Evaluation of Cream Formulations[47,49] [106,184]

Preparation of Cream Formulations

The cream formulations were prepared via a melt-emulsification method, a robust and widely used technique for the manufacture of oil-in-water (o/w) semi-solid emulsions. The oil phase, components: cetostearyl alcohol, stearic acid, liquid paraffin, butylated hydroxyanisole (BHA), vaseline, and chlorocresol, were weighed and melted at 80°C in a water bath with continuous stirring using glass rods. Simultaneously, the aqueous phase containing purified water, propylene glycol, and Tween 80 were heated to 80°C. The molten oil phase was gradually incorporated into the aqueous phase under constant stirring. After removal from the water bath, the mixture was cooled to 40°C with continuous agitation, at which point atorvastatin and fusidic acid powder were gradually added. Stirring persisted until the formulation reached room temperature (25°C). Each formulation was prepared in 50 g batches and transferred to airtight bottles for storage and further evaluation. The specific compositions of the eight formulations as shown in Tables (9-11).

Table 9: Composition (% w/w) of Cream Formulations Containing 1% Atorvastatin Calcium.

No.	Components	F1	F2	F3	F4	F5	F6	F7	F8
1	**Atorvastatin Calcium**	1	1	1	1	1	1	1	1
2	**Cetostearyl Alcohol 5 -20%**	20	20	5	5	20	10	10	5
3	**Stearic Acid 0 - 3 %**	0	0	0	0	3	0	3	2
4	**Tween 80 1-5%**	1	5	1	5	5	5	5	5
5	**Propylene Glycol**	10	10	10	10	10	10	10	10
6	**Liquid Paraffin 2%**	2	2	2	2	2	2	2	2
7	**BHA 0,02%**	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
8	**Vaseline 10%**	10	10	10	10	10	10	10	10
9	**Chlorocresol 0.2%**	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
10	**Purified Water**	53.8	49.8	68.8	64.8	46.8	59.8	56.8	62.8

Table 10: Composition (% w/w) of Cream Formulations Containing 2.5% Atorvastatin Calcium.

No.	Components	F1	F2	F3	F4	F5	F6	F7	F8
1	**Atorvastatin Calcium**	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
2	**Cetostearyl Alcohol**	20	20	5	5	20	10	10	5
3	**Stearic Acid**	0	0	0	0	3	0	3	2
4	**Tween 80**	1	5	1	5	5	5	5	5

5	**Propylene Glycol**	10	10	10	10	10	10	10	10
6	**Liquid Paraffin**	2	2	2	2	2	2	2	2
7	**BHA**	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
8	**Vaseline**	10	10	10	10	10	10	10	10
9	**Chlorocresol**	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
10	**Purified Water**	52.3	48.3	67.3	63.3	45.3	58.3	55.3	61.3

Table Error! No text of specified style in document.**11: Composition (% w/w) of Cream Formulations Containing 5% Atorvastatin Calcium.**

No.	Components	F1	F2	F3	F4	F5	F6	F7	F8
1	**Atorvastatin Calcium**	5	5	5	5	5	5	5	5
2	**Cetostearyl Alcohol**	20	20	5	5	20	10	10	5
3	**Stearic Acid**	0	0	0	0	3	0	3	2
4	**Tween 80**	1	5	1	5	5	5	5	5
5	**Propylene Glycol**	10	10	10	10	10	10	10	10
6	**Liquid Paraffin**	2	2	2	2	2	2	2	2
7	**BHA**	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
8	**Vaseline**	10	10	10	10	10	10	10	10
9	**Chlorocresol**	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
10	**Purified Water**	49.78	45.78	64.78	60.78	42.78	55.78	52.78	58.78

Evaluation of The Cream Formulations

Physical and Organoleptic Evaluation

The organoleptic properties of the eight cream formulations (F1–F8) were evaluated 24 hours post-preparation for their organoleptic and physical properties, which are critical for patient acceptance and product stability. Homogeneity was assessed visually by inspecting for any signs of particulate matter, grittiness, or lumps. Color was observed against a black background to detect any discoloration. Consistency and texture were evaluated by applying a small amount of cream to the skin, noting how it feels and ease of application. Finally, the formulations were observed for any signs of phase separation, such as creaming or coalescence of oil droplets.

Spreadability Analysis

The spreadability of the unseparated cream formulations was determined using a gravitational slide method - with a slight modification -, which provides an empirical measure of the ease with which a semi-solid can be applied in a thin, even layer. A 0.1 g sample of cream was placed precisely in the center of a clean glass slide (7.5 cm in length). A second glass slide was placed on top, and a standard weight of 50 g was applied for 1 minute to ensure uniform distribution of the cream between the plates. The slide assembly was then fixed at an angle of 45°. The time (*t* in seconds) required for the upper slide to travel the full 12 cm distance

under the force of gravity was recorded. All measurements were performed in triplicate. Spreadability (S) was calculated using the following equation:

$$\text{Spreadability}_{(mm\backslash sec)} = \frac{L}{Time} \times 10$$

Where L is the length of the glass slide (7.5 cm).

Viscosity Measurement Test

The viscosity of the unseparated cream formulation was measured using a Brookfield DV2T rotational viscometer, a standard instrument for characterizing the flow behavior of semi-solid pharmaceutical products. Prior to measurement, samples were allowed to equilibrate to a constant temperature of 19°C for 5 minutes. The viscosity was determined using spindle F96 operating at a constant rotational speed of 100 rpm. The reading, in centipoise (cP), was recorded after 2 minutes of continuous spindle rotation to allow for a stable torque reading, indicative of the apparent viscosity under the specified shear conditions. Each formulation was measured in triplicate to ensure reproducibility.

pH Determination Test

The pH of the cream formulations that did not exhibit phase separation upon organoleptic evaluation was measured to ensure that it fell within a range compatible with the physiological pH of the skin and rationalized in the previous section (typically 4.5–6.0), thereby minimizing the potential for irritation. For each formulation, a 0.5 g sample was dispersed in 50 mL of purified water. The dispersion was shaken vigorously for 5 minutes and then sonicated for an additional 5 minutes to ensure uniform distribution of the cream components in the aqueous phase. The pH of the resulting solution was measured in triplicate using a calibrated Metrohm 914 pH/Conductometer, and the mean values were recorded.

Drug Content Determination

The quantification of Atorvastatin and Fusidic acid in the optimized formulation F8, both freshly prepared and stored at room temperature for five months, was performed using an in-house high-performance liquid chromatography (HPLC) method. Chromatographic separation was achieved on a Perfect Bond C18 column (250 mm × 4.6 mm) using an isocratic mobile phase composed of 95% methanol and 5% glacial acetic acid. For sample preparation, an accurately weighed amount of cream equivalent to 25 mg of AT was dissolved in approximately 100 mL of 95% methanol 5% glacial acetic acid. Subsequently, 5 mL of this solution was diluted to 50 mL with mobile phase to yield a final concentration of

0.025 mg/mL for AT. Standard solutions were prepared at the same concentration using a similar procedure. A 20 µL aliquot of each prepared sample and standard was injected into the HPLC system at a flow rate of 1.0 mL/min, with detection carried out at 245.3 nm using a UV detector. All analyses were performed in triplicate, and drug content was calculated by comparing the peak areas of the samples with those of their corresponding standards. The results were expressed as a percentage of the drug content.

Skin Irritation Test

The skin irritation potential of the cream was evaluated on nine healthy volunteers. A small amount of the cream was applied to a clean area on the forearm, and the skin was observed for any signs of redness, swelling, itching or other irritation following application.

Microbiological Contamination Testing

Cream formulation which showed better organoleptic properties, spreadability, viscosity and pH was sent to a local laboratory for microbiological contamination testing. The analysis was conducted by the external laboratory to assess microbial load, with results reported as pass/fail based on the absence or presence of viable microorganisms.

RESULTS AND DISCUSSION

Organoleptic Evaluation

All formulations (F1–F8) exhibited uniform white coloration and characteristic odor when evaluated 24 hours post-preparation. F5, F7, and F8 demonstrated optimal characteristics: homogeneous distribution (no aggregates or phase separation), creamy consistency with low resistance to deformation, and smooth texture (no detectable particulate matter). In contrast, F1 and F2 showed high rigidity (stiff/clumpy consistency) with gritty texture, while F3, F4, and F6 exhibited phase separation, granularity, or inhomogeneity. No discoloration or mottling was observed in any formulation under natural light. As shown in Table 12.

Table 12: Organoleptic Properties of Cream Formulations.

Formulation Code	Color	Odor	Consistency	Texture	Homogeneity
F1	White	Characteristic	Clumpy	Gritty	Heterogeneous
F2	White	Characteristic	Stiff	Gritty	Homogeneous
F3	White	Characteristic	Phase-separated	Phase-separated	Heterogeneous
F4	White	Characteristic	Low viscosity	Gritty	Heterogeneous

F5	White	Characteristic	Creamy	Slightly gritty	Homogeneous
F6	White	Characteristic	Phase-separated	Phase-separated	Heterogeneous
F7	White	Characteristic	Creamy	Smooth	Homogeneous
F8	White	Characteristic	Creamy	Smooth	Homogeneous

Spreadability

Quantitative analysis via gravitational slide method revealed differences in spreadability. F8 demonstrated exceptional performance (1.88 mm/sec), with the upper slide traversing 7.5 cm in 40 seconds. F5 and F7 showed moderate spreadability (0.37 mm/sec and 0.32 mm/sec, respectively). F1 and F2 exhibited negligible spreadability (<0.05 mm/sec), indicating poor applicability. As shown in Table 13.

Table 13: Spreadability of Selected Cream Formulations.

Formulation Code	Traversal Time (s)	Spreadability (mm/sec)
F1	>1500	< 0.05
F2	>1500	< 0.05
F5	205	0.37
F7	232	0.32
F8	40	1.88

Viscosity Measurement

Brookfield viscometry (spindle F96, 100 rpm) showed inverse correlation with spreadability. F1 displayed the highest viscosity (67,900 cP), consistent with its stiff consistency. F8 demonstrated optimal flow properties (5,100 cP), while F5 (14,300 cP) and F7 (34,100 cP) showed intermediate viscosity. Triplicate measurements varied by <2% (RSD < 1.5%), confirming reproducibility. As shown in Table 14.

Table 14: Viscosity of Selected Cream Formulations.

Formulation Code	Viscosity (cP) (Mean±SD)
F1	67900 ± 980
F2	31100 ± 420
F5	14300 ± 205
F7	34100 ± 490
F8	5100 ± 75

pH Determination

Non-separated formulations exhibited physiologically compatible pH (5.09–5.99) after aqueous dispersion and sonication. F2 closely matched skin pH (5.99 ± 0.05), while F8 was slightly acidic (5.09 ± 0.03) which is desirable in such a formulation. As shown in Table 15.

Table 15: Mean pH Values of Selected Cream Formulations.

Formulation Code	Mean pH Value
F1	5.31 ± 0.03
F2	5.99 ± 0.02
F5	5.30 ± 0.02
F7	5.33 ± 0.04
F8	5.12 ± 0.03
Cream Base	6.30 ± 0.14

Drug Content Determination

The drug content of Atorvastatin in the formulated oil-in-water cream was determined using high-performance liquid chromatography (HPLC). The assay results indicated that fresh sample contained 97.59% of the labeled AT, while stored sample contained 97.38% of AT. The mean drug content across both samples was 97.49 ± 0.15% for Atorvastatin. These values fall within acceptable pharmacopeial limits, demonstrating uniform drug distribution and effective extraction from the formulation. The results confirm the suitability of the analytical method and the quality of the prepared cream. As shown in Table 16.

Table 16: Drug Content of Atorvastatin and Fusidic Acid in Cream Samples.

Sample	AT Peak Area	AT Content (%)
Standard	1,618,846	100%
Fresh Sample	1,579,922	97,59
Stored Sample	1,576,500	97.38

Microbiological Contamination Testing

Microbiological analysis of the optimized cream formulation conducted by an accredited external laboratory confirmed the absence of viable aerobic microorganisms, yeast, and mold. No microbial growth was observed in the tested samples, meeting pharmacopeial acceptance criteria for topical preparations.

DISCUSSION

In the present study successfully developed and validated a novel topical combination therapy, demonstrating that a cream formulated of Atorvastatin. First, the physicochemical characterization confirmed that the selected formulation (F8) possessed attributes suitable for dermal application. The measured pH values for all formulations (5.09–5.99) fell within the normal acidic range of human skin (pH 4 - 6), which is known to support barrier function and control microbial colonization. Notably, formulation F2 had a pH very close to skin pH (5.99) and F8 was slightly acidic (5.09) which is generally beneficial for wound healing.

Furthermore, the cream's low viscosity and excellent spreadability ensure ease of application and uniform coverage without excessive shear stress on fragile tissue, because small changes in viscosity or spreadability among otherwise similar creams can significantly alter a patient's sensory experience, which is critical for patient adherence and therapeutic success in long-term care settings.

The mean drug content across both samples was $97.49 \pm 0.15\%$ for Atorvastatin. These values fall within acceptable pharmacopeial limits, demonstrating uniform drug distribution and effective extraction from the formulation.

Homogeneity tests showed uniform drug dispersion. Finally, external microbiological assay confirmed the cream was sterile with no detectable bacterial or fungal growth. Collectively, these results indicate that the combination cream is physically stable, biocompatible, and safe for topical use, consistent with guidelines for topical formulations.

CONCLUSION

In the present study the successfully developed and validated a novel topical combination therapy, demonstrating that a cream formulated of Atorvastatin can significantly enhance wound healing. The physicochemical characterization confirmed that the optimized formulation possessed favorable attributes for dermal application, including an appropriate pH, low viscosity, excellent spreadability, homogeneity, and stability, ensuring its physical integrity and safety for topical use.

It was concluded that the best selected Cream Formulation of the Atorvastatin Cream NDDS was found to be optimized formulation possessed excellent evaluated parameters among the Cream Formulations NDDS. These formulations favorable properties and efficacy indicate it

as a promising strategy for improving outcomes in infected diabetic wounds. 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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