

PREFORMULATION STUDIES OF VITAMIN E WITH PHARMACEUTICAL EXCIPIENTS TO DEVELOPMENT CREAM COSMECEUTICAL FOR STRETCH MARKS AS NOVEL DRUG DELIVERY SYSTEMS

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ABSTRACT

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. The main objective of the present study was to the preformulation studies were performed to know the development of formulation and evaluation of Vitamin E Creams NDDS for topical application. In the present study that the compatibility was assessed by, FTIR spectroscopy, and preformulation parameters. Results showed that physical mixtures of drug and various excipients such as Vitamin E, and a blend of natural oils were evaluated for preformulation studies parameters. It was concluded that the drug Vitamin E was found to be compatible with various

excipients which were selected for the formulation development of the Vitamin E Creams 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 E (alpha-tocopherol), NDDS, Preformulation, Excipients, Development, Creams, Cosmeceutical, Stretch marks.

INTRODUCTION

Background on Stretch Marks^[1-21]

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. Adrenocorticotropic 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. Several studies have noted greater prevalence with large abdominal circumference and large weight gain (due to fetal size or polyhydramnios). One study reported that striae were more prevalent in smokers than non-smokers.

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. Electron microscopy studies have also reported mast cell degranulation, macrophage activation, and elastolysis of mid dermis.

Pharmaceutical Research Paths^[22-79]

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.

Compatibility Studies^[80-140]

Preformulation is essentials of pharmaceutical science that utilizes biopharmaceutical principles in the determination of physicochemical properties of the drug substance. Prior to the development of any dosage form new drug, it is essential that certain fundamental physical and chemical properties of drug powder are determined. This information may dictate many of subsequent event and approaches in formulation development. 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 during the preformulation stage. Formulation scientist from his experience and knowledge have to significantly in the preformulation study stage and is an important factor in the ADDS (Advanced Drug Delivery Systems) product development process. One of the objectives of this study is to development of drug delivery systems by building scientific pharmaceutical research information depend on formulation scientists to join the knowledge and experience as well as experimental and practical results of this study with regard to information in previous studies, and approved references. It was found to be that the most important concepts and basics of preformulation studies such as definitions, methods, conclusion, idea, and types of pharmaceutical analysis techniques using in evaluation of preformulation studies parameters, in this study that we focused on developing drug delivery systems and linking the formulation development to establish the basics of pharmaceutical research in studying the drug-excipient compatibility, dug with

various excipients, which is important for the safety, effectiveness, quality, formulation, stability, bioavailability, and pharmacokinetics of the drug etc.

Determination of physical chemical properties of API substance with the goal of developing a new drug which is safe stable and efficacious, each API, has intrinsic chemical and physical properties that were considered prior to the development of pharmaceutical formulation, the purpose of preformulation study is to generate useful information for the formulator in the development of stable and bioavailable dosage form, inappropriate preformulation study results in poor stability of active ingredients increase the overall cost of development and increased development time, preformulation studies help to fortify the pharmaceutical scientific foundation of the guidance, provide regulatory relief and conserve resources in the drug development and evaluation process, enhance public safety standards, improve product quality, promote the implementation of new technologies, aids policy development and regulatory decision making and after compiling all data it is transferred to the development pharmacist and for the day work on formulation of dosage form.

Preformulation Study Objectives: To establish the Physico-chemical parameters of a new API entity, determine its kinetics and stability, establish its compatibility with common excipients, it provides insights into how drug products should be processed and stored to ensure their quality, estimate problem may arise during formulation that is stability problem poor *in-vivo* dissolution, poor bioavailability, to interpret BCS classification of drugs and its significance and develop optimal drug delivery system.

Drug-Excipient Compatibility Study: The primary objective of this investigation was to identify a stable storage condition for API in solid state and identification of compatible excipients for its formulation. Incompatibilities are major concerns in formulation development. Selection of the proper excipient during preformulation studies is of prime importance.

Dosage Forms: DF contain API and pharmaceutical excipients, which are intended to generate an ideal formulation and manufacturability of pharmaceutical products, thereby enabling a much safer and more effective administration. Pharmaceutical excipients are ideally inactive and have no impact on the stability or therapeutic effect of the active ingredient. On the other hand, there are studies that have presented that some pharmaceutical excipients are just allegedly described as inactive ingredient. Some pharmaceutical excipients

have the capacity to affect API, efficacy by affecting its pharmacokinetics. Excipients can affect the physical and chemical form of pharmaceuticals by several factors such as hydrogen bond interaction, polymorphic conversion, and others. Accordingly, drug-excipient compatibility should be conducted so as to determine any drug-excipient interactions that may obstruct the stability, bioavailability, and manufacturability of pharmaceutical dosage forms.

Importance of Drug-Excipient Compatibility

Studies of active pharmaceutical ingredient (API)-excipient compatibility represent an important study in the preformulation stage of the development of new dosage forms, stability of the dosage form can be maximized, any physical or chemical interaction between API, and excipient can affect bioavailability and stability of drug, it helps to avoid the surprise problem, by performing drug excipient compatibility studies (DECS) we can know the possible reaction before formulating final dosage form, DECS data is essential for IND (investigational new drug) submission, and now, USFDA has made it compulsory to submit DECS data for any new coming formulation before its approval.

The potential physical and chemical interactions between an API, and the excipients can affect the chemical nature, the stability and bioavailability of the former and, consequently, its therapeutic efficacy and safety, solid dosage forms are generally less stable than their API components and despite the importance of API-excipient compatibility testing, there is no universally accepted protocol to assess such interactions.

Pharmaceutical Excipients: Excipients are additive substances used to improve the bulkiness, disintegration, dissolution rate, and bioavailability of a formulation etc. Different dosage forms like powders, granules, capsules, tablets, oral liquids, injectable products, implants, eye products, nasal products, inhalers, topical creams, ointments, gels, transdermal patches and suppositories etc, contains different types of excipients. To make it acceptable and compatible various pharmaceutical excipients are added in pharmaceutical dosage form for their direct therapeutic action, manufacturing process, to protect, support or enhance stability, for bioavailability or patient compliance. These must be physiologically and chemically stable, must not have any incompatibility with the API, and must meet the standards of regulatory requirements.

Evaluation of Drug-Excipient Compatibility

The compatibility study of API and excipients is important to predict the stability of the API, in the final pharmaceutical product. It's the first time that API was compatible with excipients promoted physical and chemical compatibility studies was achieved by thermal and non-thermal methods. As a part of preformulation study, a compatibility study of API with the other excipients was carried out using physical blends in analytical techniques for the evaluation of drug-excipient interactions. The most commonly used pharmaceutical analytical techniques include, thermal techniques such as Differential Scanning Calorimetry (DSC), Thermogravimetric Analysis (TGA), Isothermal Microcalorimetry (IMC) and Hot stage microscopy (HSM) etc, and non-thermal techniques such as UV-Visible Spectrophotometric (UV), Infrared, Near-Infrared and Raman Spectroscopy (FT-IR), (NIR), Powder X-Ray Diffraction (PXRD), Solid-State Nuclear Magnetic Resonance Spectroscopy (ssNMR), Microscopic techniques: Scanning Electron Microscopy (SEM), Chromatographic techniques: Thin Layer Chromatography (TLC), and High-Performance Liquid Chromatography (HPLC) etc.

Preformulation Parameters: According to dosage form of API, mainly solid state, particle size, shape, pKa, pH determination, common ion effect, temperature, partition coefficient, solubility studies, dissolution rate, melting point, powder flow properties, crystallinity, polymorphism, hygroscopicity, stability study and drug-excipient compatibility etc. While other dosage forms according to important of preformulation parameters used in study before start in development of formulation.

Drug-excipient compatibility and formulation stability is not depended on API only but also its affected by excipient. Excipient play important role in dosage form but side by side it also increases compatibility problem so proper selection of excipient is very important in development of formulation. Incompatibility can be result mainly in any of following changes: Changes in organoleptic properties, changes in dissolution performance, decrease in potency, and increase in degradation rate etc.

Drug excipient physicochemical characterization is a systematic approach towards design of therapeutically active and stable dosage forms. The rapid advancements in novel drug delivery systems development have led to an interest by formulation scientists in the role and functionality of the excipients. In the present study, it was proposed to Vitamin E -excipient compatibility 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 during the preformulation stage, with commonly different excipients using for formulation development of Vitamin E Cream NDDS for topical application.

MATERIALS AND METHODS

Vitamin E and all raw materials used in the preformulation and 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 1.

Table 1: List of Materials Used.

No.	Name of Materials
1	Turmeric powder (<i>Local market</i>), (Yemen)
2	Argan Oil (<i>Hemani</i>), (Pakistan)
3	Almond Oil (<i>Hemani</i>), (Pakistan)
4	Aloe vera Oil (<i>Hemani</i>), (Pakistan)
5	Chamomile Oil (<i>Hemani</i>), (Pakistan)
6	Coconut Oil (<i>Hemani</i>), (Pakistan)
7	Vitamin C (<i>Shaphaco</i>), (Yemen)
8	Vitamin E (<i>Shaphaco</i>), (Yemen)
9	Caffeine (<i>Shaphaco</i>), (Yemen)
10	Liquid Paraffin (<i>Shaphaco</i>), (Yemen)
11	Ceto stearyl Alcohol (<i>Shaphaco</i>), (Yemen)
12	Cremophor A25 (<i>Shaphaco</i>), (Yemen)
13	Methyl paraben (<i>Shaphaco</i>), (Yemen)
14	Propyl paraben (<i>Shaphaco</i>), (Yemen)
15	Propylene glycol (<i>Shaphaco</i>), (Yemen)
16	Zinc oxide (<i>Shaphaco</i>), (Yemen)
17	Cetyl alcohol (<i>Shaphaco</i>), (Yemen)
18	Stearic acid (<i>Shaphaco</i>), (Yemen)
19	Isopropyl myristate (<i>Shaphaco</i>), (Yemen)
20	Dimethicone (<i>Shaphaco</i>), (Yemen)
21	Glycerin (<i>Shaphaco</i>), (Yemen)
22	Menthol (<i>Shaphaco</i>), (Yemen)
23	Lanolin (<i>Shaphaco</i>), (Yemen)
24	Hexylene glycol (<i>Yedco</i>), (Yemen)
25	Phenyl trimethicone (<i>Yedco</i>), (Yemen)
26	Titanium dioxide (<i>Yedco</i>), (Yemen)
27	Triethanolamine (<i>Shaphaco</i>), (Yemen)
28	Sodium dihydrogen phosphate (<i>Shaphaco</i>), (Yemen)
29	Peppermint oil (<i>Shaphaco</i>), (Yemen)
30	Lime fragrance (<i>Shaphaco</i>), (Yemen)

Equipment

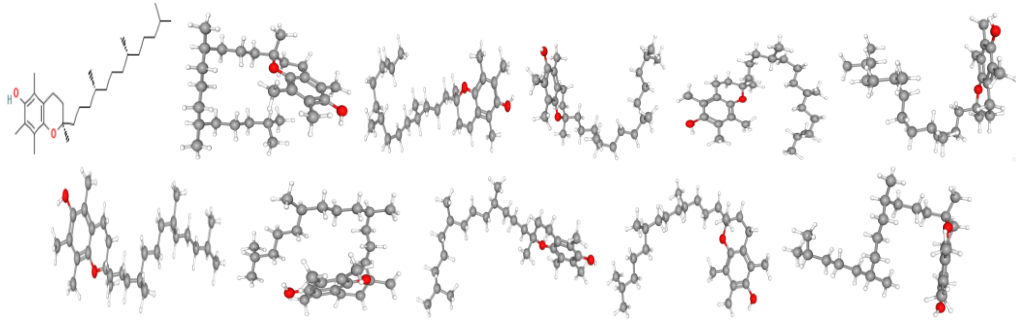
All equipment used are listed in Table Error! No text of specified style in document.

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

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

Evaluation of Drug-Excipient Compatibility Studies Methods^[111-174]

Table 3: Vitamin E Data.

Characterization of Vitamin E			
			
Vitamin E Structure and 3D Conformer			
Chemical Structure	(2 <i>R</i>)-2,5,7,8-tetramethyl-2-[(4 <i>R</i> ,8 <i>R</i>)-4,8,12-trimethyltridecyl]-3,4-dihydrochromen-6-ol	Appearance	Is a fine white or light yellow.
Chemical Formula	$C_{29}H_{50}O_2$	Drug Solubility	Solubility: Is a fat soluble -practically insoluble in pure water (20.9mg/L). It is freely soluble in organic solvents, oils, and fats. Melting Point: 210°C.
Molecular Weight	430.7 g/mol	BCS	Class-IV Drug
Drug Action and Use	<p>Vitamin E is an important Vitamin required for the proper function of many organs in the body. It is also an antioxidant. Vitamin E that occurs naturally in foods (RRR-α-tocopherol) is different from man-made Vitamin E that is in supplements (all-rac-α-tocopherol). Vitamin E is a nutrient you need for good health. It's important for your eyes, skin, blood, and brain. One of its most important roles is acting as an antioxidant, which means it protects your cells against damaging molecules known as free radicals.</p> <p>Benefits of Vitamin E</p> <p>An inherited condition that affects motor control (ataxia with Vitamin E deficiency or AVED). Taking Vitamin E by mouth is effective for treating</p>		

	<p>Vitamin E deficiency due to this genetic movement disorder. Your body uses Vitamin E for multiple purposes, including protecting you from oxidative stress and supporting your immune system. Vitamin plays many roles in your body, including:</p> <ul style="list-style-type: none"> protecting your cells from oxidative damage by neutralizing harmful molecules called free radicals. supporting proper immune function. promoting cellular signaling and metabolic processes. <p>Other potential health benefits of vitamin E</p> <p>Vitamin E supplements have also been linked to several other potential health benefits:</p> <p>Benefit skin health</p> <p>Vitamin E supplements may be helpful trusted source for those with certain skin disorders, such as eczema and psoriasis trusted source. However, the research is currently limited, and more studies are needed to support this potential benefit.</p> <p>Benefit cognitive health</p> <p>Maintaining optimal Vitamin E levels and taking supplements may help prevent cognitive decline. However, it's still unclear whether the supplements benefit people with cognitive conditions like Alzheimer's disease.</p> <p>Benefit older adults</p> <p>Because Vitamin E plays important roles in health, such as reducing inflammation and improving immune function, increased intake may benefit Trusted Source people with increased needs or don't get enough in their diets. This may include older adults.</p> <p>Improve lung function</p> <p>A small 2019 study suggests Vitamin E supplements could improve lung function and certain asthma symptoms in adults.</p>			
Vitamin E Pharmacokinetics				
<p>Drug Absorption</p>	<table border="1"> <tr> <td data-bbox="379 1294 858 2027"> <p>Vitamin E (alpha-tocopherol) is directly solubilized into mixed micelles by bile salts and amphipatic lipids present in GIT. Vitamin E has a high bioavailability of ca. 50–80% and follows the general absorptive route of dietary fats. Vitamin E is absorbed even in the absence of dietary lipids, but its uptake in the small intestine can be enhanced by simultaneous fat consumption.</p> </td> <td data-bbox="858 1294 1066 2027"> <p>Drug Distribution</p> </td> <td data-bbox="1066 1294 1415 2027"> <p>Volume of Distribution</p> <p>Lipoproteins are the major, if not the only, carriers of plasma lipid-soluble antioxidants, including Vitamin E. Indeed, plasma α-tocopherol levels are very well correlated with plasma lipid levels.</p> <p>Protein binding</p> <p>Vitamin E</p> <p>The liver preferentially incorporates α-tocopherol into lipoproteins that are released into the bloodstream for distribution of lipids to</p> </td> </tr> </table>	<p>Vitamin E (alpha-tocopherol) is directly solubilized into mixed micelles by bile salts and amphipatic lipids present in GIT. Vitamin E has a high bioavailability of ca. 50–80% and follows the general absorptive route of dietary fats. Vitamin E is absorbed even in the absence of dietary lipids, but its uptake in the small intestine can be enhanced by simultaneous fat consumption.</p>	<p>Drug Distribution</p>	<p>Volume of Distribution</p> <p>Lipoproteins are the major, if not the only, carriers of plasma lipid-soluble antioxidants, including Vitamin E. Indeed, plasma α-tocopherol levels are very well correlated with plasma lipid levels.</p> <p>Protein binding</p> <p>Vitamin E</p> <p>The liver preferentially incorporates α-tocopherol into lipoproteins that are released into the bloodstream for distribution of lipids to</p>
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			peripheral tissues.
Drug Metabolism	<p>Metabolic studies have shown a short half-life (≈ 12 min) for plasma α-tocopherol in circulation with predominant accumulation in liver, adipose tissue and skeletal muscle 24 h after intravenous injection.</p> <p>The enzymatic degradation of Vitamin E to its short-chain metabolites, destined for urinary excretion, in the small intestine and liver is the most important factor regulating the retention of the different Vitamin E congeners in the organism.</p>	Drug Excretion	<p>Route of Elimination Vitamin E The Vitamin E incorporated into chylomicrons ultimately reaches the liver parenchymal cells transported in remnant lipoprotein particles.</p> <p>Clearance: In the liver, the cytosolic α-tocopherol transfer protein is required for the secretion of Vitamin E into the blood and appears to limit the excretion of mainly α-tocopherol, but to a smaller extent also the non-α-tocopherol congeners, from the body, thus making sure that sufficient Vitamin E is retained for its essential biological functions.</p>
The Elimination Half-Life (T_{1/2})	Vitamin E, Plasma elimination half-life is approximately 48 hours.	Availability	Tablets, Capsules, Oil, Creams, Gels.

According to Vitamin E data as shown in Table 3, it was selected that the different excipients to preformulation study with Vitamin E in the present study.

Pre-Formulation Study

A stage of development during which the physicochemical properties of the drug substance are characterized and established. A complete knowledge of the relevant therapeutic and physicochemical properties of the drug enables determination of its proper formulation and delivery method. Preformulation study is to develop the elegant (stable, effective, and safe) dosage form by establishing kinetic rate profile, compatibility with the other ingredients and establish physico-chemical parameter of new drug substance.

Drug and Excipients Compatibility Study

FTIR Spectroscopy Study: IR study was aimed to study the compatibility of excipients with drug in room condition. Each excipient was mixed with drug in equal amounts, then from each sample a small amount was taken (approx 1:1 %) and mixed with about 100 mg of potassium bromide. The KBr- sample mixtures were grinded separately for each sample using agate mortar and pestle. The grinded powders were compressed into discs under pressure of about 10000 pounds per square inch. The tablets were mounted in IR compartment and analyzed. The infrared spectra of the drug - excipient mixtures were recorded over a wave number of 4000 cm^{-1} to 500 cm^{-1} . On analysis of the IR spectra of the reference spectra given in British Pharmacopoeia and pure drug, no major differences were observed in the characteristic absorption peak pattern as shown in Table 4.

Table 4: The Drug and Excipients Compatibility Studies.

Sample Code	Drug with Excipients	Ratio (Drug: Excipient)
1	Vitamin E	1
2	Vitamin E + Cetostearyl Alcohol	1:1
3	Vitamin E + Cremophor A25	1:1
4	Vitamin E + Menthol	1:1
5	Vitamin E+ Zinc Oxide	1:1
6	Vitamin E + Cetyl Alcohol	1:1
7	Vitamin E + Propyl Paraben	1:1
8	Vitamin E + Methyl Paraben	1:1
9	Vitamin E + Stearic Acid	1:1

RESULTS AND DISCUSSION

Excipient and Drug Compatibility Study

Characterization of Drug by FTIR

FTIR spectrum studies indicated that major functional groups present in drug show characteristic peaks in IR spectrum. Figures (1) to (7) show peaks observed at different wave numbers and the functional group associated with these peaks for drug and drug with different excipients. The major peaks are identical to functional group of drug. Hence, it was confirmed that there was compatibility between drug and various excipients, thus conforming that no interaction of drug occurred with the components of the formulation excipients.

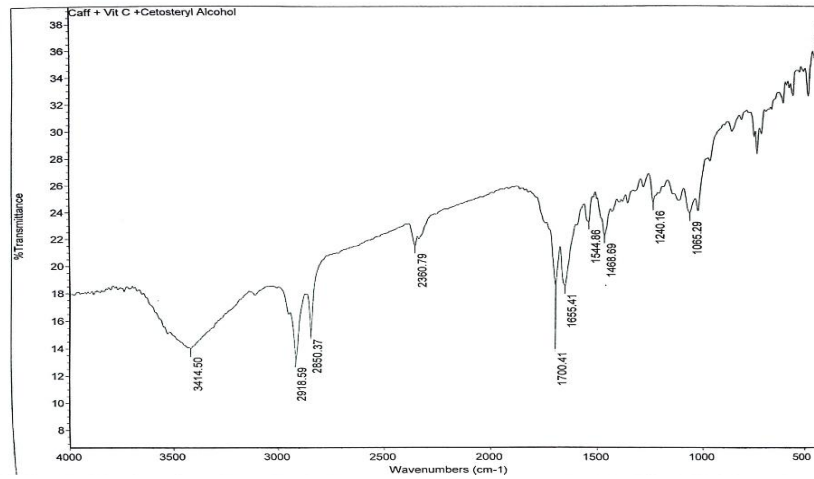


Fig. 1: FTIR Spectra of Active ingredient and Cetosteryl alcohol.

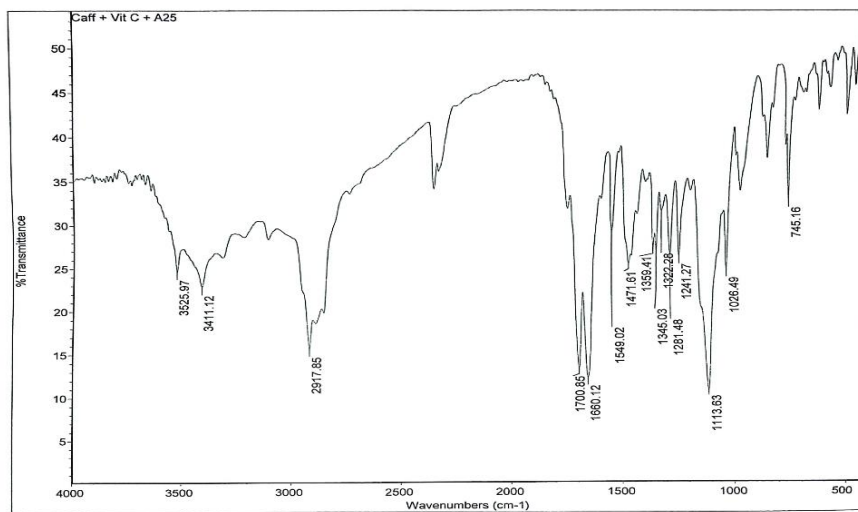


Fig. 2: FTIR Spectra of Active ingredient and Cremophor A25.

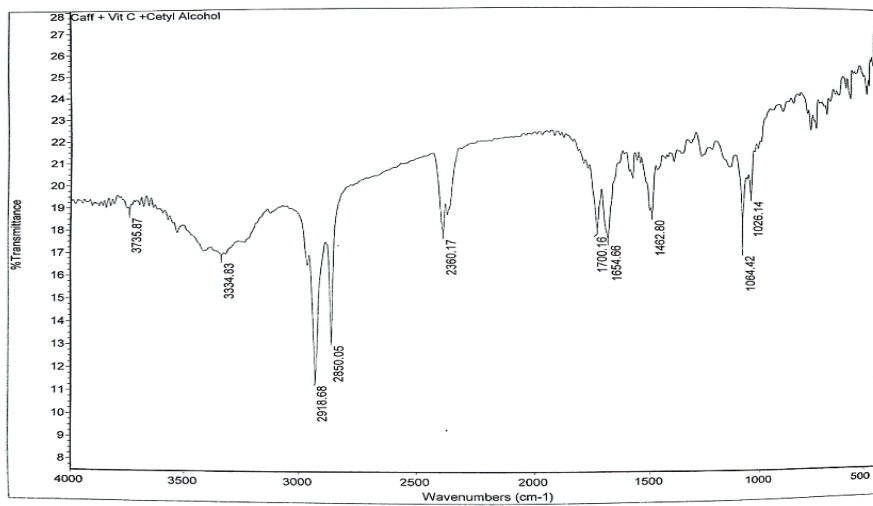


Fig. 3: FTIR Spectra of Active ingredient and Cetyl alcohol.

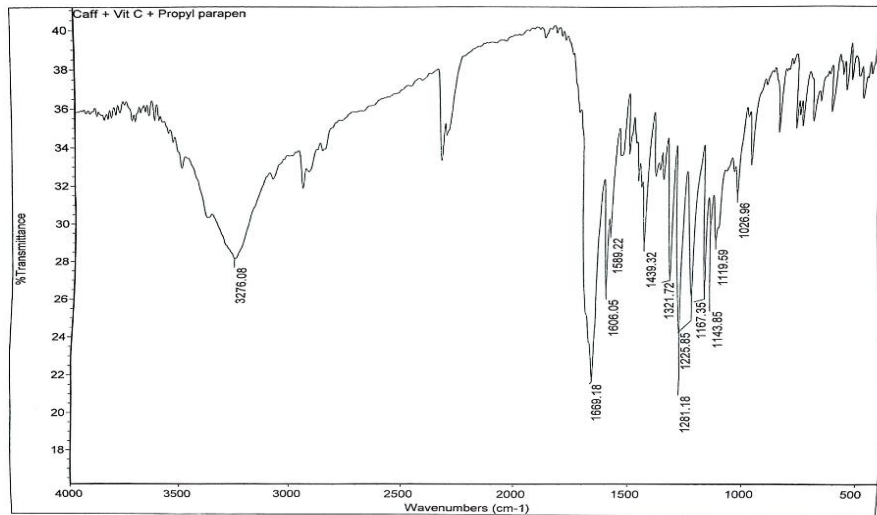


Fig. 4: FTIR Spectra of Active ingredient and Propyl Paraben.

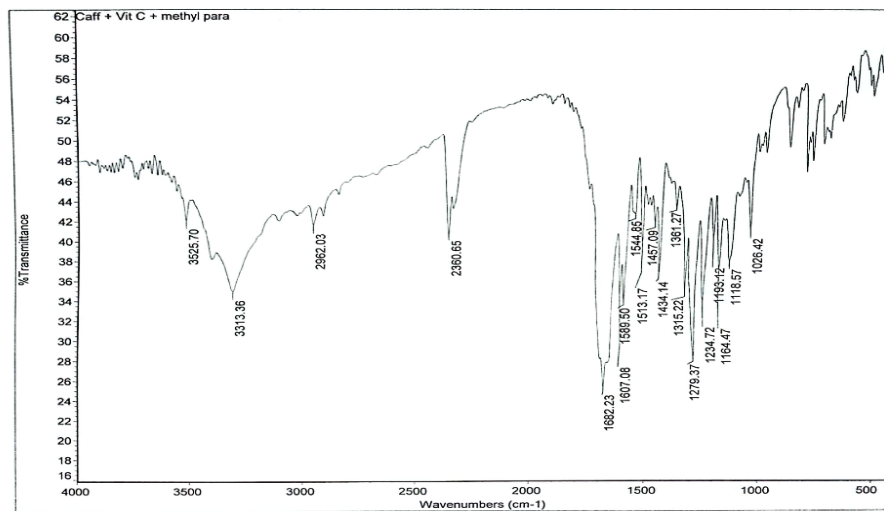


Fig. 5: FTIR Spectra of Active ingredient and Methyl paraben.

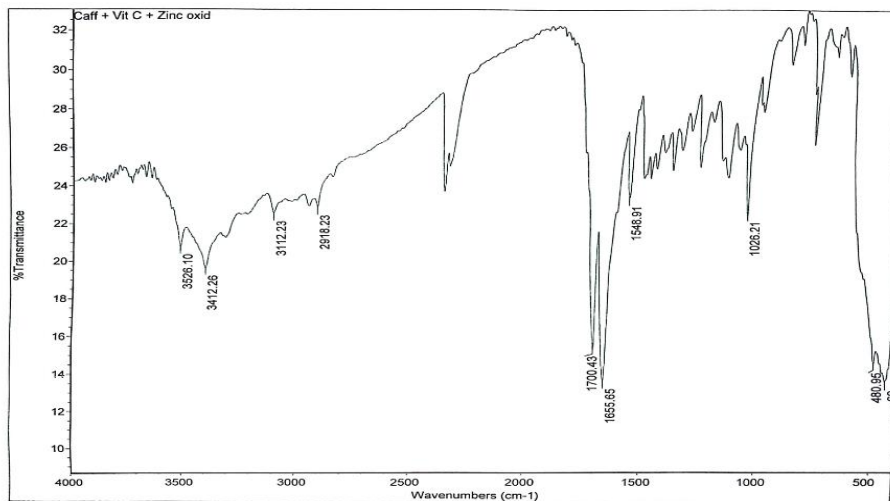


Fig. 6: FTIR Spectra of Active ingredient and Zinc oxide.

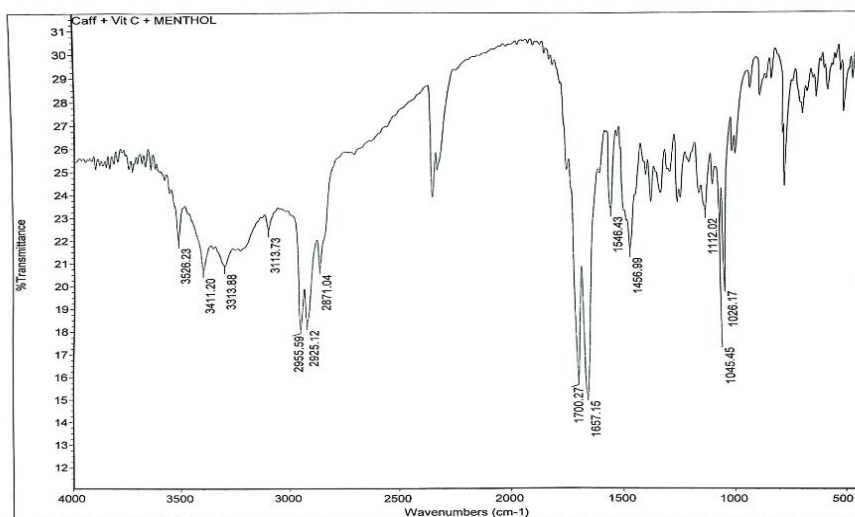


Fig. 7: FTIR Spectra of Active ingredient and Menthol.

The pre-formulation studies confirmed the identity and purity of the active drugs. FTIR analysis showed that Vitamin E retained its diagnostic bands and in mixtures with formulation excipients. These findings demonstrate full physicochemical compatibility of Vitamin E with all components. In other words, none of the excipients caused chemical degradation or new interactions with the drug.

CONCLUSION

The compatibility studies of physical mixtures of drug with different used excipients such as Vitamin E, and a blend of natural oils were evaluated for preformulation studies parameters were investigated by FTIR it was detected that there was no variation or minor deviation in the characteristic peaks in FTIR spectroscopy. It was concluded that the drug Vitamin E was found to be compatible with various excipients which were selected for the formulation development of the Vitamin E Cream 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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