Research Article…

Formulation and Development of Solid Lipid Nanoparticles Based Nanogel for Dermal Delivery of Borago Officinalis.

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Abstract:

Topical administration of medications at diseased areas may have the advantage of delivering the drug directly to the site of action. The primary purpose of this work was to Formulation and Development of Solid Lipid Nanoparticles Based Nanogel for Dermal Delivery of Borago Officinalis.

Fungal infections are growing more widespread throughout the world. Oral therapy for fungal infections is associated with unpleasant side effects, a lengthy treatment interval, and patient intolerance. In contrast, topical therapy is associated with superficial fungal infections due to limited drug solubility, skin irritation, and low skin permeability. Top topical therapy aims to improve the penetration of poorly soluble drugs while minimizing adverse effects such as irritation and providing immediate symptomatic relief from fungal illnesses. a skin irritation study formulations were reported to be non-irritant and safe for use. The Borago Officinalis - Solid Lipid nanoparticles gel showed enhanced anti-fungal activity and stability.

Key Words: Topical Drug Delivery System, Solid Lipid Nanoparticles, Dermal Delivery System, Borago Officinalis.

Introduction:

Topical drug delivery (TDD) is a route of drug administration that allows the topical formulation to be delivered across the skin upon application, hence producing a localized effect to treat skin disorders like eczema. The formulation of topical drugs can be classified into corticosteroids, antibiotics, antiseptics, and anti-fungal. The delivery of topical drugs needs to pass through multiple skin layers and undergo pharmacokinetics, hence factor like dermal diseases minimize the bioavailability of the topical drugs. The wide use of topical drugs leads to the advancement in topical drug delivery. These advancements are used to enhance the delivery of topical medications to the skin by using chemical and physical agents. For chemical agents, carriers like liposomes and nanotechnologies are used to enhance the absorption of topical drugs. On the other hand, physical agents, like micro-needles is other approach for enhancement of absorption. Besides using carriers, other factors such as pH, lipophilicity, and drug molecule size govern the effectiveness of topical formulation.

- **Skin absorption:**

- **Skin layers -**

The human body's largest organ is the skin layers, which protects against foreign particles. Human skin contains several layers, including the subcutaneous layer, the dermis, the epidermis, the stratum corneum, and the appendages. Each of these layers have an effect on the absorption of topical drug. When the topical drug is applied to the skin, it must pass via the stratum corneum, which is the outermost skin layer. Stratum corneum's function includes prevention of water loss in skin and inhibit the penetration of foreign molecules into the dermal

layers. Hence, it also prevents the hydrophilic molecules to get absorbed into the skin since it is made out of bilayer lipids.

- **Diffusion -**

When drugs are applied to skin topically, the drug molecules will undergo passive diffusion. This process occurs down the concentration gradient when drug molecules move to one area to another region. Diffusion is described by a mathematical equation. The drug molecule (J), known as flux and it represents the entry of topical drug molecules across the skin membrane. The skin membrane is the area (A) for the topical drug molecules to travel across. The skin membrane thickness is known as (h) in the expression, and it determines the diffusion path length. The (C) is the concentration of the diffusing substance across the skin layers and the (D) is the diffusion coefficient. The expression illustrates the transportation of topical drug molecules across the stratum corneum membrane through diffusion. Mechanism Upon application of the topical drug on the skin, it will diffuse to the outer layer of the skin, known as stratum corneum.

Advantages of topical drug delivery system:

1. It avoids first pass metabolism.
2. Expedient and easy to apply.
3. Avoids the disadvantages and risks of intravenous therapy
4. Target the drug more selectively to a specific site.

- **Solid lipid nanoparticles:**

Solid lipid nanoparticles (SLN) were developed as a colloidal carrier at the beginning of the 1990s as an alternative system to the existing traditional carriers like emulsions, liposomes, niosomes and polymeric nanoparticles. Nanoparticles made up of solid lipid have more advantageous than any other carrier system. SLN have more entrapment of drug in solid lipid. Solid lipid nanoparticles are composed of lipid in solid form at room temperature along with surfactant (emulsifier) for stabilizing of SLN dispersion.

The reasons for the increasing interest in lipid-based system are many – fold and include.

1. Lipids enhance oral bioavailability and reduce plasma profile variability.
2. Better characterization of lipoid excipients.
3. An improved ability to address the key issues of technology transfer and manufacture scale-up.

Advantages of SLN:

- Control and / or target drug release.
- Excellent biocompatibility
- Improve stability of pharmaceuticals
- High and enhanced drug content.

Disadvantages of SLN -

- Particle growth.
- Unpredictable gelation tendency.
- Unexpected dynamics of polymeric transitions.

Preparation of solid lipid nanoparticles:

SLNs are prepared from lipid, emulsifier and water/solvent by using different methods and are discussed below.

Methods of preparation of solid lipid nanoparticles:

1. High pressure homogenization

A. Hot homogenization B. Cold homogenization

2. Ultrasonication/high speed homogenization

1. **High pressure homogenization (HPH)**

It is a reliable and powerful technique, which is used for the production of SLNs. High pressure homogenizers push a liquid with high pressure (100–2000 bar) through a narrow gap (in the range of a few microns). The fluid accelerates on a very short distance to very high velocity (over 1000 Km/h). Very high shear stress and cavitation forces disrupt the particles down to the submicron range. Generally, 5-10% lipid content is used but up to 40% lipid content has also been investigated. Two general approaches of HPH are hot homogenization and cold homogenization, work on the same concept of mixing the drug in bulk of lipid melt.

A. Hot homogenization:

Hot homogenization is carried out at temperatures above the melting point of the lipid and can therefore be regarded as the homogenization of an emulsion. A pre-emulsion of the drug loaded lipid melt and the aqueous emulsifier phase (same temperature) is obtained by high-shear mixing device. HPH of the prefusion is carried out at temperatures above the melting point of the lipid. In general, higher temperatures result in lower particle sizes due to the decreased viscosity of the inner phase. However, high temperatures increase the degradation rate of the drug and the carrier. Increasing the homogenization pressure or the number of cycles often results in an increase of the particle size due to high kinetic energy of the particles.

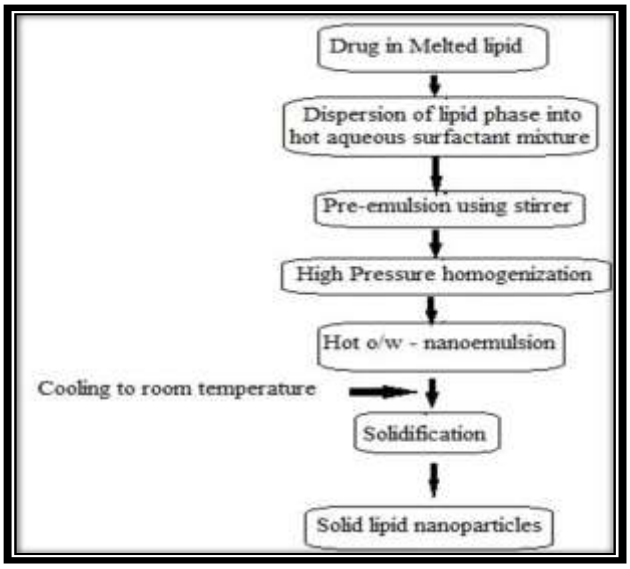

Figure 1: Solid lipid nanoparticles preparation by hot homogenization process.

B. Cold homogenization:

Cold homogenization has been developed to overcome various problems associated with hot homogenization such as: Temperature-induced drug degradation, drug distribution into the aqueous phase during homogenization, Complexity of the crystallization step of the Nano emulsion leading to several modifications and/or super cooled melts. In this technique the drug containing lipid melt is cooled, the solid lipid ground to lipid microparticles and these lipid microparticles are dispersed in a cold surfactant solution yielding a pre-suspension. Then this pre-suspension is homogenized at or below room temperature, the gravitation force is strong enough to break the lipid microparticles directly to solid lipid nanoparticles.

Disadvantages

- Energy intensive process.
- Demonstrated at lab scale Biomolecule damage.
- Polydisperse distributions.
- Unproven scalability.

2. Ultrasonication/high speed homogenization

SLNs are also prepared by ultrasonication or high speed homogenization techniques. For smaller particle size combination of both ultrasonication and high speed homogenization is required.

- **Advantages**

1. Reduced shear stress

- **Disadvantages**

1. Potential metal contamination.
2. Physical instability like particle growth upon storage.

➢ **DRUG PROFILE -**

Name: Borago Officinalis

Borago officinalis, also known as borage, is a medicinal and culinary herb belonging to the Boraginaceae family. Characterized by its star-shaped blue flowers and bristly leaves, it is rich in bioactive compounds such as gamma-linolenic acid, flavonoids, and alkaloids. These components contribute to its therapeutic applications in reducing inflammation, promoting skin health, and managing hormonal imbalances. Borage is also valued for its antioxidant properties and is used in scientific studies for its pharmacological potential. Its historical use in traditional medicine and contemporary relevance make it a noteworthy subject for research and development.

Figure 2: Borago Officinalis

Chemical Composition:

Borage (Borago officinalis) is an annual herb which is cultivated for medicinal and culinary uses, although it is commercially cultivated for borage seed oil. Borage seed oil is the plant rich in the gamma-linolenic acid (26%-38%) which is used as dietary or food supplement. Other than seed oil it contains a lot of fatty acids such as linoleic acid (35%-38%), oleic acid (16%-20%), palmitic acid (10%-11%), stearic acid (3.5%-4.5%), eicosanoid acid (3.5%-5.5%) and erucic acid (1.5%-3.5%).

Pharmacology

Borago officinalis, commonly known as borage, is a medicinal plant with a wide range of pharmacological properties. It contains phytochemicals such as alkaloids, tannins, flavonoids, phenolic acids, essential oils, and gamma-linolenic acid (GLA), which contribute to its therapeutic effects.

Anti-inflammatory:
Borage oil contains gamma-linolenic acid (GLA), which has anti-inflammatory effects.
Antioxidant: The plant's phenolic compounds and flavonoids contribute to its strong antioxidant properties.

- **EXCIPIENT**

1. GELRITE:
Name: Gellan Gum
Functional Uses: Thickener, gelling agent, stabilizer
Melting Point: Browns at 190–200°C; chars at 225–230°C. / Glass transition temperature is 170–180.

2. Polyoxymethylene Sorbitan Fatty Acid Esters (Tween 20, 40, 60, 80)
Name: Polyoxymethylene Sorbitan Fatty Acid Esters
Chemical Name: Polysorbate 20, Polysorbate 40, Polysorbate 60, Polysorbate 80
Molecular Formula: Polysorbate 20- $C_{58}H_{114}O_{26}$ 1128, Polysorbate 40- $C_{62}H_{122}O_{26}$ 1284 Polysorbate, 60- $C_{64}H_{126}O_{26}$ 1312 Polysorbate, 80- $C_{64}H_{124}O_{26}$ 1310.
3. Transcutol:
Name: Transcutol
Chemical Name: 2-(2-ethoxyethoxy) ethanol
Molecular Formula: $C_6H_{14}O_3$

- **MATERIALS AND METHODS –**

S. No	Name
1	Borago Officinalis
2	Polysorbate 20
3	Polysorbate 80
4	GELRITE (Gellan Gum)
5	Methanol
6	DMSO
7	Triethanolamine
8	Propylene Glycol
9	Ethanol
10	Sodium Hydroxide
11	Glycerin
12	Sodium Chloride
13	Potassium phosphate monobasic
14	Sodium phosphate dibasic

Table No 1: Material Use

- **Equipment Used:**

S. No	Instruments
1	Microgram Electronic balance
2	UV-Vis Double beam Spectrophotometer
3	Magnetic Stirrer
4	Hot Air Oven
5	FTIR
6	Differential Scanning Calorimetry

Table No 2: Instrument Use

➢ **PREPARATION OF STOCK & BUFFER SOLUTIONS -**

1. Hydrochloric acid buffer pH1.2: 50ml of 0.2M potassium chloride and 85ml of 0.2 M HCl were taken in a 200 ml volumetric flask and made up to the volume with water.
2. Phosphate buffer pH 6.8: Dissolve 60.5 g of disodium hydrogen phosphate and 46 g of potassium dihydrogen phosphate in water add 100 ml of 0.02 M disodium edetate and 20 mg of mercuric chloride and dilute with water to produce 1000ml.
3. Phosphate buffer pH 7.4: 50 ml of 0.2 M potassium dihydrogen phosphate and 39.1 ml of 0.2 M NaOH were taken in a 200 ml volumetric flask and made up to the volume with water.
4. Sodium hydroxide solution (0.2 M): Accurately weighed 8.0 gm of sodium hydroxide was dissolved in 1000 ml of distilled water.
5. Potassium dihydrogen phosphate (0.2 M): Accurately weighed 27.218 gm of potassium dihydrogen orthophosphate was dissolved in 1000 ml of distilled water.
6. Potassium chloride (0.2 M): Accurately weighed 14.91 gm of potassium chloride was dissolved in 1000 ml of distilled water.

➢ **SOLID STATE CHARACTERIZATION OF DRUG:**

- **Fourier Transfer Infrared Spectroscopy:**

Drug was mixed with Potassium Bromide in a ratio of 9:1 which was triturated and blended evenly. The mixture was further compressed into pellets on a motorized pellet press at pressure of 15 ton. The prepared pellets were then scanned over range of 4000 – 400 cm-1 to get the IR spectra. Functional group determination was studied visually by interpreting the peaks observed.

- **Differential Scanning Calorimetry:**

Drug was hermitically sealed in perforated aluminium pan using crimper and heated at constant rate of 10°C/min over the temperature ranges of 30-300°C at 20mL/min nitrogen purging.

- **Melting Point Determination:**

Capillary Method was employed for Melting Point Determination. Drug was filled in a one end sealed capillary tube and was placed in a Liquid Paraffin bath in a Thiele's Tube. Upon visual inspection, temperature on which the solid starts turning into a liquid was noted down.

➢ **DRUG-EXCIPIENTS INCOMPATIBILITY STUDIES:**

Fourier Transfer Infrared Spectroscopy:

The Fourier Transform – Infrared (FT-IR) spectroscopy has numerous application in Pharmaceutical field. It is widely used in determination of identification of known and

unknown compound. Apart from this it can also be used in evaluating the drug interaction. During formulation the active ingredient are used mixed with various excipients to give proper shape and appearance.. Drug was mixed with all excipients in equal proportion forming a physical mixture were all compressed as a KBr pellet respectively for each sample at a ratio of 9:1. The prepared pellets were then scanned over range of 4000 – 400 cm-1 to get the IR spectra. Functional group determination was studied visually by interpreting the peaks observed and any changes in parent peaks were observed

Differential Scanning Calorimetry:
Physical Mixture of drug and excipients was prepared for both drugs and sealed in a prewashed ampoule. It was set aside in a Programmable Environmental Test Chamber, Remi Instruments Ltd. Mumbai for 28 days. Following that the sample was hermitically sealed in perforated aluminium pan and heated at constant rate of 10°C/min over the temperature ranges of 30-300°C at 20mL/min nitrogen purging.

- **ANALYTICAL METHOD DEVELOPMENT**

Determination of ƛmax for Borago Officinalis:
10 mg drug was suspended in 100 ml methanol to prepare a stock solution and 10ppm sample was taken out and studied for its UV Spectra photometrically on a UV- 2450 UV-Vis Spectrophotometer.

Preparation of Stock Solution: Accurately weighed 10 mg of Borago Officinalis was transferred to a 100 ml volumetric flask, dissolved in 10 ml Methanol by shaking manually for 10 min. The volume was adjusted with the same up to the mark to give the final strength, i.e.100 µg/ml.

Preparation of Calibration Curve of APZ: Different aliquots of Borago Officinalis in the range 0.2-1 ml were transferred into series of 10 ml volumetric flasks, and the volume was made up to the mark with distilled water to get concentrations 2, 4, 6, 8 and 10 µg/ml, respectively. The solutions were scanned on a spectrophotometer in the UV range 200–400 nm. The absorbance was recorded at 354 nm.

- **FORMULATION OF BORAGO OFFICINALIS SOLID LIPID NANOPARTICLES SLN:**

Were prepared by film hydration technique. The mixture of vesicle-forming ingredients namely lecithin and cholesterol was dissolved in a volatile organic solvent (dichloromethane and methanol) in a round-bottom flask. The rotary evaporator was rotated at 60°C for 45 min. Then the organic solvent was removed with gentle agitation and the organic solvent evaporated at 60°C, leaving a thin film of lipid on the wall of the rotary flash evaporator. The aqueous phase containing Meloxicam drug was added slowly with intermittent shaking of the flask at room temperature and sonicated for 30 min. The obtained nano lipid solution was cooled by placing in the freezer.

Ingredients (%)	F1	F2	F3	F4	F5
Borago Officinalis	5	5	5	5	5
Lecithin	5	2.5	7.5	4	6

Cholesterol	5	7.5	2.5	6	4
Dichloromethane : Methanol (1:1)	25	25	25	25	25
Water	60	60	60	60	60

Table No 3: Formulation design for Quercetin

Formulation of Nanogel was prepared on the basis of drug entrapment efficiency of prepared SLNs. The batch of SLN that gave maximum entrapment was selected for preparation of Nanogel

- **FORMULATION OF BORAGO OFFICINALIS NANOGEL**

Design of experiments is a method by which purposeful changes to input factors of process in order to observe the effects on the output can be made. DOE's can and have been performed in virtually every industry on the planet, agriculture, chemical, pharmaceutical, electronics, automotive, hard goods manufacturing, etc. Service industries have also benefited by obtaining data from their process and analysing it appropriately. Traditionally, experimentation has been done in a haphazard one-factor-at-a time (OFAT) manner. This method is inefficient and very often yields misleading results. On the other hand, factorial designs are a very basic type of DOE, require only a minimal number of runs, yet they allow you to identify interactions in the process. This information leads to breakthroughs in process understanding, thus improving quality, reducing costs and increasing profits. Various factors were studied under hit and trial method and out of them, two independent factors suited the experiment's need viz. The concentration of GELRITE (%) and Ratio of Tween 20:80 (%). Dependent factors were Entrapment Efficiency (%) and In-Vitro drug release (%) as these three parameters address the essence of oral films.

Formulation Code	**Borago Officinalis (%)**	**GELRITE (%)**	**Tween 20:80 (%)**	**Diluent to make 100%**
F1	5	10	10	Q.S
F2	5	20	10	Q.S
F3	5	10	20	Q.S
F4	5	20	20	Q.S
F5	5	7.92893	15	Q.S
F6	5	22.0711	15	Q.S
F7	5	15	7.92893	Q.S
F8	5	15	22.0711	Q.S
F9	5	15	15	Q.S

Table No 4: Formulation Table for Quercetin Nanogel

The Borago Officinalis nanogel was synthesized with the aid of Gel rite as a polymer. Accurately weighed 5 mg of Borago Officinalis SLNs and variable concentration of GELRITE was dissolved in 1% v/v methanol followed by the drop wise addition of Tween 20:80 (1:1) at the rate of 2 ml/min with constant stirring for 3 h by using magnetic stirrer at 1000 rpm. pH was adjusted by gel Triethanolamines(0.05%). The mixture was allowed to achieve room temperature which resulted in gel formation

- **CHARACTERIZATION OF BORAGO OFFICINALIS SLNs AND NANOGEL:**

Mean Particle size: The MPS were determined by PCS with a Malvern Zetasizer (Nano ZS 90, Malvern ltd., UK). The measurement using PCS is based on the light scattering phenomena in which the statistical intensity fluctuations of the scattered light from the particles in the measuring cell are measured. Prior to the measurements, all samples were diluted with double distilled water to produce a suitable scattering intensity. The z-average and PDI values were obtained at an angle of 90° using disposable polystyrene cells having 10 mm diameter cells at 25°C, which were equilibrating for 120 seconds.

Entrapment Efficiency and Drug loading: Percent Entrapment efficiency (EE) is defined as the percentage of drug incorporated into the polymeric nanogel relative to the total drug added. It specifies how much percent of drug is included in the particles and how much percent of free drug are still present in the dispersion medium. For this both, Borago Officinalis SLNs and NG were centrifuge at 45,000 rpm for 35 min; 1.0 mL of the supernatant collected after centrifugation was diluted with 3.0 mL of DMSO and methanol and then make up volume up to 10 ml in 10ml volumetric flask and measured spectrophotometrically at 354 nm using UV-Visible spectrophotometer The entrapment efficiency and standard deviation was calculated. Drug loading (DL) refers to the percentage of drug incorporated into the polymeric nanogel relative to the total weight of the nanogel (i.e. polymer + drug). For this, CRM from Lyophilized flakes was extracted by triturating 10mg powder with DMSO and methanol in mortar pestle and diluted up to 10 ml in volumetric flask. Borago Officinalis content in methanolic extract was analysed spectrophotometrically at 354 nm, against the standard methanolic solution of Borago Officinalis. Entrapment efficiency (%) = (Total amount of drug-un-entrapped drug)/(Total amount of drug) x 100 Drug loading (%) = (Actual amount drug in nanogel)/ (Total amount of drug) x 100.

Differential Scanning Calorimetry: Thermal analysis was performed using a differential scanning calorimetry (DSC) (Mettler Toledo, Zurich, Switzerland) for optimized formulation. The samples, weighing 2 mg, were analysed in sealed and pin-holed standard 40 µl aluminium pan, with a heating rate of 10°C/min from 30°C to 300°C and during the measurement the sample cell were continuously purged with nitrogen at a flow rate of 40 ml/min.
Accelerated stability study: The stability study was done for the optimized film formulation of Borago Officinalis NG. The prepared NG was kept in glass vial, then placed in desiccators for period of 90 days at room temperature, ambient humidity and then evaluated for analysing MPS, ZP and % EE with a time interval of 30 days.

RESULT: (Solid State Characterization of Drug)

- **Fourier Transfer Infrared Spectroscopy:**

Fourier transformed infrared spectra of Borago Officinalis was taken by using the KBr disk method. The scanning range was 450 to 4000 cm-1 and the resolution was 1cm-1. The obtained IR spectra of drug sample given Observed peaks of the drug are shown in Table which are similar to the standard IR spectra of drug reported in the literature.

Figure 3: FTIR spectra of Borago Officinalis

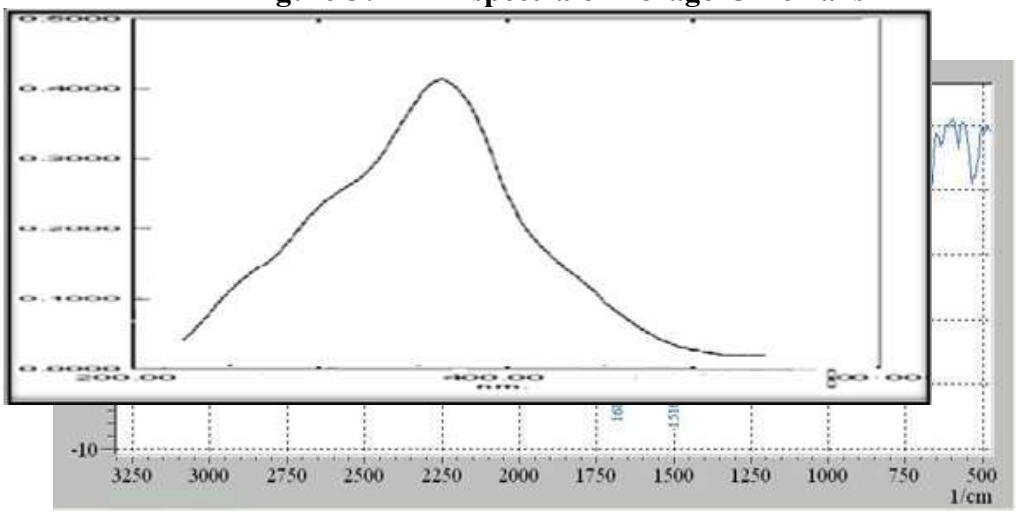

Table 5: Principal peak and chemical group present in IR spectra of Borago Officinalis

Observed peaks	Reported peaks	Interpretation of chemical groups
3510.56	3500-3450	C=O stretch carbonyl
3014.84	3100-3000	=C-H stretching alkene
2943.47	3000-2850	C-H stretching alkane
1602.90	1650-1580	C=O, carbonyl group
1585.54	1685-1550	C=C stretch aromatics
1429.30	1450-1400	C-H bend alkenes
1381.08	1320-1000	C-O stretch alcohols, esters, carboxylic acid

- **Differential Scanning Calorimetry:** To verify the existence in the physical interaction between drug and excipients, sample was analyzed by differential scanning calorimetry (DSC). The DSC results presented in demons fig trated an endothermic peak for Borago Officinalis at 250 ^{0}C corresponding to the melting point. The physical mixture Thermogram was nearly identical to that of pure Borago Officinalis and showed an endothermic peak at 270^{0}C.

Figure 4: Overlay of DSC Thermogram of Borago Officinalis, Physical mixture

- **Melting Point Determination**:

Melting point of Borago Officinalis was found by glass capillary method to be 245- 256 0C. The observed melting point of Borago Officinalis was confirmed with the standard melting point of Borago Officinalis.

- **DRUG-EXCIPIENTS INCOMPATIBILITY STUDIES:**

Fourier Transfer Infrared Spectroscopy: Identification of any possible incompatibilities between the drug and excipients is major task to be achieved through preformulating and compatibility studies. Compatibility studies deal with understanding of any physicochemical interactions of drug and excipients. Development of a robust and effective formulation necessitates careful selection of the excipients that maintain the quality, safety, efficacy and stability of the drug product. FTIR is a widely used technique to evaluate any incompatibilities between the drug and excipients. The FTIR spectroscopic analysis of the pure drug and lipid physical mixture measures changes in the frequency and bandwidth of interacting groups during any physicochemical interactions. It also reflects the molecular-level changes in oscillation of molecular dipoles FTIR study of Borago Officinalis, its physical mixture in ratios of 1:9 and 1:1 shows no significant drug-drug interactions.

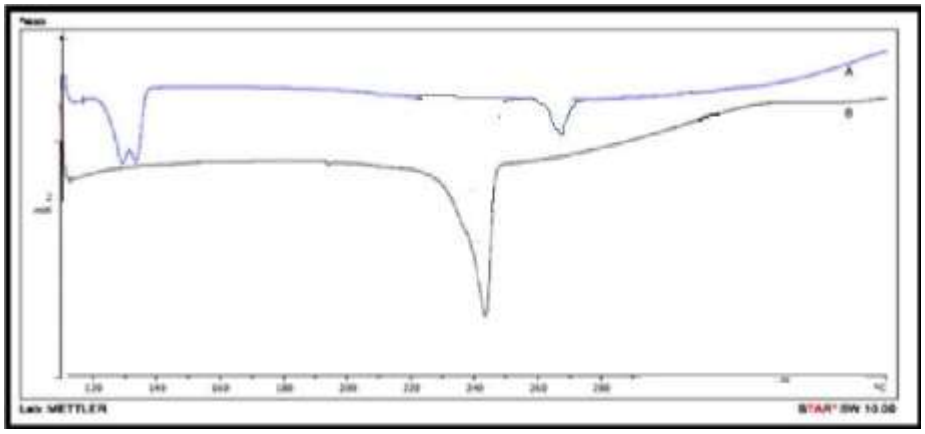

Figure 5: FTIR Spectra of Borago Officinalis and their Physical

- **ANALYTICAL METHOD DEVELOPMENT:**

Determination of ƛmax for BORAGO OFFICINALIS

The solution of Borago Officinalis in methanol was found to exhibit maximum absorption at 354 nm after scanning on the UV-Vis spectrophotometer which was reported as λmax in the literature. Thus, the procured drug sample of Borago Officinalis complies with the reference spectra

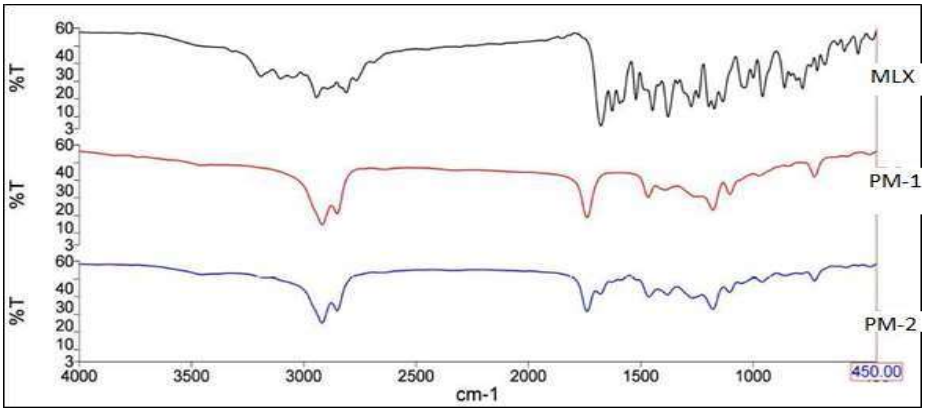

Figure No 6: UV spectrum of Borago officinalis in Methanol

➢ CHARACTERIZATION OF BORAGO OFFICINALIS SLNs AND NANOGEL:

Selection of suitable Borago Officinalis SLN formula for further preparation of Nano gel: Formula F1 was selected as the most optimized formula for preparation of Nano gel. This decision was based upon the Entrapment Efficiency results (99.98 %) for F1 SLNs.

Mean Particle size: The particle size and PDI the drug free NG was found to be 201nm and 0.3 respectively. After then drug loading particle size of Borago Officinalis loaded NG was increase 226 nm there was no significant change in PDI. Practical size of NG a crucial factor because it determines the rate and extent of drug release as well as drug absorption. The smaller droplet size provides a larger interfacial surface area for drug absorption. The particles having average diameter up to 300 nm could be easily transported Parental route.

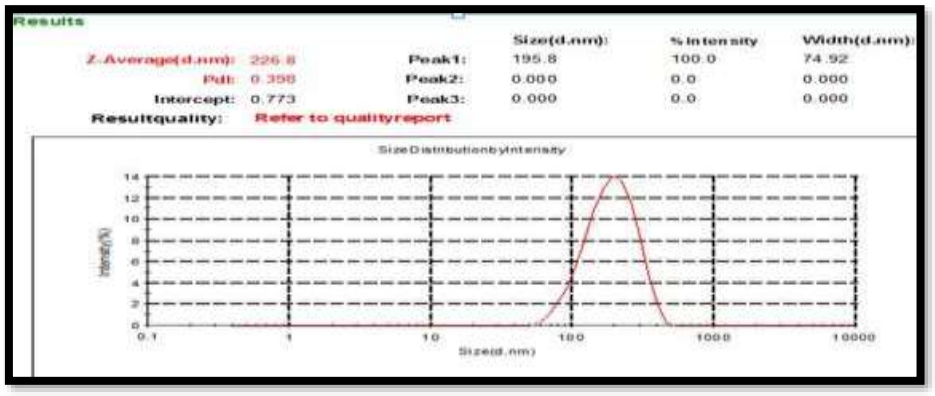

Figure7 : Particle size analysis of Optimized Formulation of Borago Officinalis NG

➢ Production yield, Entrapment Efficiency and Drug loading:

Table 5: Results

Formulation Code	Production yield (%)	Entrapment Efficiency (%)	Drug loading (%)
F1	77.2	98.7	7.3
F2	69.8	99.8	6.5
F3	74.6	89.0	7.7
F4	79.0	95.4	5.8

F5	72.1	99.9	7.4
F6	74.2	100.8	8.2
F7	78.0	94.3	9.5
F8	73.2	89.1	8.3
F9	70.0	91.1	7.1

- **Accelerated stability study:**

Stability parameter	**Test period**			
	0 Days	**30 Days**	**60 Days**	**90 Days**
MPS (nm)	226.2 ± 0.027	227.2 ± 1.80	229.9 ± 0.03	230.1 ±0.013
PDI	0.3 ± 0.19	0.3 ± 0.53	0.3 ± 0.57	0.3 ± 0.96
% EE	96.66 ± 1.18	94.02 ± 0.02	90.98 ± 1.05	87.01 ± 1.35

Table 6: Stability studies

From stability studies, it was observed that particle size was slightly increased from 226.2 ± 0.027 nm to 227 ± 1.80 nm and % EE was decreased to 87.01 ± 1.35 % during storage. Additionally, there was not much change in PDI means, initially it was 0.189 ± 0.89 and changed to 0.262 ± 1.045. Minimum loss of % EE indicates that the drug was retained within the matrix carriers during the stability period and minimum loss of drug was occurred. The obtained results revealed that there was no significant change in the MPS, PDI and % EE indicating that they were found to be stable at 25 ± 2°C, 60 ± 5% RH for a total period of 3 months.

Reference:

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