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Research Article

"Formulation and Evaluation of Solid Lipid Nanoparticles by Using High-Pressure Homogenization Technique for the Treatment of Cancer"

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1. Abstract:
In this study, Solid lipid Nanoparticles were produced using a high pressure homogenization method and the resulting drug samples were examined during preformulation studies. A high-pressure homogenization procedure was used to produce (SLN) Solid lipid Nanoparticles containing Docetaxel API. The produced Nanoparticles were examined for numerous characteristics, including zeta potential, particle size, percentage entrapment efficiency, Polydispersity index, and scanning electron microscopy examinations.
The present study describes Docetaxel-loaded solid lipid Nanoparticles including a variety of lipids and surfactants. The Nanoparticles were manufactured in the form of dry powder for injection purposes. Formulated Nanoparticles were characterized for appearance, PH, drug content, and consistency index and the results of the above studies revealed that formulated Nanoparticles were found to be stable and can be used to treat cancer patients, owing to the formulation of SLN loaded with Docetaxel demonstrating better drug release at targeted sites to treat cancer cells.

Keywords: Nanoparticles, Docetaxel, SLN, Homogenization, and cancer cells.

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2. Introduction:

For the past 20 years, the development of nanotechnology has had a significant impact on clinical therapies. For the administration of a variety of medications, nanoscale drug carriers including polymeric Nanoparticles have been shown to be safer and more effective. Longer circulation half-lives, less adverse effects, less frequent dosage, and patient compliance are benefits of Nanoparticles drug delivery, particularly at the systemic level. For greater accumulation at tumour locations during cancer therapy, Nanoparticles can also depend on the higher permeability and retention effect brought on by leaky vasculature. Due to these benefits, therapeutic Nanoparticles are a possible alternative to

conventional chemotherapy, which involves the intravenous delivery of harmful drugs, which seriously endangers healthy tissue and has dose-limiting negative effects.

The most frequent cancer in women, breast cancer accounts for roughly one-third of all cancers in females. It is the top cause of death for American women between the ages of 40 and 55 and is second only to lung cancer in terms of cancer mortality.

A woman has a 12.6% lifetime risk of acquiring invasive breast cancer [1].

A clinically proven anti-mitotic chemotherapy drug is **Docetaxel** (i.e., it interferes with cell division). It is mostly used to treat non-small cell lung cancer, breast cancer, ovarian cancer, and prostate cancer. Docetaxel is a class II medication under the Biopharmaceutical Classification System (BCS). Only solution, powder for solution, and solution for infusion are available for intravenously (IV) administration. 20 mg/0.5 ml of solution is the typical dosage. It is soluble in ethanol and dimethyl sulfoxide but insoluble in water.

Drug targeting is a unique method of drug delivery in which the pharmacological agent is targeted specifically to the organ or cell where it will have the greatest impact. Drug that is encapsulated in Nanoparticles is delivered to the area that needs it, protecting other tissues from potential injury. As a result, it results in a decrease in side effects and negative responses.

The majority of chemotherapeutic anticancer drugs are dispersed throughout the body and do not target tumour cells specifically. The therapeutic index of conventional chemotherapy drugs is poor. Solid tumours are challenging to treat with chemotherapy for this reason. To increase tumour targeting, polymeric carriers containing therapeutic molecules conjugated or entrapped are utilised. These polymeric Nanoparticles alter pharmacokinetic properties at drug and cellular level[2].

High proportions of proliferating cells, a lack of pericytes, abnormal basement development, and enhanced tortuosity are all characteristics of tumour blood arteries. So, tumor blood vessels vascularise rapidly which require more oxygen and nutrients, This causes a reduction in lymphatic outflow and an increase in macromolecule permeability. The inability to efficiently remove persistent macromolecules from the tumour cell due to inadequate lymphatic outflow causes them to be maintained. The "enhanced permeability and retention (EPR) effect" is the name of this passive targeting mechanism [3].

Optimum size for Nanoparticles for the effectiveness to tumor is not decided precisely but based on study of liposomes and Nanoparticles, the cut-off size of pore in tumor vessel ranges between 200-1.2 μm[4-5] and direct observation demonstrated a tumor dependant pore cut-off size ranges from 200 nm -2 μm[6-7].

Nanoparticles are solid colloidal particles ranging from 10 to 1000 nm (1.0 μm), in which the active drug or biologically active material are dissolved, entrapped, and/or to which the active principle is adsorbed or attached.

As, nanotechnology may be defined:

- Nanotechnology is the preparation of nanosized structures containing the API as shown in fig: 1.
- Nanotechnology, as defined by the National Nanotechnology Initiative (NNI), is the study and use of structures roughly in the size range of 1 to 100 nm.
- Goal of nanotechnology is same as that of medicine: to diagnose as accurately and early as possible and to treat as effectively as possible without any side effects using controlled and targeted drug delivery approach

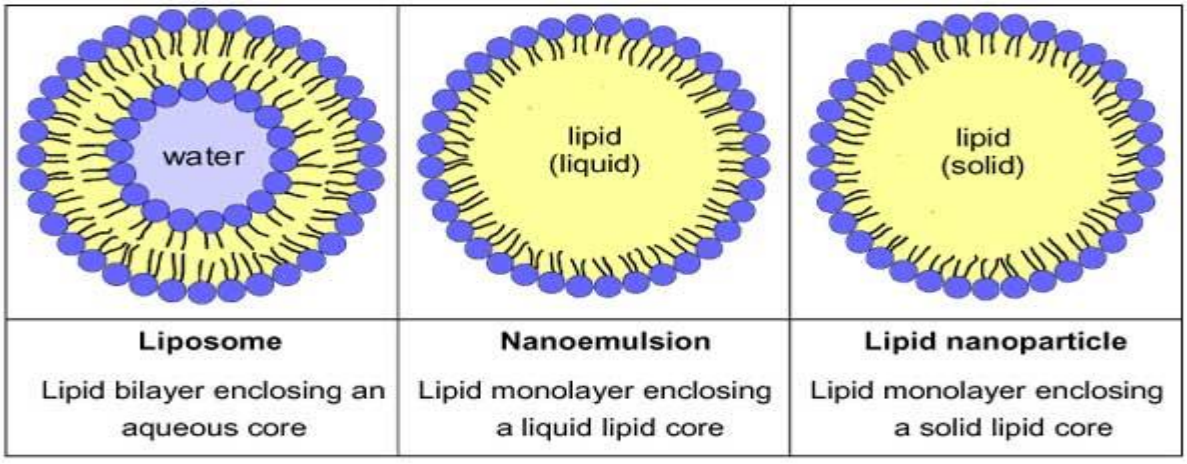

Fig.1: Nanosized Structures.

Nanocarrier platforms are beneficial as their large surface-area-to-volume ratio permits functionalization with payloads of targeting ligands providing tissue-specific delivery, labels for tracking or disease diagnosis, and drugs for therapy.

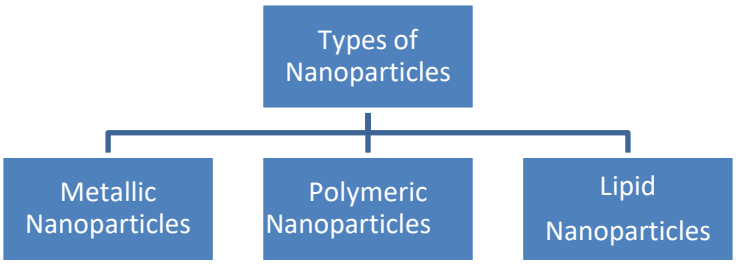

Fig.2: Classification of Nanoparticles.

Nanoparticulate drug carriers investigated for many years include oil-in-water (O/W) emulsions, liposomes, microparticles and Nanoparticles based on synthetic polymers or natural macromolecules the major concern of metallic and polymeric Nanoparticles is toxic effect of metal and polymer used in preparation. Lipid Nanoparticles are classified as two types,

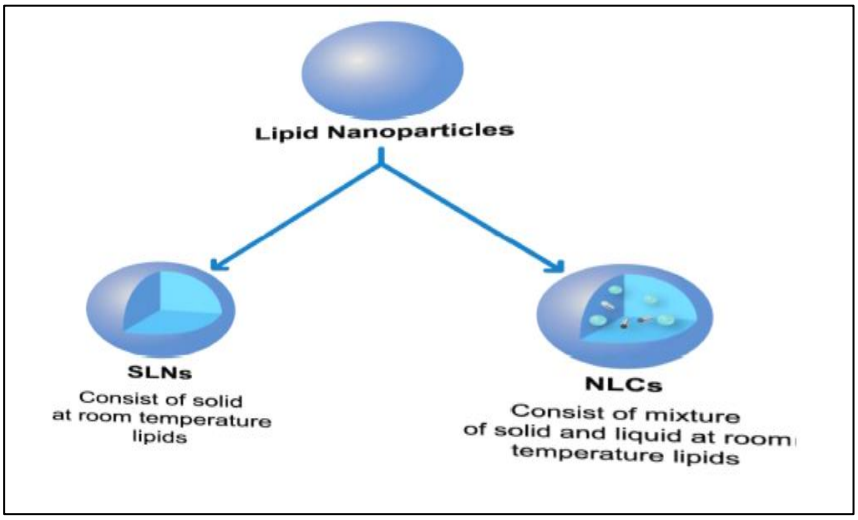

Fig.3: lipid Nanoparticles.

Lipid-based drug delivery systems may contain a broad range of oils, surfactants, and co-solvents. They represent one of the most popular approaches to overcome the absorption barriers and to improve the bioavailability of poorly water-soluble drugs

The use of solid lipids instead of liquid oils is a very attractive idea to achieve controlled drug release, because drug mobility in a solid lipid should be considerably lower compared with liquid oil. As the lipids used in the preparation are categorized as GRAS (Generally Recognized as Safe) substances.

3. Material and Method:

3.A. Drug and Excipients:

Sr.No.	Drug / Excipients	Supplier
1	Docetaxel	Manbro Pharma Pvt.Ltd.
2	Tween 80	Manbro Pharma Pvt.Ltd.
3	Poloxamer 188	Manbro Pharma Pvt.Ltd.
4	Glycerol monostearate	Manbro Pharma Pvt.Ltd.
5	Glyceryl monooleate	Manbro Pharma Pvt.Ltd.

Table1. Drug and Excipients used

3.B. Equipment's:

Sr.No.	Equipment's	Make /company
1	Weighing balance	AUX120, Shimadzu, Japan
2	Mechanical stirrer	Remi Laboratory, Mumbai
3	U V Spectrophotometer	Shimadzu UV-1800, Japan
4	Sonicator	PCI analyticals, Model-100HPOTC, India

5	Dissolution test apparatus	Electrolab Dissolution tester USP TDT- 08L, India
6	Hot air oven	Bio-Techniqes, India
7	pH meter	Labtronics, Model:LT-10, Delhi
8	Magnetic stirrer	Remi Laboratory, Mumbai
9	Diffusion cell	Orchid Scientific, Nasik

Table 2. Equipments used

3.1 Drug Profile:

3.1.1 Docetaxel:

Docetaxel is a taxoid antineoplastic drug used to treat several malignancies, including head and neck cancer, metastatic prostate cancer, locally advanced or metastatic breast cancer, and gastric adenocarcinoma.

3.1.2 Background: Docetaxel is a chemotherapy medication with anti-mitotic activity that has been clinically shown to be effective in treating non-small cell lung, breast, and ovarian cancers. A 1:1 stoichiometric ratio of high affinity Docetaxel to tubulin allows for reversible attachment.

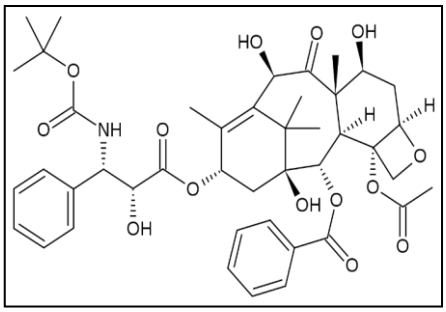

Fig. 4: Structure of Docetaxel

3.1.3 Weight: Monoisotopic-807.346605409Average-807.8792

3.1.4 Chemical Formula: C43 H53 NO14

3.1.5 Indication: The failure of earlier chemotherapy, for the treatment of patients with locally advanced or metastatic breast cancer. Following the failure of earlier platinum-based chemotherapy, it is also utilized as a single agent in the treatment of patients with locally advanced or metastatic non-small cell lung cancer. Additionally, it is used in conjunction with prednisone to treat individuals with metastatic prostate cancer that is androgen independent (hormone refractory). Docetaxel is also used to treat head and neck cancer as well as stomach adenocarcinoma.

3.1.6 Half-life: Dose-dependent. A dose of 70 mg per square meter of body surface area (mg/m 2) or more results in a triphasic elimination profile. It was impossible to determine the terminal elimination phase at lower dosages due to assay limitations. The half-lives of the alpha, beta, and gamma phases are 4 minutes, 36 minutes, and 11.1 hours, respectively.

3.1.7 Clearance: After receiving 20–115 mg/m2 through IV, cancer patients' total body clearance was 21 L/h/m2.

4.4 Calibration curve of Docetaxel :[97]

2, 4, 6, 8, and 10 ml of the standard stock solution were taken out, and ethanol was used to dilute them to a volume of 10 ml with a concentration of 2, 4, 6, 8, and

4.5 Solubility study of Docetaxel:[98]

4.Preformulation Study:

4.1 Identification of drug:

Identification of Docetaxel was carried out by melting point determination, Infrared spectroscopy and UV spectroscopy.

4.2 Melting point determination:[96]

A little amount of the drug was placed in a capillary tube that was closed at one end to measure the drug's melting point. The capillary tube was put into a melting point device, and the temperature at which the medication melted was recorded. This operation was done three times, and the average value was documented.

4.3Determination of λ max and plotting of calibration curve of Docetaxel:[97]

Accurately weighed 10 mg of Docetaxelwas dissolved in 10 ml of methanol and volume made up to 100 ml by methanol to make concentration of 100 µg/ml. From this solution 1 ml was withdrawn and the volume was made up to 10 ml with methanol to prepare stock solution.

The solution containing concentration of 10µg/ml Docetaxel was scanned over the wavelength of 200-400 nm in UV spectrophotometer to determine the wavelength of maximum absorbance

10 g/ml. For Docetaxel, the absorbance of these solutions was measured against a standard of distilled water, and the calibration curve was constructed.

The solubility of saturation Docetaxel solubility tests were conducted using several solvents. Studies on solubility were performed by adding extra Docetaxel to a 25 ml volumetric flask that was saturated with 10 ml of solvent. The mixture was then maintained in a mechanical shaker for three days at 37 ℃ to aid in solubilisation. To measure the amount of Docetaxel in the supernatant using UV spectroscopy at a certain wavelength, the supernatant was obtained, dilute with methanol up to ten times, and filtered through Whatman filter paper.

5. Drug and Excipients Compatibility Study:

5.1Fourier Transform Infrared Spectroscopy (FTIR):[99]

For the compatibility research, a physical combination of the medication and Excipients was used. FTIR spectroscopy was used to conduct a compatibility evaluation. Solid state KBr dispersion media was used to scan samples of pure drugs and Excipients as well as physical mixtures of drugs and Excipients. The scanning range was maintained between
4000 and 400 cm-1.

5.2 Differential Scanning Calorimetry (DSC):[100]

A differential scanning calorimeter (Mettler Toledo) was used to measure the thermal behaviour of a pure drug, optimised SLN batch at a heating rate of 10°C/min. The measurements were carried out in nitrogen atmospheres with a heating range of 30-400 °C.

6. Formulation of Solid lipid Nanoparticles:

6.1 Preparation of Docetaxel loaded Solid Lipid Nanoparticles:

High pressure homogenization and the ultrasonication technique were used to create the Docetaxel-loaded SLN. One part methanol to one part chloroform was used to dissolve the Docetaxel and monoglyceride. A rotary flash evaporator was used to eliminate organic solvents. Heating to 5 °C above the melting point of the lipid melted the buried lipid layer. Tween 80, poloxamer 188, or span 20 stabilisers were dissolved in distilled water to make 30 ml, and the aqueous phase was then heated to the same temperature as the oil phase. The hot aqueous phase was introduced to the oil phase, and a high-pressure homogenization was used for 30 min. at 2500 rpm and 70 °C. The resulting coarse oil in water emulsion was subjected to a 25-minute probe sonication procedure. The heated nano emulsion was eventually allowed to cool to room temperature and was kept refrigerated at 4 °C to produce the Docetaxel-loaded SLN.

In table 3.[101], the various formulations' compositions are listed.

In all SLN formulation the lipid concentration was kept constant (as 6 % w/v).

Table 3. Composition of Docetaxel loaded solid lipid nanoparticles containing different lipids and surfactants and its entrapment efficiency

Formulation	Solid lipid	% W/V	Surfactant	% W/V	Entrapment Efficiency % ± S.D
F1	GMS	6	Tween 80	1.0	77.62 ± 0.65
F2	GMS	6	Tween 80	1.5	79.16 ± 0.36
F3	GMS	6	Tween 80	2.0	80.32 ± 0.50
F4	GMS	6	Poloxamer 188	1.0	80.86 ± 0.69
F5	GMS	6	Poloxamer 188	1.5	83.03 ± 0.33
F6	GMS	6	Poloxamer 188	2.0	84.69 ± 0.25
F7	GMS	6	Span 20	1.0	71.49 ± 0.78
F8	GMS	6	Span 20	1.5	73.76 ± 0.13
F9	GMS	6	Span 20	2.0	76.45 ± 0.10
F10	GMO	6	Tween 80	1.0	74.32 ± 0.08
F11	GMO	6	Tween 80	1.5	75.52 ± 0.51
F12	GMO	6	Tween 80	2.0	76.66 ± 0.19
F13	GMO	6	Poloxamer 188	1.0	78.54 ± 0.25
F14	GMO	6	Poloxamer 188	1.5	83.54 ± 0.66
F15	**GMO**	**6**	**Poloxamer 188**	**2.0**	**85.64 ± 0.25**
F16	GMO	6	Span 20	1.0	73.85 ± 0.31
F17	GMO	6	Span 20	1.5	78.74 ± 0.18
F18	GMO	6	Span 20	2.0	81.43 ± 0.57

Abbreviation: GMS- Glyceryl monostearate, GMO- Glyceryl monooleate

7. Evaluation of Solid Lipid Nanoparticles Loaded with Drug Docetaxel:

7.1 Preformulation Study:

Physicochemical properties of drug.

7.2 Description:

The Docetaxel drug is the white powder.

7.3 Solubility:

It is soluble in ethanol, isopropyl alcohol and insoluble in water.

7.4 Melting Point:

The melting point of Docetaxel was found to be 232 ^{0}C.

Determination of λ max and Calibration Curve of Docetaxel in m methano

7.5 Wavelength selection:

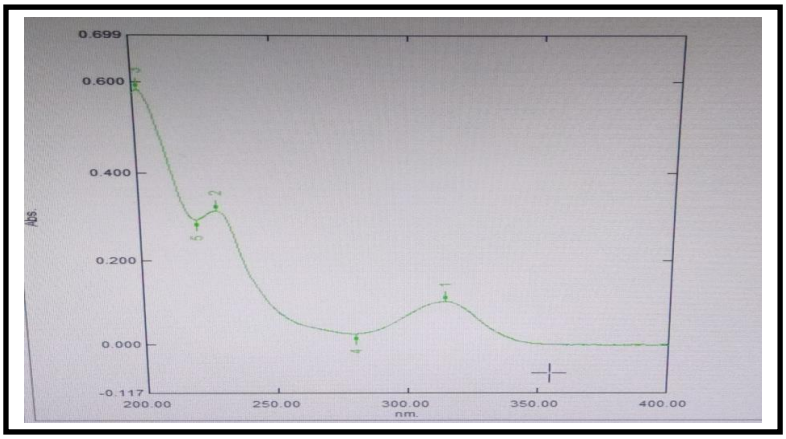

Fig. 5.UV Spectrum of Docetaxel

An absorption maximum was found to be at 230 nm. Hence 230 nm was selected as λ max for further studies.

7.6 Calibration curve:

Table 4. Results for calibration curve

Sr. No.	Concentration (µg/ml)	Absorbance			Mean ± SD
		I	II	III	
1	2	0.128	0.132	0.131	0.130 ± 0.0017
2	4	0.247	0.251	0.250	0.249 ± 0.0015
3	6	0.373	0.377	0.376	0.375 ± 0.0018
4	8	0.496	0.499	0.501	0.498 ± 0.0022
5	10	0.614	0.618	0.617	0.616 ± 0.0017

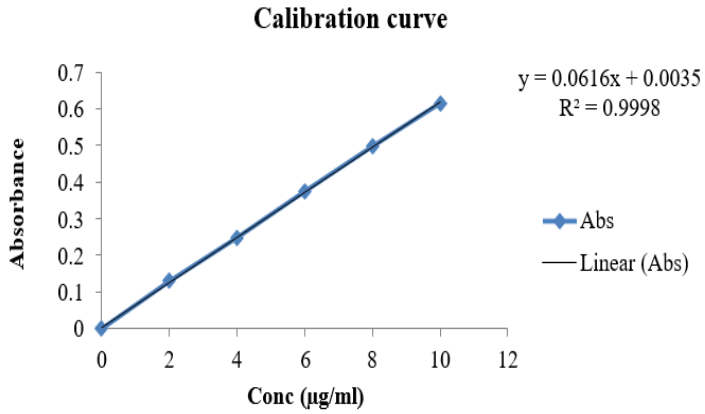

Fig.6. Calibration curve of Docetaxel

Absorbance of various standard concentrations of Docetaxel solutions were read at 230 nm λ max and calibration curve was plotted to check the linearity.

7.7. Solubility study:
Saturation solubility of Docetaxel with different solvents

Table 5. Saturation solubility of Docetaxel with different solvents

Sr. No.	Solvent	Saturation solubility (mg/ml)	% Drug Saturation Solubility
1	0.1 N HCL	0.5730	76.40 %
2	Acetate Buffer (pH 4.4)	0.1103	44.12 %
3	Phosphate Buffer (pH 6.4)	0.1670	59.71 %
4	Phosphate Buffer (pH 7.2)	0.2840	67.61 %
5	Phosphate Buffer(pH 8.6)	0.1899	49.97 %

6	Water	0.001623	0.676 %

7

.8 Compatibility Study:

7.8.1 Fourier Transform Infrared Spectroscopy (FTIR):

The picture depicts the FTIR spectrum of a pure drug, Excipients, and a physical mixing of drug and Excipients. By using FTIR spectroscopy, the potential interaction between the medicine and Excipients was investigated. The following table displays and interprets the main FTIR peaks of the physical mixture, formulation, and pure drugs Docetaxel, Tween 80, and Poloxamer 188.

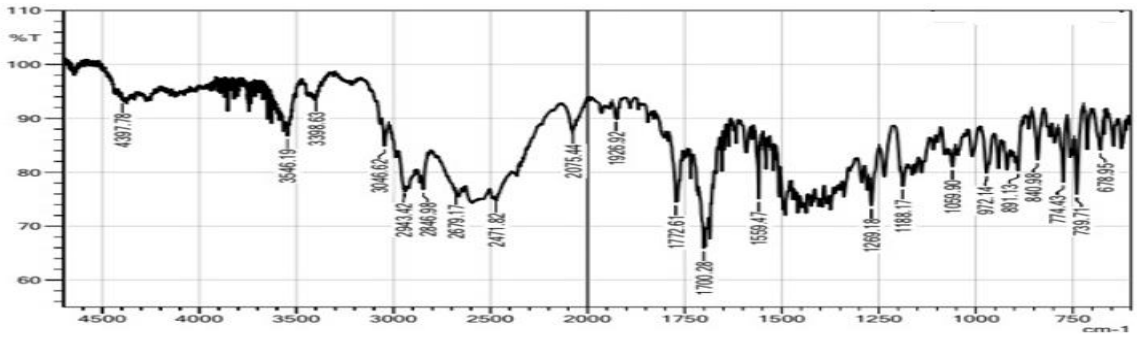

Fig.7. FTIR Spectra of Docetaxel

Table 6. Spectral interpretation of Docetaxel

Functional Group	FTIR Peak (cm-1)	Range FTIR Peak (cm-1)
(–NH) stretching	3398.63	3500-3100
C-N Stretching	1069.90, 1188.17, 1269.18	1350-1000

After interpretation of FT-IR Spectrum of drug, it was concluded that all the characteristic peaks corresponding to the functional group present in the molecular structure of Docetaxel were found within the reference range and confirming its identity.

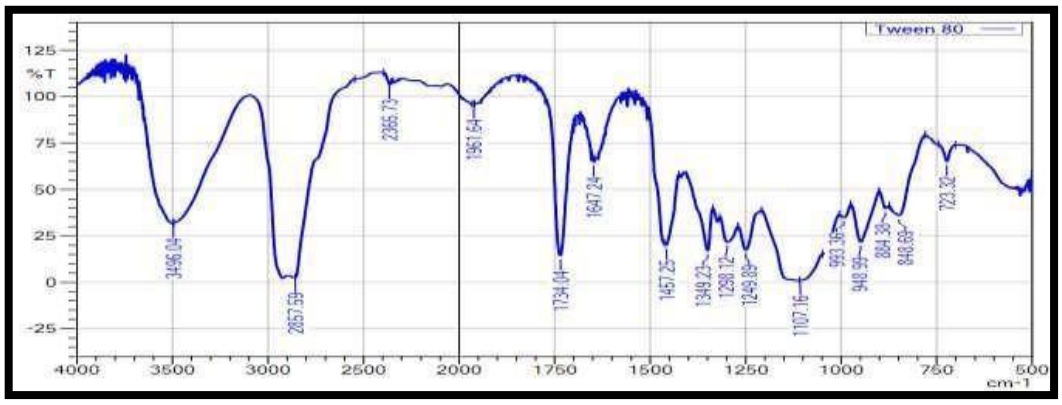

Fig.8. FTIR spectrum of Tween 80

Table 7. Spectral interpretation of Tween 80

Functional Group	FTIR Peak (cm-1)	Range FTIR Peak (cm-1)
C-O stretching	1734.04	1740-1730
C-O stretching	1647.24	1680-1660
O−H stretching	3496.04	3560-3500
C=O stretching	1653.99	1670−1630
C-H stretching	2857.59	2900-2700
C−H deformation	948.09	975−780

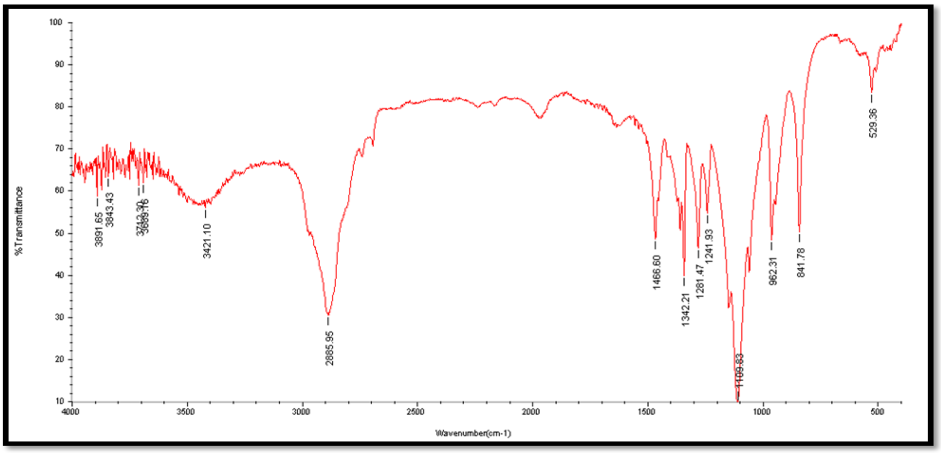

Fig.9. FTIR spectrum of Poloxamer 188

Table 8. Spectral interpretation of Poloxamer 188

Functional Group	FTIR Peak (cm-1)	Range FTIR Peak (cm-1)
O−H stretching	3421.10	3550-3200
C−H stretching	2885.95	2972-2850
O-H bending	1342.21	1420-1330
C-O stretching	1109.83	1124-1087

After interpretation of FT-IR Spectrum of polymer, it was concluded that all the characteristic peaks corresponding to the functional group present in molecular structure of both the polymers were found within the reference range, confirming its identity.

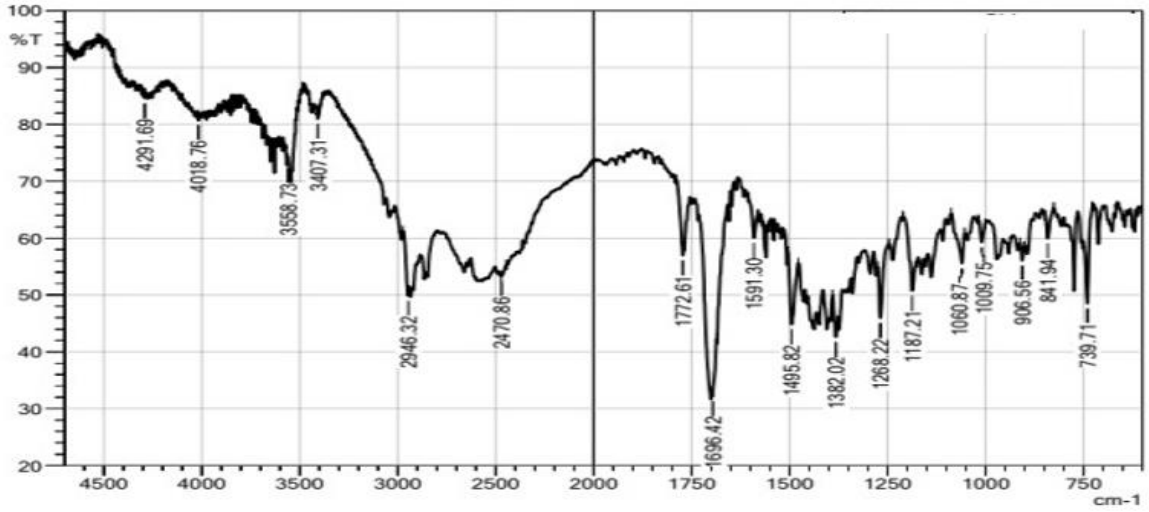

Fig.10.FTIR spectrum of physical mixture of Docetaxel and Excipients

After interpretation of FT-IR Spectrum of Excipients and its physical mixture with drug, it was concluded that all the characteristic peaks corresponding to the functional group present in molecular structure of Docetaxel were not found intact within the reference range, confirming its reactivity with polymers. This interaction further supports the selection of polymer.

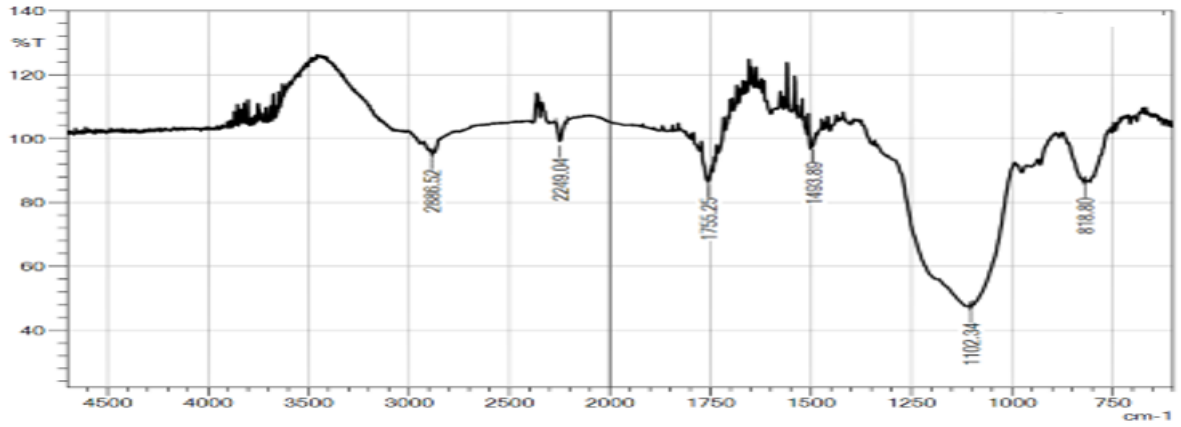

Fig.11. FTIR spectrum of optimized formulation of SLN F15 batch

There was no considerable change in the positions of characteristic absorption bands and bonds of various functional groups present in the drug. This observation clearly suggests that the Docetaxel shows no prominent change in its characteristics even in its physical mixture. The results of FTIR spectra indicated the interaction between drug and Excipients. It showed that Docetaxel was compatible with above Excipients.

7.8.2 Differential Scanning Calorimetry (DSC):

The differential scanning calorimeter (DSC) thermogram study was used to characterize the pure drug and chosen formulation of SLN batch F15. Records of the DSC patterns were made. Each sample was heated in a platinum crucible using a reference of alpha alumina powder at a scanning rate of 10°C/min in a nitrogen environment (150 mL/min). Periodically, the temperature calibrations were carried out with indium serving as the standard.

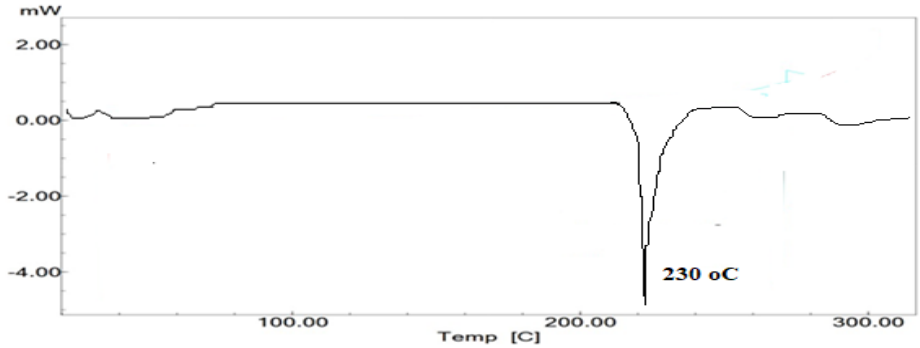

Fig.12. DSC of pure Docetaxel

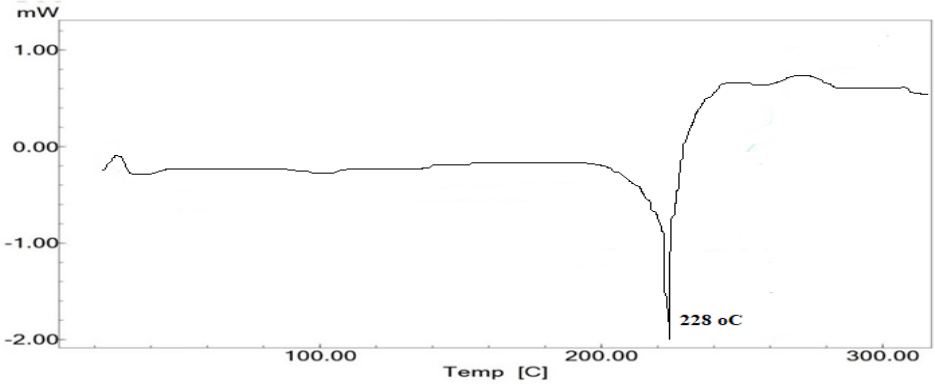

Fig.13. DSC of optimized SLN batch F15

Figure reports the DSC thermograms of the pure medication and preparation. The drug's endothermic peak is clearly visible around 230 °C (Fig.), which is very near to its actual melting point. Furthermore, a clear endothermic peak at 228 °C was visible in the optimized SLN batch F15. Since no such typical pure drug peak

was present, it can be assumed that drug melting behavior had not changed. Because the crystalline state is usually favored, the solid particles present remain in a highly dissolved state. Nevertheless, shows an endothermic peak with a nearly identical initiation temperature to the endothermic peak. Sharp peaks that match to pure Docetaxel melting point indicated that there is no interaction between the medicine and polymers.

7.8.3 Entrapment efficiency:

An essential factor in characterizing solid lipid Nanoparticles is entrapment efficiency. The type and concentration of the lipid and surfactant material utilized were a few of the variables that were changed in order to get the best encapsulation efficiency. The table below displays the entrapment effectiveness of each created SLN compound. The SLN dispersions' entrapment effectiveness was discovered to be between 71.49% and 85.64%.

7.8.4 Evaluation of SLNs by % Drug content, % Practical yield and Drug loading (%):

Table 9 :% Practical Yield, % Drug Content and % Drug loading

Sr. No.	Formulation Code	% Drug content	% Practical yield	Drug Loading (%)
1.	F1	67.33 %	58.48 %	2.57 %
2.	F2	69.78 %	60.44 %	3.57 %
3.	F3	71.43 %	62.47 %	5.77 %
4	F4	71.89 %	64.38 %	5.98 %
5	F5	72.78 %	67.85 %	6.63 %
6	F6	74.37 %	69.78 %	7.47 %
7	F7	76.48 %	72.47 %	7.89 %
8	F8	77.45 %	73.63 %	8.46 %
9	F9	79.38 %	73.88 %	8.79 %
10	F10	81.46 %	74.75 %	9.03 %
11	F11	81.87 %	74.96 %	9.34 %
12	F12	82.56 %	75.12 %	9.56 %
13	F13	83.02 %	75.23 %	9.87 %
14	F14	83.06 %	75.29 %	10.46 %
15	**F15**	**87.76 %**	**75.87 %**	**12.46 %**
16	F16	83.91 %	75.36 %	10.96 %
17	F17	84.22 %	75.48 %	11.21 %
18	F18	85.37 %	75.67 %	11.87 %

7.8.5 Evaluation of SLNs by Particle size, zeta potential analysis and Polydispersity index (PDI):

Table 10. Particle size, zeta potential analysis and Polydispersity index (PDI) of formulations (All values expressed are mean ± SD where n = 3)

Sr. No.	Formulation code	Particle size (nm)	Zeta Potential (mv)	Polydispersity index (PDI)
1.	F1	246.05 ± 2.26	-25.23 ± 0.44	0.174 ± 0.06
2.	F2	258.32 ± 2.13	-25.43 ± 0.32	0.179 ± 0.09
3.	F3	263.57 ± 0.29	-25.88 ± 0.74	0.181 ± 0.01
4	F4	281.23 ± 1.59	-26.57 ± 0.44	0.183 ± 0.03
5	F5	297.03 ± 1.16	-27.56 ± 0.11	0.185 ± 0.07
6	F6	305.32 ± 2.56	-27.76 ± 0.55	0.189 ± 0.02
7	F7	332.06 ± 0.87	-27.89 ± 0.78	0.191 ± 0.03
8	F8	348.12 ± 4.05	-28.50 ± 0.22	0.193 ± 0.08
9	F9	350.29 ± 2.03	-28.10 ± 0.12	0.195 ± 0.04
10	F10	354.12 ± 1.74	-28.19 ± 0.22	0.198 ± 0.05
11	F11	359.04 ± 0.67	-28.44 ± 0.87	0.200 ± 0.08
12	F12	365.32 ± 3.44	-28.87 ± 0.24	0.218 ± 0.06
13	F13	374.09 ± 0.73	-29.43 ± 0.29	0.223 ± 0.09
14	F14	378.14 ± 1.45	-29.68 ± 0.21	0.243 ± 0.01
15	**F15**	**235.66 ± 4.12**	**-32.23 ± 0.45**	**0.285 ± 0.13**
16	F16	239.53 ± 2.04	-30.10 ± 0.33	0.258 ± 0.03
17	F17	240.23 ± 1.46	-30.89 ± 0.37	0.266 ± 0.04
18	F18	243.11 ± 3.84	-31.98 ± 0.64	0.279 ± 0.01

The following assessment of all SLN batches was completed. Particle size, Zeta potential analysis, Practical Yield, Drug Content, Drug Loading, and Polydispersity Index (PDI). The results are all within predetermined ranges. As a result of the observations made above, the F15 batch is regarded as an optimized batch due to its superior performance when compared to other batches.

8. RESULT AND DISCUSSION:

In the current study, Docetaxel was employed as a model pharmaceutical to develop and evaluate solid lipid Nanoparticles for enhancing anticancer drug solubility and permeability. The selected Excipients functioned effectively with Docetaxel. The concentration of Docetaxel in SLNs was measured using a UV visible spectroscopic method. Docetaxel SLNs were manufactured in 18 batches with a range of Excipients, including GMS, GMO, Tween 80, span 20, and poloxamer 188.

The primary goals of developing SLNs were to increase the drug's solubility and permeability, which contribute to low and variable bioavailability. These variables include low water solubility, low permeability, inconsistent and poor absorption, inter- and intra-subject variability, and a high dietary impact.

The physical and chemical parameters of Docetaxel SLN formulations, such as drug content, practical yield, entrapment efficiency, drug loading, particle size, zeta potential, and Polydispersity index, were investigated. The results lead to the selection of an optimal batch. The SLNs were also evaluated for FTIR, DSC, and research. When SLN batches were evaluated, batch F15 outperformed the others. The batch F15 was shown to have higher values for drug content, practical yield, entrapment efficiency, and percent drug release. Compared to the other batches, hence the batch F15 shows greater results in the assessment research.

As a result, the SLNs achieve the desired benefits of increasing the drug's solubility and permeability for parenteral delivery. We concluded that the high pressure homogenization approach creates solid lipid Nanoparticles containing Docetaxel that are the appropriate particle size.

The optimized SLN batch F15 showed the largest cumulative amount of drug penetration per cm2 when compared to pure Docetaxel. As a result, medication penetration becomes more effective.

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