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Formulation Development and Invitro Evaluation of Lansoprazole Nanostructured Lipid Carriers

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Abstract: *The present investigation was aimed at formulation development and in vitro evaluation of nanostructured lipid carriers (NLCs) containing Lansoprazole for enhancement of solubility, stability, and bioavailability. Lansoprazole is a proton pump inhibitor used in the treatment of peptic ulcer, gastroesophageal reflux disease, and Zollinger–Ellison syndrome. However, the drug exhibits poor aqueous solubility and instability in acidic pH, leading to reduced oral bioavailability. Nanostructured lipid carriers have emerged as promising lipid-based nanocarriers capable of improving drug entrapment, controlled release, and gastrointestinal stability.*

The NLC formulations were prepared using high shear homogenization followed by ultrasonication technique employing solid lipids, liquid lipids, surfactants, and co-surfactants. The prepared formulations were evaluated for particle size, polydispersity index, zeta potential, entrapment efficiency, drug content, viscosity, pH, in vitro drug release, and stability studies.

The optimized formulation exhibited nanosized particles with high drug entrapment efficiency and sustained drug release profile. Stability studies indicated satisfactory physical stability of the prepared system. The study concluded that NLCs are promising carriers for effective delivery of lansoprazole.

Keywords Lansoprazole, Nanostructured Lipid Carriers, Lipid Nanoparticles, Entrapment Efficiency, Drug Release, Nanoformulation, Proton Pump Inhibitor.

I. INTRODUCTION

1.1 Introduction to Novel Drug Delivery Systems

Novel Drug Delivery Systems (NDDS) are advanced pharmaceutical formulations developed to improve the therapeutic efficacy and safety of conventional drug delivery. These systems are designed to overcome the limitations associated with traditional dosage forms such as poor bioavailability, rapid degradation, low solubility, dose fluctuations, and poor patient compliance. NDDS aims to deliver the drug at a predetermined rate, for a specified period, and to the targeted site of action.

Conventional oral dosage forms release the drug immediately after administration, resulting in fluctuations in plasma drug concentration. Such fluctuations may lead to reduced therapeutic effectiveness and increased adverse effects. To overcome these limitations, researchers have developed advanced drug delivery systems capable of controlled, sustained, and targeted drug release.

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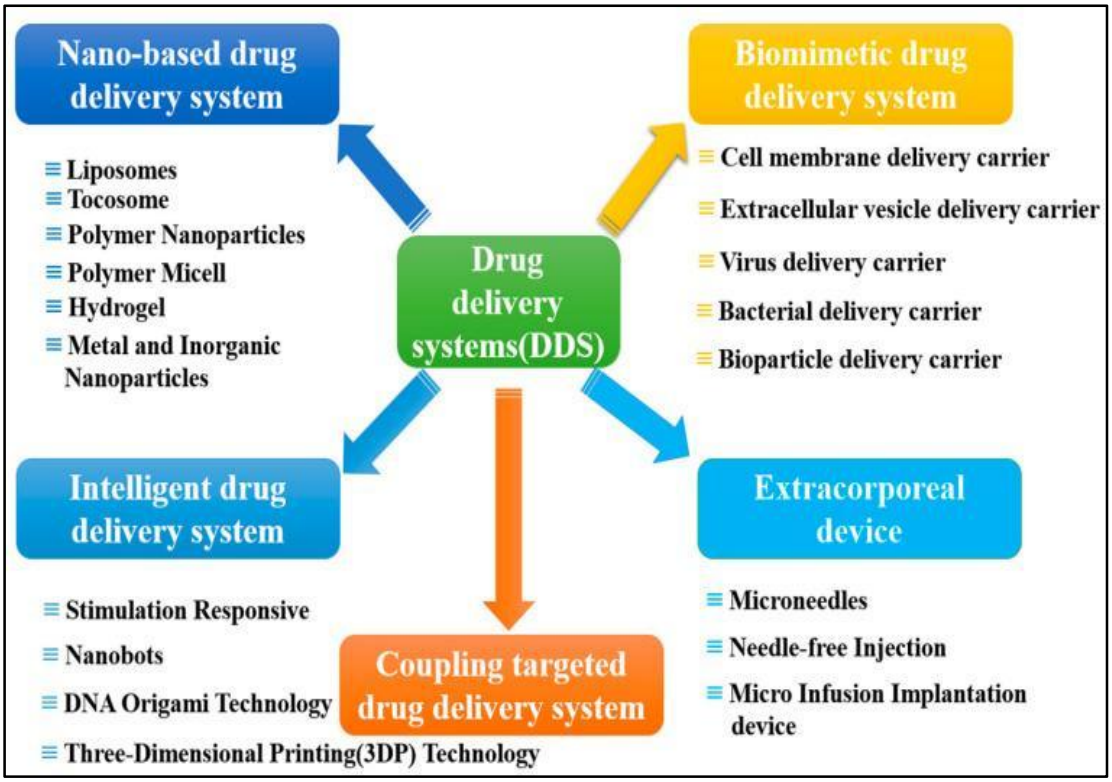

Fig. 1: Novel Drug Delivery Systems (NDDS)

The major objectives of NDDS include:

- Improvement of drug bioavailability
- Reduction in dosing frequency
- Site-specific drug targeting
- Controlled and sustained release
- Enhancement of therapeutic efficacy
- Reduction of side effects
- Improvement in patient compliance

1.2 Nanotechnology in Pharmaceutics

Nanotechnology is the science and application of materials at the nanoscale level, generally ranging from 1 to 1000 nanometers. In pharmaceutical sciences, nanotechnology has revolutionized drug delivery by enabling the development of nanocarriers capable of improving the therapeutic performance of drugs.

Nanoparticles possess unique physicochemical properties such as:

- Large surface area
- Enhanced dissolution rate
- Improved cellular uptake
- Better drug targeting capability
- Controlled release characteristics

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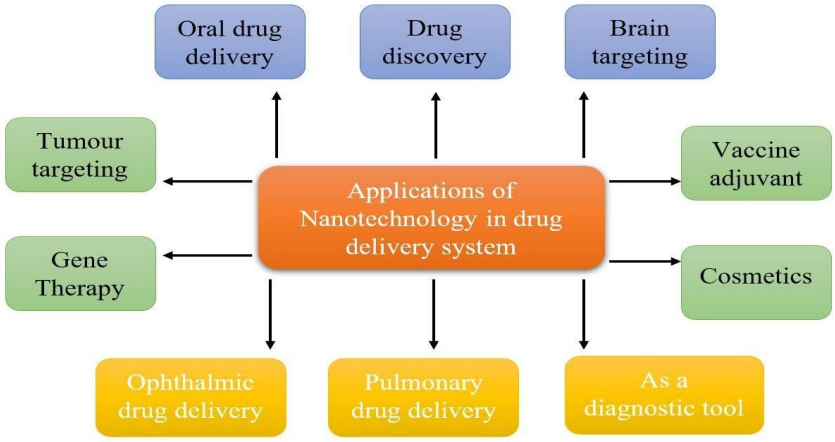

Fig. 2: Applications of Nanotechnology in DDS

The application of nanotechnology in pharmaceutics has significantly improved the treatment of chronic diseases by enhancing bioavailability and reducing systemic toxicity.

1.3 Lipid-Based Nanocarriers

Lipid-based nanocarriers are colloidal systems composed of physiological lipids that are generally recognized as safe (GRAS). These systems are capable of encapsulating both hydrophilic and lipophilic drugs.

Advantages of lipid nanocarriers:

- Biocompatibility
- Low toxicity
- Improved drug stability
- Enhanced oral absorption
- Controlled drug release

Among these, Nanostructured Lipid Carriers have emerged as promising systems due to improved drug loading and reduced drug expulsion during storage.

1.4 Solid Lipid Nanoparticles (SLNs)

Solid Lipid Nanoparticles are submicron colloidal carriers composed of solid lipids stabilized by surfactants. SLNs combine the advantages of polymeric nanoparticles and emulsions while minimizing toxicity.

To overcome these limitations, Nanostructured Lipid Carriers were developed as second-generation lipid nanoparticles.

1.5 Nanostructured Lipid Carriers (NLCs)

Nanostructured Lipid Carriers are advanced lipid nanoparticles prepared using a blend of solid lipids and liquid lipids. The incorporation of liquid lipids into the solid lipid matrix creates imperfections in the crystal lattice, allowing higher drug accommodation. NLCs are considered second-generation lipid nanoparticles with improved drug loading capacity and enhanced stability compared to SLNs.

1.6 Types of Nanostructured Lipid Carriers

NLCs are classified into three major types based on lipid composition and internal structure.

Imperfect Type NLCs

These contain a mixture of solid and liquid lipids producing imperfections in the crystal structure, resulting in enhanced drug loading.

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Amorphous Type NLCs

These formulations remain in amorphous form and minimize drug expulsion during storage.

Multiple Type NLCs

These contain tiny oil nanocompartments within the solid lipid matrix, enhancing drug solubility and release control.

1.7 Components of NLCs

Solid Lipids: Solid lipids form the structural matrix of NLCs.

Examples:

- Glyceryl monostearate
- Stearic acid
- Compritol
- Cetyl palmitate

Liquid Lipids

Liquid lipids improve drug loading and reduce crystallinity.

Examples:

- Oleic acid
- Castor oil
- Miglyol

Surfactants

Surfactants stabilize nanoparticles and prevent aggregation.

Co-surfactants

These improve emulsification and formulation stability.

1.8 Oral Drug Delivery Using NLCs

Oral administration is the most preferred route due to convenience and patient compliance. However, many drugs exhibit poor oral bioavailability because of:

- Poor solubility
- Acid degradation
- First-pass metabolism
- Poor permeability

NLCs improve oral drug delivery by:

- Enhancing dissolution rate
- Increasing lymphatic uptake
- Protecting drugs from acidic degradation
- Improving intestinal permeability

1.9 Proton Pump Inhibitors (PPIs)

Proton pump inhibitors are widely used antiulcer agents that suppress gastric acid secretion by inhibiting the H+/K+ ATPase enzyme system present in gastric parietal cells.

Examples:

- Omeprazole
- Lansoprazole
- Pantoprazole
- Rabeprazole
- Esomeprazole

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1.10 Drug Profile of Lansoprazole

Chemical Information

Parameter	Description
Drug Name	Lansoprazole
Category	Proton Pump Inhibitor
Molecular Formula	C16H14F3N3O2S
Molecular Weight	369.36 g/mol
Appearance	White to brownish white powder
Solubility	Slightly soluble in water

Mechanism of Action

Lansoprazole suppresses gastric acid secretion by irreversible inhibition of the H+/K+ ATPase enzyme system in gastric parietal cells.

H+/K+ ATPase Inhibition → Reduced Gastric Acid Secretion

Pharmacological Uses

- Gastric ulcer
- Duodenal ulcer
- GERD
- Zollinger–Ellison syndrome
- NSAID-induced ulcers

These limitations necessitate the development of advanced delivery systems for improved therapeutic performance.

1.12 RATIONALE FOR SELECTION OF LANSOPRAZOLE NLCs

Lansoprazole is acid labile and poorly water soluble, leading to poor oral bioavailability. Encapsulation into nanostructured lipid carriers offers several advantages:

- Protection from gastric degradation
- Improved drug solubility
- Enhanced absorption
- Sustained release
- Improved stability
- Better therapeutic efficacy

NLCs can significantly enhance the pharmacokinetic profile of lansoprazole and improve patient compliance.

II. REVIEW OF LITERATURE

2.1 Review of literature

Review of literature is an essential part of pharmaceutical research that provides detailed information regarding previously reported studies, formulation approaches, evaluation methods, and recent advancements related to the selected research topic. It helps in understanding the current status of research, identifying knowledge gaps, and designing suitable experimental methodologies.

Nanostructured lipid carriers (NLCs) are considered promising lipid-based nanosystems for improving the delivery of poorly soluble and acid-labile drugs. Several researchers have reported successful formulation and evaluation of NLCs

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for enhancing drug solubility, stability, permeability, and bioavailability. Lansoprazole, being a proton pump inhibitor with poor aqueous solubility and acid instability, is an ideal candidate for lipid-based nanoformulations.

This chapter summarizes various research works related to:

- Nanostructured lipid carriers
- Lipid nanoparticle systems
- Oral nano drug delivery
- Formulation approaches for NLCs
- Evaluation methods of NLCs
- Nanoformulations of proton pump inhibitors
- Lansoprazole delivery systems

2.2 literature review related to nanostructured lipid carriers

Müller RH et al. (2002) Müller and coworkers introduced nanostructured lipid carriers as second-generation lipid nanoparticles developed to overcome the limitations of solid lipid nanoparticles. The study reported that blending solid and liquid lipids produced imperfections in the crystal matrix, thereby increasing drug loading capacity and reducing drug expulsion during storage.

The researchers concluded that NLCs provide:

- Improved stability
- Better drug incorporation
- Controlled release behavior
- Enhanced therapeutic effectiveness

This study laid the foundation for extensive research on lipid nanoparticle systems.

Jenning V et al. (2000) Jenning and colleagues developed lipid nanoparticles for topical drug delivery and demonstrated that incorporation of liquid lipids enhanced drug accommodation within the lipid matrix. Their findings showed improved drug penetration and sustained release properties.

The study highlighted:

- Importance of lipid composition
- Effect of surfactants on particle size
- Enhanced physical stability of NLCs

Mehnert W and Mäder K (2001) Mehnert and Mäder extensively reviewed solid lipid nanoparticles and lipid carrier systems. They explained the advantages of lipid nanoparticles over conventional colloidal carriers such as emulsions and polymeric nanoparticles.

The review emphasized the future potential of NLCs in oral and topical delivery systems.

2.3 Literature Related To Oral Nanoparticle Delivery

Pardeike J et al. (2009) Pardeike and coworkers reviewed lipid nanoparticles for oral drug delivery. The authors reported that lipid nanoparticles improve gastrointestinal absorption by enhancing lymphatic transport and avoiding first-pass metabolism.

Major findings:

- Enhanced oral bioavailability
- Increased dissolution rate
- Improved stability of poorly soluble drugs
- Better absorption profile

The review suggested that NLCs are highly suitable for oral delivery of BCS Class II drugs.

Doktorovova S et al. (2014)

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The researchers investigated oral lipid nanoparticles for controlled drug delivery. Their work demonstrated that particle size and surface charge significantly influence intestinal uptake and bioavailability.
Important conclusions:
• Smaller particle size enhances absorption
• Surfactants improve stability
• Controlled release reduces dose frequency

2.4 literature related to preparation methods of NLCS

Das S et al. (2012)
Das and colleagues studied various preparation techniques for lipid nanoparticles including:
• High pressure homogenization
• Ultrasonication
• Solvent evaporation
• Microemulsion method
The study concluded that high shear homogenization followed by ultrasonication produced nanoparticles with:
• Uniform particle size
• High entrapment efficiency
• Good stability
Shah R et al. (2015)
Shah and coworkers prepared NLCs using melt emulsification technique and evaluated formulation variables affecting nanoparticle properties.
The study revealed:
• Surfactant concentration influences particle size
• Lipid ratio affects entrapment efficiency
• Homogenization speed impacts stability
Optimized formulations exhibited prolonged drug release and improved stability.

2.5 literature related to lansoprazole formulations

Patel DM et al. (2011)
Patel and coworkers developed gastro-resistant formulations of lansoprazole to protect the drug from acidic degradation.
The study reported:
• Lansoprazole undergoes rapid degradation in acidic pH
• Enteric protection improves stability
• Controlled release enhances therapeutic effect
The authors suggested the need for advanced delivery systems for improved oral delivery.
Lin WJ et al. (2016)
Lin and colleagues formulated lipid nanoparticles containing lansoprazole and evaluated their stability and release profile.
Major findings:
• Enhanced drug encapsulation
• Improved stability against acidic degradation
• Sustained drug release pattern
• Increased drug permeability
The study concluded that lipid nanoparticles are promising carriers for lansoprazole delivery.

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III. AIM, OBJECTIVES AND PLAN OF WORK

3.1 Aim of the Study

The present research work aims to formulate and evaluate Lansoprazole-loaded Nanostructured Lipid Carriers (NLCs) for enhancement of drug stability, solubility, and controlled drug release characteristics. The study is intended to develop a stable lipid-based nanoformulation capable of improving the oral delivery and therapeutic performance of lansoprazole.

3.2 Objectives of the Study

The major objectives of the present investigation are as follows:

Primary Objectives

- To develop Nanostructured Lipid Carriers containing Lansoprazole.
- To enhance the solubility and stability of Lansoprazole.
- To improve oral bioavailability through lipid-based nanoformulation.
- To achieve controlled and sustained drug release.

Secondary Objectives

- To perform preformulation studies of Lansoprazole.
- To select suitable solid lipids, liquid lipids, and surfactants.
- To prepare NLCs using high shear homogenization and ultrasonication technique.
- To optimize formulation variables affecting nanoparticle characteristics.
- To evaluate prepared formulations for particle size and zeta potential.
- To determine entrapment efficiency and drug content.
- To perform in vitro drug release studies.
- To conduct stability studies according to ICH guidelines.
- To compare optimized formulation with conventional formulations.

3.3 Hypothesis of the Work

The present study is based on the hypothesis that incorporation of Lansoprazole into Nanostructured Lipid Carriers will:

- Improve drug stability
- Increase drug entrapment
- Enhance dissolution and absorption
- Provide sustained release
- Improve oral bioavailability

Thus, NLCs may serve as a promising nano drug delivery system for effective delivery of Lansoprazole.

3.4 PLAN OF WORK

The research work is planned systematically in various stages to achieve the objectives of the study.

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3.5 FLOW CHART OF PLAN OF WORK

Fig. 3: PLAN OF WORK

IV. MATERIALS AND METHODS

4.1 Materials

The materials used in the present investigation for formulation development of Lansoprazole-loaded Nanostructured Lipid Carriers were of analytical and pharmaceutical grade.

4.1.1 Drug

Sr. No.	Material	Category	Supplier
1	Lansoprazole	Active Pharmaceutical Ingredient	Yarrow Chem Products, Mumbai

4.1.2 Lipids

Sr. No.	Material	Function
1	Glyceryl Monostearate	Solid Lipid
2	Oleic Acid	Liquid Lipid

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4.1.3 Surfactants and Stabilizers

Sr. No.	Material	Function
1	Tween 80	Surfactant
2	Poloxamer 188	Stabilizer
3	Lecithin	Co-surfactant

4.1.4 Chemicals and Reagents

Sr. No.	Chemical	Purpose
1	Methanol	Solvent
2	Ethanol	Solvent
3	Distilled Water	Vehicle
4	Hydrochloric Acid	pH Adjustment
5	Phosphate Buffer pH 6.8	Dissolution Medium

4.2 Equipment's Used

The instruments and equipments used during the study are listed below.

Sr. No.	Equipment	Manufacturer
1	UV-Visible Spectrophotometer	Shimadzu
2	FTIR Spectrophotometer	Bruker
3	High Shear Homogenizer	Remi
4	Probe Sonicator	Sonics Vibra Cell
5	Digital Balance	Shimadzu
6	Magnetic Stirrer	Remi
7	pH Meter	Elico
8	Centrifuge	Remi
9	Hot Air Oven	Thermolab
10	Particle Size Analyzer	Malvern Zetasizer

4.3 Method of preparation of Nanostructured Lipid Carriers

Lansoprazole-loaded Nanostructured Lipid Carriers were prepared using High Shear Homogenization followed by Ultrasonication method.

4.4 Principle of NLC Preparation

Nanostructured Lipid Carriers are prepared by dispersing melted lipid phase into aqueous surfactant phase under high-speed homogenization. Subsequent ultrasonication reduces particle size to nanoscale range. The mixture of solid lipid and liquid lipid forms an imperfect crystal lattice which enhances drug accommodation and minimizes drug expulsion.

4.5 Formulation Design

Different formulations were prepared by varying concentrations of:

- Solid lipid
- Liquid lipid
- Surfactant

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4.6 Composition of Formulations

Table 4.1 Composition of Lansoprazole NLC Formulations

Ingredients	F1	F2	F3	F4	F5
Lansoprazole (mg)	30	30	30	30	30
Glyceryl Monostearate (mg)	100	120	140	160	180
Oleic Acid (mg)	20	25	30	35	40
Tween 80 (%)	1	1.5	2	2.5	3
Poloxamer 188 (%)	0.5	0.5	0.5	0.5	0.5
Distilled Water (mL)	q.s	q.s	q.s	q.s	q.s

4.7 Procedure for Preparation OF NLCs

Step 1: Preparation of Lipid Phase

Accurately weighed quantity of Glyceryl Monostearate was melted at temperature 5–10°C above its melting point. Oleic acid was added to the molten lipid phase with continuous stirring. Lansoprazole was dissolved in the lipid mixture under constant stirring to obtain a uniform lipid phase.

Step 2: Preparation of Aqueous Phase

Tween 80 and Poloxamer 188 were dissolved in distilled water and heated to the same temperature as the lipid phase.

Step 3: Emulsification

The hot aqueous phase was added slowly into molten lipid phase under continuous homogenization using high shear homogenizer at 10,000–15,000 rpm for 20 minutes.

Step 4: Ultrasonication

The obtained coarse emulsion was subjected to probe ultrasonication for 10–15 minutes to reduce particle size into nanometer range.

Step 5: Cooling

The nanoemulsion formed was cooled to room temperature, resulting in formation of Nanostructured Lipid Carriers.

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4.8 Flow Chart of Preparation Method

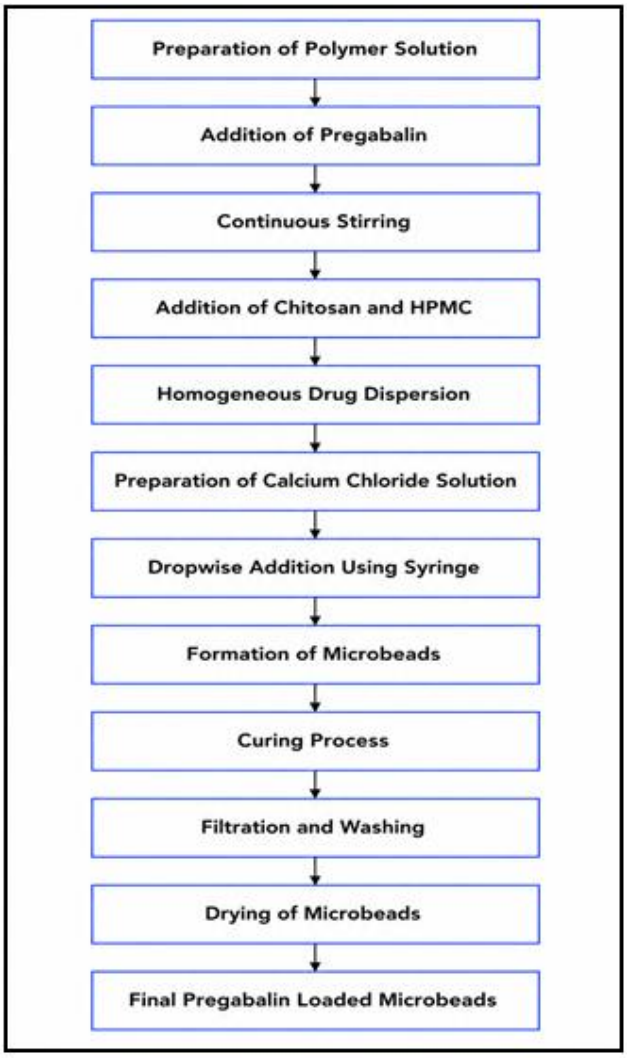

Fig. 4: Flow Chart of NCL Preparation

4.9 Preformulation Studies

Preformulation studies were carried out to determine physicochemical properties of Lansoprazole.

4.9.1 Organoleptic Properties

The drug was evaluated for:

- Color
- Odor
- Appearance
- Texture

4.9.2 Solubility Studies

Solubility of Lansoprazole was determined in:

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• Water
• Methanol
• Ethanol
• Phosphate buffer
• Lipid components

Excess quantity of drug was added to solvents and shaken for 24 hours. Samples were filtered and analyzed spectrophotometrically.

4.9.3 Melting Point Determination

Melting point was determined using capillary melting point apparatus.

4.9.4 Determination of λmax

Accurately weighed Lansoprazole was dissolved in methanol and scanned using UV-visible spectrophotometer between 200–400 nm to determine wavelength of maximum absorbance.

4.9.5 Calibration Curve of Lansoprazole

Standard solutions were prepared and absorbance measured at λmax.

$A=\varepsilon bcA=\varepsilon bcA=\varepsilon bc$

Where:

• A = Absorbance
• ε = Molar absorptivity
• b = Path length
• c = Concentration

4.9.6 Drug-Excipient Compatibility Studies

Compatibility studies were carried out using:

• FTIR spectroscopy
• Differential Scanning Calorimetry (DSC)

These studies help identify possible interactions between drug and excipients.

V. PREFORMULATION STUDIES

5.1 Preformulation Investigation of Lansoprazole

Preformulation studies are essential preliminary investigations carried out before formulation development of pharmaceutical dosage forms. These studies provide information regarding physicochemical properties of the drug and help in selection of suitable excipients, formulation methods, and processing conditions.

The present work involved detailed characterization of Lansoprazole to evaluate its suitability for development into Nanostructured Lipid Carriers (NLCs).

The following studies were performed:

• Organoleptic properties
• Solubility analysis
• Melting point determination
• Determination of λmax
• Calibration curve preparation
• Partition coefficient
• FTIR studies
• Drug-excipient compatibility studies

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5.2 Organoleptic Properties

Organoleptic evaluation involves characterization of the drug based on physical appearance and sensory properties.

Table 5.1 Organoleptic Properties of Lansoprazole

Parameter	Observation
Color	White to brownish white
Odor	Odorless
Appearance	Crystalline powder
Texture	Fine powder

The obtained results were found to comply with standard pharmacopoeial specifications.

5.3 Solubility Analysis

Solubility studies are important for selection of suitable solvents, lipids, and surfactants for formulation development. Lansoprazole is a poorly water-soluble drug; therefore, its solubility was determined in various solvents and lipid components.

5.3.1 Procedure

An excess amount of Lansoprazole was added separately into different solvents and lipid components in tightly closed vials. The mixtures were shaken continuously for 24 hours at room temperature.

5.3.2 Solubility Results

Table 5.2 Solubility of Lansoprazole in Various Solvents

Solvent	Solubility
Distilled Water	Slightly soluble
Methanol	Freely soluble
Ethanol	Soluble
Phosphate Buffer pH 6.8	Moderately soluble
Oleic Acid	Highly soluble
Glyceryl Monostearate	Soluble on heating

The results indicated that Lansoprazole exhibited maximum solubility in Oleic acid among selected lipid components.

5.4 Melting Point Determination

Melting point determination is useful for identification and purity assessment of the drug.

Procedure

A small quantity of Lansoprazole was filled into a capillary tube sealed at one end. The capillary was placed in melting point apparatus and heated gradually until complete melting occurred.

5.4.2 Observation

Table 5.3 Melting Point of Lansoprazole

Drug	Observed Melting Point
Lansoprazole	178°C – 182°C

The observed melting point was found to be within reported standard range, confirming purity of the drug sample.

5.5 Determination of λmax

Determination of wavelength of maximum absorbance (λmax) is essential for spectrophotometric estimation of the drug.

5.5.1 Procedure

Accurately weighed 10 mg of Lansoprazole was dissolved in methanol and diluted appropriately.

The prepared solution was scanned in UV-visible spectrophotometer between 200–400 nm.

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5.5.2 Observation

The maximum absorbance of Lansoprazole was observed at 284 nm.

Table 5.4 λmax of Lansoprazole

Parameter	Observation
λmax	284 nm

5.6 Preparation of Calibration Curve

Calibration curve was prepared for quantitative estimation of Lansoprazole using UV-visible spectrophotometry.

5.6.1 Procedure

• Preparation of Stock Solution

• 10 mg of Lansoprazole was dissolved in methanol and volume adjusted to 100 mL to obtain stock solution of 100 µg/mL.

• Preparation of Working Standards

• Aliquots of stock solution were diluted to obtain concentrations ranging from 2–12 µg/mL.

• Absorbance of each solution was measured at 284 nm.

5.6.2 Calibration Data

Table 5.5 Calibration Curve Data of Lansoprazole

Concentration (µg/mL)	Absorbance
2	0.121
4	0.243
6	0.362
8	0.486
10	0.604
12	0.728

The calibration curve showed good linearity.

Where:

• y = Absorbance

• x = Concentration

5.7 Partition Coefficient Study

Partition coefficient determines lipophilic nature of the drug and its affinity towards lipid phase.

5.7.1 Procedure

Equal volumes of n-octanol and water were mixed and saturated. A known quantity of Lansoprazole was added and shaken for 24 hours.

After equilibration, concentration of drug in aqueous phase was analyzed spectrophoto metrically.

5.7.2 Formula

P = Concentration in Octanol Concentration in Water

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5.7.3 Observation

Lansoprazole showed higher partition coefficient indicating lipophilic nature of the drug, which supports its incorporation into lipid nanoparticles.

5.8 FTIR Spectroscopic Analysis

Fourier Transform Infrared Spectroscopy (FTIR) was performed to identify characteristic functional groups of Lansoprazole and evaluate compatibility with excipients.

5.8.1 Principle

FTIR spectroscopy measures absorption of infrared radiation by functional groups present in molecules.
Different functional groups absorb IR radiation at specific wavelengths.

5.8.2 Procedure

FTIR spectra of:

- Pure drug
- Physical mixture of drug and excipients

were recorded using FTIR spectrophotometer over range of 4000–400 cm^{-1}.

5.8.3 Interpretation of FTIR Peaks

Table 5.6 FTIR Peak Interpretation of Lansoprazole

Functional Group	Observed Peak (cm^{-1})
N-H Stretching	3410
C-H Stretching	2950
S=O Stretching	1045
C=N Stretching	1580
Aromatic Ring Stretching	1450

The characteristic peaks of Lansoprazole were retained in physical mixture indicating absence of chemical interaction between drug and excipients.

VI. FORMULATION DEVELOPMENT

6.1 Formulation Development Strategy

The present investigation focused on development of Nanostructured Lipid Carriers (NLCs) containing Lansoprazole for enhancement of drug stability, solubility, and controlled release characteristics.
Formulation development involved systematic selection and optimization of:

- Solid lipid
- Liquid lipid
- Surfactants
- Preparation method
- Process parameters

The formulation was designed to produce stable nanosized particles with high drug entrapment efficiency and sustained drug release profile.

6.2 Selection of Formulation Components

Selection of excipients plays an important role in development of stable and effective NLC formulations.

6.2.1 Selection of Solid Lipid

Solid lipids were selected based on:

- Drug solubility
- Biocompatibility
- Melting point
- Stability characteristics

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Glyceryl Monostearate (GMS) was selected as solid lipid because:
• It showed good solubility for Lansoprazole.
• It possesses excellent biocompatibility.
• It forms stable lipid matrix.
• It provides sustained release characteristics.

6.2.2 Selection of Liquid Lipid

Liquid lipids reduce crystallinity of solid lipid matrix and improve drug accommodation.
Oleic acid was selected because:
• It exhibited high solubilizing capacity for Lansoprazole.
• It improves drug loading.
• It enhances flexibility of lipid matrix.
• It supports formation of stable nanoparticles.

6.2.3 Selection of Surfactant

Surfactants stabilize nanoparticles and reduce interfacial tension.
Tween 80 was selected because:
• It provides better emulsification.
• It reduces particle size.
• It stabilizes lipid nanoparticles.
• It improves formulation homogeneity.
Poloxamer 188 was used as stabilizer to improve physical stability of nanoparticles.

6.3 Optimization of Formulation Variables

Several formulation and process variables influence characteristics of NLCs.
The following parameters were optimized:
• Lipid concentration
• Surfactant concentration
• Homogenization speed
• Sonication time
• Lipid-to-drug ratio

6.4 Method Selection

Among different preparation methods, High Shear Homogenization followed by Ultrasonication was selected because:
• It is simple and reproducible.
• It produces smaller particle size.
• It provides higher entrapment efficiency.
• It avoids excessive use of organic solvents.
• It is suitable for large-scale production.

6.5 Preliminary Trial Formulations

Preliminary batches were prepared to optimize formulation variables and identify suitable composition for development of stable nanoparticles.
Different concentrations of:
• Glyceryl Monostearate
• Oleic acid
• Tween 80
were evaluated.

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6.6 Composition of Preliminary Formulations

Table 6.1 Composition of Preliminary Trial Batches

Ingredients	T1	T2	T3
Lansoprazole (mg)	30	30	30
GMS (mg)	100	120	140
Oleic Acid (mg)	20	30	40
Tween 80 (%)	1	1.5	2
Poloxamer 188 (%)	0.5	0.5	0.5
Water (mL)	q.s	q.s	q.s

6.7 Observation of Preliminary Batches

Table 6.2 Evaluation of Preliminary Trial Formulations

Batch	Observation
T1	Larger particle size
T2	Improved stability and particle size
T3	Good entrapment and stable dispersion

Batch T3 showed better nanoparticle characteristics and was selected for further optimization.

6.8 Final Formulation Design

Based on preliminary studies, final formulations were designed by varying lipid and surfactant concentrations.

6.9 Composition of Final Formulations

Table 6.3 Composition of Final NLC Formulations

Ingredients	F1	F2	F3	F4	F5
Lansoprazole (mg)	30	30	30	30	30
GMS (mg)	120	140	160	180	200
Oleic Acid (mg)	20	25	30	35	40
Tween 80 (%)	1	1.5	2	2.5	3
Poloxamer 188 (%)	0.5	0.5	0.5	0.5	0.5
Distilled Water	q.s	q.s	q.s	q.s	q.s

6.10 Procedure for Formulation Development

6.10.1 Preparation of Lipid Phase

Accurately weighed Glyceryl Monostearate was melted at temperature approximately 5–10°C above its melting point.
Oleic acid was added to molten lipid phase and mixed thoroughly.
Lansoprazole was dispersed into molten lipid mixture under continuous stirring until clear uniform phase was obtained.

6.10.2 Preparation of Aqueous Phase

Tween 80 and Poloxamer 188 were dissolved in distilled water and heated to same temperature as lipid phase.
Maintaining equal temperature prevents premature solidification during emulsification.

6.10.3 Formation of Coarse Emulsion

The hot aqueous phase was added slowly into lipid phase under continuous homogenization using high shear homogenizer.
Process Parameters
• Homogenization speed: 12,000–15,000 rpm

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• Homogenization time: 20 minutes

This resulted in formation of coarse emulsion.

6.10.4 Ultrasonication

The coarse emulsion was subjected to probe ultrasonication to reduce droplet size into nanometer range.

Parameters

• Sonication time: 10–15 minutes

• Pulse cycle: 30 seconds ON/OFF

Ultrasonication reduced particle aggregation and improved uniformity.

6.10.5 Cooling of Formulation

The nanoemulsion formed was cooled to room temperature with continuous stirring.

Cooling caused solidification of lipid matrix and formation of Nanostructured Lipid Carriers.

6.11 Flow Chart of Formulation Development

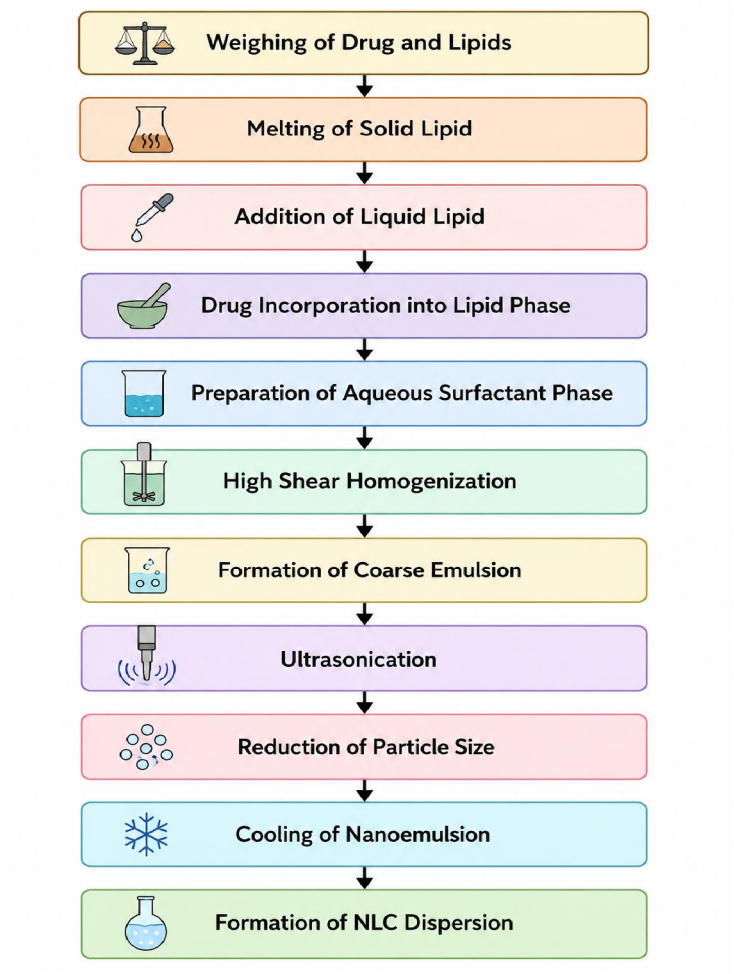

Fig. 5: Flow Chart of Formulation Development

6.12 Factors Affecting Formulation Development

Several factors influence characteristics and stability of NLCs.

• Lipid Concentration

• Surfactant Concentration

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• Homogenization Speed
• Sonication Time

6.13 Mechanism of Formation of NLCs

NLCs are formed by mixing solid and liquid lipids followed by stabilization with surfactants.
The liquid lipid creates imperfections in solid lipid crystal lattice, resulting in:
• Higher drug accommodation
• Reduced crystallinity
• Better drug retention
• Controlled release characteristics

6.14 Advantages of Developed Formulation

The developed Lansoprazole NLC formulation offers several advantages:
• Enhanced drug stability
• Improved oral bioavailability
• Protection from gastric degradation
• Sustained release behavior
• Increased drug loading
• Better patient compliance

6.15 Challenges during Formulation Development

Some difficulties encountered during formulation development included:
• Aggregation of nanoparticles
• Particle size variability
• Optimization of surfactant concentration
• Stability of nano dispersion
These problems were minimized through optimization of process parameters.

VII. EVALUATION OF LANSOPRAZOLE NANOSTRUCTURED LIPID CARRIERS

7.1 Evaluation Parameters of NLC Formulations

Evaluation of Nanostructured Lipid Carriers is essential to determine their physicochemical properties, stability, drug loading efficiency, and release behavior. The prepared formulations were subjected to detailed characterization using various analytical and instrumental techniques.
The following evaluation parameters were studied:
• Physical appearance
• Particle size analysis
• Polydispersity index
• Zeta potential
• Entrapment efficiency
• Drug content
• Surface morphology
• In vitro drug release
• Release kinetics
• Stability studies

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7.2 Physical Appearance

Prepared NLC dispersions were visually inspected for:

- Color
- Homogeneity
- Phase separation
- Aggregation

7.2.1 Observation

All formulations appeared milky white and homogeneous without visible aggregation or phase separation.

Table 7.1 Physical Appearance of Formulations

Formulation	Appearance	Homogeneity	Aggregation
F1	Milky white	Good	Absent
F2	Milky white	Good	Absent
F3	Milky white	Excellent	Absent
F4	Milky white	Good	Slight
F5	Milky white	Moderate	Slight

Formulation F3 showed best physical stability and homogeneity.

7.3 Particle Size Analysis

Particle size is one of the most important parameters affecting:

- Drug release
- Stability
- Bioavailability
- Cellular uptake

Smaller particle size increases surface area and enhances dissolution rate.

7.3.1 Method

Particle size analysis was performed using Dynamic Light Scattering (DLS) technique with Malvern Zetasizer. Samples were diluted with distilled water before analysis.

7.3.2 Results

Table 7.2 Particle Size of NLC Formulations

Formulation	Particle Size (nm)
F1	298.4
F2	245.6
F3	182.3
F4	210.8
F5	236.5

The optimized formulation F3 exhibited minimum particle size due to optimum lipid and Surfactant Concentration.

7.4 Polydispersity Index (PDI)

Polydispersity Index indicates uniformity of particle size distribution.

Lower PDI values indicate:

- Uniform particle distribution
- Better formulation stability

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7.4.1 Results

Table 7.3 Polydispersity Index of Formulations

Formulation	PDI
F1	0.412
F2	0.356
F3	0.248
F4	0.301
F5	0.378

The optimized formulation F3 showed narrow particle size distribution.

7.5 Zeta Potential

Zeta potential measures surface charge on nanoparticles and predicts physical stability of colloidal systems.
Higher zeta potential values indicate:

- Better electrostatic repulsion
- Reduced aggregation
- Improved stability

7.5.1 Method

Zeta potential was measured using Malvern Zetasizer.

7.5.2 Results

Table 7.4 Zeta Potential of NLC Formulations

Formulation	Zeta Potential (mV)
F1	-18.2
F2	-21.5
F3	-29.8
F4	-25.4
F5	-23.7

The optimized formulation F3 showed higher zeta potential indicating good physical stability.

7.6 Entrapment Efficiency

Entrapment efficiency indicates percentage of drug incorporated into lipid nanoparticles.
Higher entrapment efficiency ensures:

- Better drug loading
- Reduced drug wastage
- Sustained drug release

7.6.1 Method

Entrapment efficiency was determined using centrifugation method.
The formulation was centrifuged and free drug in supernatant was estimated spectrophotometrically.

7.6.2 Formula

$$EE(\%) = \frac{Total\ Drug - Free\ Drug}{Total\ Drug} \times 100$$

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7.6.3 Results

Table 7.5 Entrapment Efficiency of Formulations

Formulation	Entrapment Efficiency (%)
F1	71.2
F2	78.5
F3	89.4
F4	85.2
F5	82.8

Formulation F3 showed maximum entrapment efficiency due to optimized lipid matrix composition.

VIII. RESULTS AND DISCUSSION

8.1 Overview of Experimental Findings

The present investigation was carried out to formulate and evaluate Lansoprazole-loaded Nanostructured Lipid Carriers for enhancement of stability, solubility, and sustained drug release characteristics. Various formulation batches were prepared using different concentrations of solid lipid, liquid lipid, and surfactants.

The prepared formulations were evaluated for:

- Physical appearance
- Particle size
- Polydispersity index
- Zeta potential
- Entrapment efficiency
- Drug content
- Surface morphology
- In vitro drug release
- Stability studies

The obtained results were analyzed systematically to identify optimized formulation with desirable pharmaceutical characteristics.

8.2 Observation of Preformulation Studies

Preformulation studies confirmed physicochemical characteristics of Lansoprazole suitable for incorporation into lipid nanoparticles.

8.2.1 Organoleptic Properties

The drug appeared as white to brownish white crystalline powder with odorless characteristics.

Discussion

The organoleptic properties matched standard pharmacopoeial specifications, confirming identity and purity of the drug sample.

8.2.2 Solubility Analysis

Lansoprazole exhibited:

- Poor aqueous solubility
- Good solubility in methanol and ethanol
- High solubility in Oleic acid

Discussion

Poor water solubility of Lansoprazole supports the need for lipid-based nano drug delivery systems. High solubility in Oleic acid justified its selection as liquid lipid for NLC formulation.

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8.2.3 Melting Point Determination

Observed melting point: 178°C – 182°C

Discussion

The obtained melting point was within standard reported range, indicating purity and absence of significant impurities.

8.2.4 UV Spectrophotometric Analysis

Maximum absorbance was observed at: 284 nm

Discussion

The UV analytical method showed good sensitivity and reproducibility for quantitative estimation of Lansoprazole.

8.2.5 Calibration Curve

The calibration curve showed linearity within concentration range of 2–12 µg/mL.

Discussion

The linear relationship between concentration and absorbance confirmed suitability of UV spectrophotometric method for drug estimation.

8.3 Interpretation of FTIR Studies

FTIR spectra of pure drug and physical mixture were analyzed for compatibility studies.

8.3.1 Characteristic Peaks of Lansoprazole

Table 8.1 FTIR Peak Interpretation

Functional Group	Peak (cm^{-1})
N-H Stretching	3410
C-H Stretching	2950
S=O Stretching	1045
C=N Stretching	1580

8.3.2 Discussion

The characteristic peaks of Lansoprazole were retained in physical mixture without significant shift or disappearance. This indicated:

- Absence of chemical interaction
- Good compatibility between drug and excipients
- Stability of drug within formulation matrix

8.4 Discussion of DSC Analysis

DSC thermograms showed characteristic endothermic peak of Lansoprazole near its melting point.

Discussion

The sharp peak confirmed crystalline nature of the drug. No major shift in thermal peak was observed in physical mixture, indicating compatibility between drug and excipients.

The reduction in peak intensity in formulation suggested partial conversion of crystalline drug into amorphous state, which may improve drug dissolution.

IX. CONCLUSION AND FUTURE PROSPECTS

9.1 Conclusion

The present investigation entitled “Formulation Development and In Vitro Evaluation of Lansoprazole Nanostructured Lipid Carriers” was successfully carried out with the objective of improving stability, solubility, and sustained release characteristics of Lansoprazole through lipid-based nano drug delivery system.

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Lansoprazole is a proton pump inhibitor widely used in treatment of gastric ulcer, peptic ulcer, and gastroesophageal reflux disease. However, its therapeutic effectiveness is limited due to:

- Poor aqueous solubility
- Acid instability
- Low oral bioavailability
- Rapid degradation in gastric environment

To overcome these limitations, Nanostructured Lipid Carriers (NLCs) were developed using Glyceryl Monostearate as solid lipid, Oleic acid as liquid lipid, Tween 80 as surfactant, and Poloxamer 188 as stabilizer.

The formulations were successfully prepared using High Shear Homogenization followed by Ultrasonication technique.

9.2 Future Prospects

Further research can be carried out in the following areas:

In Vivo Studies

Animal studies and pharmacokinetic investigations may be performed to evaluate bioavailability enhancement and therapeutic effectiveness.

Scale-Up Studies

Industrial scale-up studies can be conducted to assess commercial feasibility of the developed formulation.

Surface Modification

Surface functionalization of nanoparticles may improve targeting and absorption characteristics.

Clinical Evaluation

Clinical studies may be performed to establish safety and efficacy in human subjects.

Development of Alternate Dosage Forms

The developed NLCs may be incorporated into:

- Capsules
- Tablets
- Oral suspensions
- Sachets

for improved patient acceptability.

Application to Other Drugs

The same approach may be utilized for delivery of:

- Poorly soluble drugs
- Acid-labile drugs
- BCS Class II drugs
- Controlled release formulations

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