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FORMULATION AND DEVELOPMENT OF DEXIBUPROFEN TABLETS BY SOLID DISPERSION TECHNIQUE

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ABSTRACT

Dexibuprofen, the pharmacologically active S(+)-enantiomer of ibuprofen, is a non-steroidal anti-inflammatory drug widely used for the treatment of pain and inflammatory conditions. However, its poor aqueous solubility limits its dissolution rate and oral bioavailability. The present study aimed to enhance the dissolution characteristics of Dexibuprofen by formulating solid dispersions using gelatin and sodium lauryl sulfate (SLS) as hydrophilic carriers through fusion, hot melt, and solvent evaporation techniques. Preliminary studies were conducted to select the most suitable preparation method based on dissolution performance. Solid dispersions prepared by the fusion and hot melt methods showed slower dissolution rates, whereas the solvent evaporation method using purified water demonstrated significantly improved solubility and dissolution behavior. Various polymer ratios were evaluated, and the solid dispersion containing gelatin and SLS in a 2:1 ratio exhibited the least dissolution time and superior drug release characteristics. The optimized solid dispersion was further loaded with Dexibuprofen and compressed into tablets. In vitro dissolution studies of the formulated tablets revealed a marked improvement in drug release compared to the pure drug, with more than 80% release within 60 minutes. The results confirm that the solid dispersion technique using gelatin and SLS is an effective approach for enhancing the dissolution rate of poorly water-soluble drugs like Dexibuprofen and can be successfully employed in tablet formulation.

KEYWORDS: Dexibuprofen, Solid dispersion, Solvent evaporation method, Gelatin, Sodium lauryl sulfate, Dissolution enhancement.

1. INTRODUCTION

Poor aqueous solubility remains one of the major challenges in the formulation of orally administered drugs, as it directly affects dissolution rate, bioavailability, and therapeutic efficacy. A significant proportion of newly developed and existing drugs fall under the Biopharmaceutics Classification System (BCS) Class II, characterized by low solubility and high permeability. Improving the solubility and dissolution behavior of such drugs is essential for achieving optimal clinical outcomes.

Dexibuprofen, the S(+)-enantiomer of ibuprofen, possesses superior pharmacological activity compared to the racemic mixture and is associated with reduced gastrointestinal side effects at lower doses. Despite these advantages, Dexibuprofen exhibits poor water solubility, which limits its dissolution rate and oral absorption. Conventional formulation approaches often fail to overcome this limitation effectively.

Solid dispersion technology is a well-established and efficient technique for enhancing the dissolution rate of poorly soluble drugs. In this approach, the drug is molecularly dispersed or finely distributed within a hydrophilic carrier matrix, leading to improved wettability, reduced particle size, and partial or complete amorphization. Polymers such as gelatin and surfactants like sodium lauryl sulfate have been widely employed due to their excellent solubilizing properties and pharmaceutical acceptability.

The present study focuses on the preparation and evaluation of Dexibuprofen solid dispersions using gelatin and sodium lauryl sulfate by different techniques, with an emphasis on selecting an optimized formulation based on dissolution performance and compressibility into tablets.

2. DRUG PROFILE

- **Drug Name:** Dexibuprofen
- **Trade Names:** Seractil®, Dexib®, Racemid® (varies by country)
- **IUPAC Name:** (2S)-2-(4-isobutylphenyl) propionic acid
- **Molecular Formula:** $C_{13}H_{18}O_2$
- **Molecular Weight:** 206.28 g/mol

- **Chemical Class:** Non-steroidal anti-inflammatory drug (NSAID) Propionic acid derivative
- **Stereochemistry:** Dexibuprofen is the S (+)-enantiomer of ibuprofen, which is the pharmacologically active form.
- **Mechanism of Action:** Dexibuprofen exerts its analgesic, anti-inflammatory, and antipyretic effects by inhibiting cyclooxygenase enzymes (COX-1 and COX-2), thereby reducing the synthesis of prostaglandins involved in pain, inflammation, and fever.
- **Appearance:** White or almost white crystalline powder
- **Solubility:** Practically insoluble in water, Soluble in organic solvents such as ethanol and methanol, Freely soluble in alkaline solutions.
- **Routes of Administration:** Oral (tablets, capsules, suspension), Topical (gel, cream)
- **Bioavailability:** Approximately 80–90% after oral administration
- **Protein Binding:** 99% bound to plasma proteins (mainly albumin)
- **Metabolism:** Hepatic metabolism primarily via CYP2C9
- **Elimination Half-Life:** Approximately 1.8 – 3.5 hours
- **Excretion:** Renal: ~70–80%, Fecal: ~20%
- **Storage Conditions:** Store in a well-closed container, protected from moisture and light, at room temperature.
- **Therapeutic Uses:** Dexibuprofen is used in the management of: Mild to moderate pain, Rheumatoid arthritis, Osteoarthritis, Musculoskeletal pain, Dysmenorrhea, Dental pain, Post-operative pain.
- **Adverse Effects:** Gastrointestinal irritation, Nausea and vomiting, Dyspepsia, Headache, Dizziness, Rare: gastric ulceration and renal impairment (with prolonged use)
- **Contraindications:** Hypersensitivity to NSAIDs, History of peptic ulcer disease, Severe renal or hepatic impairment, Third trimester of pregnancy.
- **Clinical Significance:** Due to its improved efficacy and safety profile, Dexibuprofen is considered a superior alternative to conventional ibuprofen, especially in patients requiring long-term anti-inflammatory therapy.

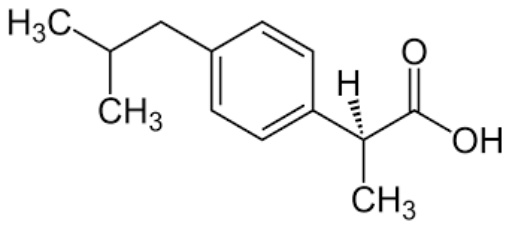

Fig. 1: Chemical Structure Of Dexibuprofen.

3. MATERIALS AND METHOD

3.1 Experimental Work: (Solid Dispersion)

Methods Planned

- Hot melt method
- Fusion method
- Solvent component method

Fusion Method: The fusion method is sometimes referred to as the melt method, which is correct only when the starting materials are crystalline. Therefore, the more general term fusion method is preffered. The first solid dispersion created for pharmaceutical application were prepared by the fusion method.

Hot Melt Extrusion: Melt extrusion is essentially the same as the fusion method expect that intense mixing of the components is induced by the extruder. When compared to melting in a vessels, the product stability and dissolution are similar but melt extrusion offers the potential to shape the heated drug-matrix mixture into implants, ophthalmic inserts, or oral dosage forms just like in the traditional fusion process, miscibility of drug and matrix can be a problem.The theoretical approach to understanding the melt extrusion process.

3.2 Preparation

- **Polymers:** Gelatin**,** Sodium lauryl sulfate
- **Drug:** Dexibuprofen

Step 1: The Gelatin and sodium laureyl sulfate was taken as a ratio of 1:1, 2:1, 3:1 and melt in water bath for sufficient time and evaporate the water and till dry to kept in hot air oven till it dried and collect the dried powder.

Step 2: The second step was also performed as similar to that of step 1 procedure with adding the water for that rations of 1:1, 2:1, 3:1 And again using hot air oven and collect the powder.

Step 3: The Gelatin and alcohol was taken as a ratio of 1:1, 2:1, 3:1 and evaporate the alcohol by using hot air oven and finally collect the powder.

Step 4: Analysis of dissolution times of the various solid dispersions.

Step 5: The compression of solid dispersion tablets are tested by using dissolution method. From this dissolution method select the best one which is giving the more soluble.

3.3 Process

Step 1: The solid dispersion from the step1 prepared by hot melt method was tested by solubility in water. The first product 1:1 add a dissolution time of 10 min**.** The second product 2:1 has a solubility of more than 10min. The third product 3:1 has a freely soluble.

Step 2: The product prepared by the solvent method were tested for solubility. The first product in the ratio of 1:1 partially solubility. The second product in the ratio of 2:1 has a solubility time a less than 2 min. The third product in the ratio of 3:1 has a solubility time a 3min.

Step 3: The product prepared by the Ethanol were tested for solubility. The first product in the ratio of 1:1 has a solubility time a 10min. The second product in the ratio of 2;1 has a solubility time a 6min. The third product in the ratio of 3:1 has a not dissolved.

Step 4: After the dissolution test in product in the ratio of 2:1. Gelatin and Sodium laurel sulfate performed by solvent method was found to give a least dissolution time and it was selected for drug Entrapment (Derxibuprofen)

Final Step: The solid dispersion was prepared by 2:1 of Gelation and SLS with drug.

3.4 Drug Entrapment

The 5gm of 2:1 ratio of Gelatin and SLS was drug entrapped with 0.5gm of Dexibuprofen. The 5gm of 2:1 ratio of Gelatin and SLS was drug entrapped with 1gm of Dexibuprofen. The 5gm of 2:1 ratio of Gelatin and SLS was drug entrapped with 1.5gm of Dexibuprofen. On the analysis of the three formulations the one with 5gm of 2:1 Gelatin and SLS 1.5gm Dexibuprofen was shown to have dissolution with 2 minutes. So, this solid dispersion was selected to formulate into tablets after addition of magnesium stearate and talc as additive (to contain 200mg of Dexibuprofen) This solid dispersion was selected to the formulated into tablets. The tablets were in good shape and hardness and stable with solubility less than 10 mins in water Dissolution testing was done for the tablets.

3.5 Dissolution Test For Dexibuprofen Tablets

- **Apparatus:** USP Dissolution Test Apparatus
- **Dissolution Medium:** Purified Water
- **Rpm:** 50
- **Temperature:** 37± 2 °C
- **Sample Points:** 5,10,15,20,25,30 mins

Procedure: The dissolution study was carried out in USP dissolution test apparatus type 2. The water is taken as dissolution medium. An amount of 900ml of dissolution fluid was used at 37+_ 2.C with stirring speed of 50 RPM samples were withdrawn at 5,10,15,20,25 & 30 min time intervals by replacing with same dissolution medium and samples were analyzed by measuring the absorbents at 254 nm by UV spectrophotometer.

3.6 Preparation of standard solution

The standard stock solution of dexibuprofen are made in 100ml of water further dilution was made in water to prepare the respective concentration to prepare the standard curve for the dexibuprofen as follows 10, 20, 30, 40 & 100mcgs. The both test and standard are obtained and observed 254nm.

4. RESULTS

4.1 Standard curve for Dexibuprofen

Table 1: Standard Curve.

Concentration	Absorbance
10	0.135
20	0.262
30	0.411
40	0.534
50	0.675

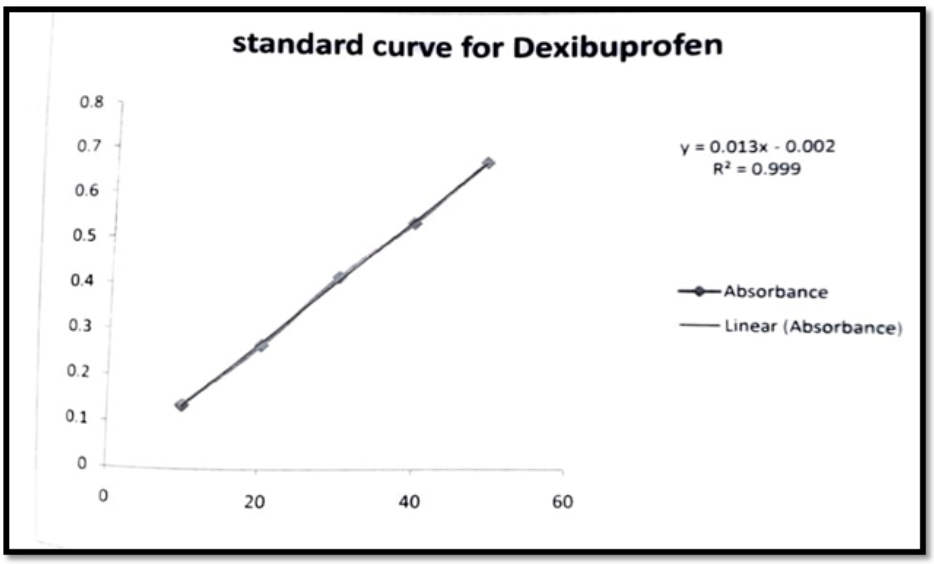

Fig. 2: Standard Curve.

4.2 Dissolution Profile For Dexibuprofen Tablet

Table 2: Dissolution Study.

Time(min)	%Drug release
5	11
10	27
20	36
30	51
40	64
50	73
60	82

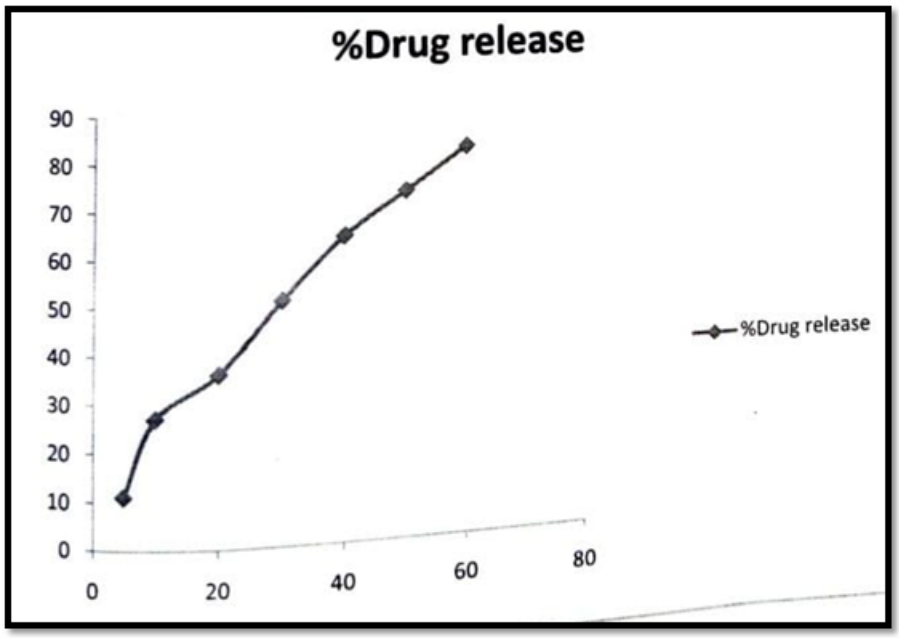

Fig. 3: Dissolution Study.

DISCUSSION

For the preparation of solid dispersions first the fusion method was tried. Since the formulations formed were having very slow dissolution rate the method was not selected. In the next stage the solvent evaporation method was planned with purified water and ethanol as solvents. The experiments were planned with different ratios of gelatin and sodium lauryl sulphate.It was planned to formulate the solid dispersions without the drug for confirming the compatibility of the polymers. After the confirmation of the compatibility the solid dispersions were formulated with various concentrations of carriers. The solid dispersions were formulated with purified water and ethanol as solvents of the various formulation those which were formulated with ethanol were found to have longer dissolution times when compared to those formulated with purified water.

5. CONCLUSION

The present study was performed to improve the dissolution rate of Dexibuprofen, a poorly soluble drug using solvent evaporation solid dispersion techniques. Solid dispersion is an innovative technology in the information development of biologically active molecules, small molecular weight drugs, where the drug or bioactive compound is covalently linked to the macromolecular back bone through a physiological labile bond. Gelatin and SLS are particularly attractive polymers for conjugation. The specific characteristics of these moieties relevant to pharmaceutical applications are water solubility, high mobility in solution , ready clearance from the body.

The increased dissolution rates were observed with all the solid dispersions when compared to pure drug and corresponding physical mixture. The faster dissolution rate was obtained for the Dexibuprofen and Gelatin: SLS (2:1) compared to other solid dispersions. Hence, solid dispersion technique is proved as a successful technique for enhancing the in-vitro dissolution rate of the selected poorly soluble drug, and the formulated solid dispersion was compressed into tablets with good hardness and friability and dissolution rates. The complete profile of the tablets formulated using the solid dispersion technique is to be studied in detail in continuation of the present work.

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