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Different doses of Lornoxicam

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ABSTRACT: Lornoxicam belongs to the oxicam group of nonsteroidal anti-inflammatory drugs (NSAIDs) and exerts analgesic and antipyretic effects, particularly in conditions like Rheumatoid arthritis and postoperative pain, by inhibiting cyclo-oxygenase-1 and -2 non-selectively. Alongside its peripheral inhibition of COX-1 and COX-2 receptors, it also elevates endogenous dynorphin and beta-endorphin levels, leading to central analgesic and anti-inflammatory effects. Recently introduced in the Indian market, Lornoxicam is available in oral, intravenous, and intramuscular formulations. Oral administration results in complete absorption, with peak plasma concentrations of 280 mg/L observed within 2.5 h post a 4 mg dose, while intramuscular injection achieves maximum plasma concentrations in approximately 20 to 25 min. Liver metabolism via cytochrome P4502DC9 leads to the formation of inactive metabolite 5′-Hydroxy Lornoxicam, with a mean elimination half-life of 3 to 4 hours. Various formulations of Lornoxicam are available, including bi-layer tablets, fast mouth dissolving tablets, transdermal matrix patches, gels, suppositories, loaded transfersome gels, sustained-release matrix tablets, emulgels, oral disintegrating tablets, osmotic drug delivery systems, and mini-tablets-filled-pulsincap delivery systems. The present study aims to explore these different formulations of Lornoxicam, detailing their uses, advantages, and disadvantages, while ensuring originality and integrity in the presentation of information.

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INTRODUCTION:

Belonging to the oxicam category of nonsteroidal anti-inflammatory drugs (NSAIDs), Lornoxicam, also known as chlortenoxicam, exhibits analgesic and antipyretic properties through the non-selective inhibition of cyclo-oxygenase-1 and -2. Apart from its peripheral inhibition of COX-1 and COX-2 receptors, it enhances endogenous levels of beta and dynorphin, thereby facilitating central anti-inflammat ory and analgesic effects [1,2].

The compound (3E)-6-chloro-3-[hydroxyl (pyridin2-ylamino) methylene], linoxicam Three-dihydro-4H-thieno-2-methyl-2 [2, 3-e] thiazin-4-one 1,1-dioxide is a potent nonsteroidal anti-inflammatory medication [3]. Lornoxicam, known for its analgesic, anti-inflammatory, and antipyretic properties, falls under the category of NSAIDs as a member of the oxicam class and biopharmaceutical class II due to its low solubility and high permeability. Its bioavailability ranges from 90 to 100 %. To maintain therapeutic plasma concentrations, it's advisable to administer Lornoxicam in divided daily doses, either twice or thrice daily, as its plasma half-life is relatively short, lasting between 3 to 5 h [5]. Commercially, Lornoxicam is available in three forms: conventional immediate-release tablets (4 and 8 mg), rapid-release tablets (8 mg), and parenteral formulations (4 mg/ml) designed for intravenous and intramuscular usage [4].

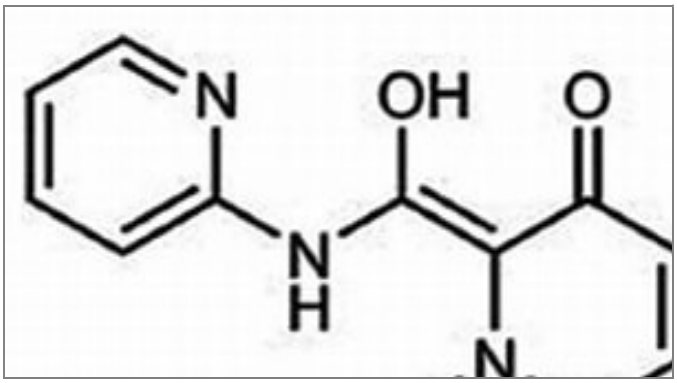

Fig 1. Structure of Lornoxicam.

Pharmacodynamic properties:

Lornoxicam (chlortenoxicam), akin to other nonsteroidal anti-inflammatory drugs (NSAIDs), operates by inhibiting cyclooxygenase, thereby impeding prostaglandin (PG) synthesis, albeit without affecting 5-lipoxygenase. Its inhibitory effects extend to polymorphonuclear (PMN)-leukocyte migration and the prevention of superoxide release from human PMN-leukocytes and platelet-derived growth factor (PDGF) release from human platelets. Moreover, Lornoxicam fosters proteoglycan synthesis in cartilage tissue culture. *In vitro* studies reveal Lornoxicam to be substantially more potent, around 100 times on a molar basis, than tenoxicam in inhibiting PGD2 production in rat polymorphonuclear leukocytes [5].

Aside from peripheral COX-1 and COX-2 receptor inhibition, Lornoxicam elevates endogenous beta- and dynorphin levels, thereby fostering central anti-inflammatory and analgesic effects. Its efficacy in animal pain models surpasses that of indomethacin and diclofenac by 4 to 6 times and exceeds tenoxicam and piroxicam by approximately 12 and 13-fold, respectively. In the management of postoperative pain, intravenous Lornoxicam (8 mg) exhibits comparable effectiveness to morphine (20 mg), pethidine (50 mg), and tramadol (50 mg) [6].

Pharmacokinetic properties:

Following oral treatment, Lornoxicam is totally absorbed; 2.5 h after a 4 mg dose, peak plasma concentrations of 280 mg/L are reached [7]. The area under the serum drug concentration-time curve (AUC) is proportional in young, healthy volunteers who received Lornoxicam doses ranging from 2 to 6 mg twice a day for two weeks. Lornoxicam's Cmax and AUC did show drug accumulation after repeated doses [8]. A 15 % drop in AUC and an increase in t-max from 1.5 to 2.3 h indicate that intragastric food delays and decreases Lornoxicam absorption. Maximum plasma concentrations are reached 20 to 25 min after intramuscular administration. After intramuscular injection, 97 % of the material is bioavailable in its whole body. Both its unmodified form and its hydroxylated metabolite are present in plasma [9].

Lornoxicam binds to plasma proteins with a 99 % success rate. Lornoxicam has a limited apparent volume of distribution (0.3L/Kg). Cytochrome P4502DC9 substantially metabolizes Lornoxicam in the liver to produce the inactive metabolite 5'-hydroxy-Lornoxicam. Roughly, 51 % of the drug is eliminated through faces, and 42 % is eliminated as an inactive compound by the kidneys. About 3 to 4 hours is the average elimination half-life. Patients who are elderly, have poor renal function, or have impaired hepatic function have all been determined to be safe users of the medication [9].

Used:

It is frequently used to alleviate the symptoms of pain and inflammation in people with osteoarthritis and rheumatoid arthritis [1].

Side effects:

Like other NSAIDs, Lornoxicam can induce moderate gastrointestinal adverse effects like headache, nausea, and diarrhea. Severe yet rare side effects may include bleeding, bronchospasms, the exceedingly uncommon Stevens-Johnson syndrome, CNS effects, abdominal pain, nephrotoxicity, photosensitivity, hypertension, insomnia, palpitations, and fluid retention [2].

Formulation Development and Evaluation of Bi-Layer Tablets ofLornoxicam [1,19]:

The objective of this research was to develop bi-layer Lornoxicam tablets that conform to sustained-release criteria while exhibiting an initial burst of drug release in the stomach. Lornoxicam, a potent non-steroidal anti-inflammatory medication with a brief half-life, necessitates a formulation that balances immediate relief with prolonged analgesic effects. The proposed bi-layer tablets consist of immediate-release and sustained-release layers, strategically designed to initiate rapid drug release in the stomach for prompt symptom alleviation, followed by sustained release in the intestine to maintain prolonged pain relief.

Bi-layer tablet technology is well-suited for delivering drugs with differing release patterns, such as providing one layer for immediate relief and another for sustained release, thereby reducing dosing frequency while ensuring prolonged drug efficacy. Sodium citrate functions as a buffer, creating a basic microenvironmental pH within the tablets conducive to drug release under acidic conditions, thus forming the immediate-release layer via the dry granulation method. Ac-di-sol serves as a disintegrant to facilitate the immediate release of the drug. To achieve a 24 h sustained release profile, two grades of HPMC, namely HPMC K4M and HPMC K100M, are utilized in the sustained-release layer, with HPMC also serving as a release retardant in the formulation.

Formulation Development and Evaluation of LornoxicamGel [5,6]:

Various polymers and Lornoxicam were combined to create transdermal anti-inflammatory gels, and their rheological properties, including viscosity and spreadability, as well as pH and drug content, were evaluated. The results of the assessment were deemed satisfactory.

Analysis of the data revealed that Pluronic Lecithin Organogel (PLO) Gel outperformed Carbopol Gel. In vitro drug release studies were conducted on all eleven formulations, indicating that Carbopol Gel exhibited 67 % penetration through the membrane, a lower percentage compared to PLO Gel formulations. This suggests that PLO Gel facilitates greater drug penetration across the membrane when compared to Carbopol Gel.

Formulation and Evaluation of Lornoxicam Suppositories [3,4]:

Water-soluble and oil-soluble bases were utilized to produce Lornoxicam suppositories, each subjected to evaluation for physical parameters like weight variation, drug content, hardness, liquefaction duration and temperature, disintegration, and macro-melting range. In-vitro release testing was conducted using the USP type I apparatus with phosphate buffer pH 7.4 as the dissolution medium. The manufactured suppositories met all specified physical criteria. Notably, drug release from water-soluble bases (e.g., PEG) exceeded that from oil-soluble bases. Agar suppositories for controlled release incorporate Glyceryl Behenate and HPMC. Varied proportions of PEG with differing molecular weights resulted in distinct release profiles. Beeswax is suitable as a base in cocoa butter, and HPMC and Glyceryl Behenate can be included in agar-based suppositories to achieve sustained release.

Formulation and Evaluation of Lornoxicam Mouth Dissolving Tablet [6]:

The concept driving the development of fast-dissolving drug delivery systems aims to offer patients a more convenient method of ingesting their prescribed medications, particularly for those who struggle with swallowing conventional gelatin capsules and tablets. The primary objective of this study is to devise a reproducible formulation of fast-dissolving tablets containing Lornoxicam to enhance drug efficacy and mitigate potential side effects like gastric discomfort. Utilizing the direct compression technique, multiple batches of tablets were prepared using different concentrations of superdisintegrants such as chitosan, gum karaya, and powdered fenugreek seed mucilage. Prior to compression, pre-formulation investigations, including blend characterization and physical compatibility tests with excipients, were conducted. The impact of varying superdisintegrant concentrations on the formulation was examined, and the effectiveness of these superdisintegrants in the Lornoxicam MDT formulation was evaluated by comparing the final batches. Assessment parameters encompassed weight variation, thickness, hardness, friability, drug content, *in-vitro* disintegration time, and in-vitro drug release of the tablets.

Formulation and Characterization of LornoxicamTransdermal Matrix Patch [7]:

Transdermal therapy systems are self-contained, discrete dosage forms that, when applied to undamaged skin, allow the drug(s) to be delivered to the systemic circulation at a controlled pace through the skin. In the current investigation, hydrophilic and hydrophobic polymers were used to create transdermal Lornoxicam patches. The use of a transdermal drug delivery system may prevent first pass metabolism in the liver, sustain steady blood levels for an extended length of time, minimize the need for frequent dosing, enhance bioavailability, lessen gastrointestinal irritation brought on by local contact with the stomach mucosa, and increase patient compliance.

One of the most recent NSAIDs in the oxicam class, Lornoxicam is used to treat anti-inflammatory qualities in a variety of painful and inflammatory illnesses, such as postoperative pain and rheumatoid arthritis. Using HPMC various grades and Eudragit RS 100 as a polymer, PEG-400 and Tween 80 were used as plasticizers, and methanol and dichloromethane were utilised as solvents to make Lornoxicam Patch by the solvent casting process. LXTMP1 was chosen as the optimised batch because it outperformed the other seven batches in the following areas: % Drug Content, Thickness, Folding Endurance, Flatness, Diffusion Study, Sensitivity Study on Animal, and Kinetic Model Study.

Formulation and Evaluation of LornoxicamLoaded TransfersomeGel [8]:

While transdermal drug delivery has significantly advanced medical practice, its full potential as an alternative to oral medication and hypodermic injections remains untapped. To explore this avenue, a study was conducted to investigate the feasibility of utilizing transfersomal vesicles for transdermal administration of the poorly soluble medication Lornoxicam. Various transfersomal formulations, composed of different ratios of distinct spans (80, 60, and 40) and tween-80, were prepared using the thin-film hydration method. Characterization of the formulations involved assessing entrapment efficiency (EE %), drug content, stability, and in vitro drug release through a cellophane membrane.

Transmission electron microscopy revealed the spherical structure of the vesicles, with Lornoxicam exhibiting EE % ranging from 82.84 to 89.85 %. The study demonstrated successful entrapment of Lornoxicam with consistent drug content across formulations. The optimal formulation (F6) identified was a transfersomal gel containing 20 mg of the medication and 20 % span 80, exhibiting the highest drug entrapment (89.84 %) and cumulative percent drug release. Stability tests conducted over several weeks at 5 °C indicated reasonably good stability characteristics, highlighting transfersomes as a promising sustained delivery system for Lornoxicam. Thus, Lornoxicam-loaded transfersomes hold potential for utilization as a transdermal drug delivery system.

Formulation and Evaluation of Sustained Release Matrix Tablet of Lornoxicam [9]:

This study aimed to develop sustained-release matrix tablets of Lornoxicam to extend its duration of action for managing conditions such as ankylosing spondylitis, low back pain, acute sciatica, and rheumatoid arthritis. Preliminary research suggests that the formulation of these sustained-release matrix tablets can be achieved by employing both hydrophilic and hydrophobic polymers effectively. An optimized formulation, with the ideal ratio of xanthan gum to HPMC K15M, successfully prolonged drug release for 24 h. Drug release was observed in vitro in optimized batch matrix tablets, demonstrating the effectiveness of Lornoxicam sustained-release matrix tablets. Subsequent testing and analysis indicated that biocompatible polymers hold promise for extending drug release from matrix tablets.

Formulation and Evaluation of LornoxicamEmulgel [10,14-15]:

The transdermal route of medication delivery is considered efficient for various reasons. In this study, the objective was to develop a systemic Lornoxicam emulgel while minimizing side effects and dosing frequency. Lornoxicam, a COX-1 and COX-2 inhibitor (NSAID), is commonly used to manage rheumatoid arthritis and associated pain and inflammation.

The Lornoxicam emulgel was formulated using triethanolamine (5 %) as the solvent, along with gelling agents such as Carbopol 934 and Carbopol 940, and various preservatives. The composition of the gel was evaluated based on several physicochemical factors, including pH, viscosity, and drug content percentage. Desirable physical characteristics encompassed homogeneity, color, consistency, pH value, grittiness, spreadability, and the percentage of drug content in each emulgel batch. In vitro drug release studies revealed that

the emulgel containing Carbopol 940 (0.4 gm) exhibited superior drug release. Moreover, the concentration of the gelling agent was identified as the primary determinant affecting drug release from the emulgel formulation.

Formulation and Evaluation of Oral Disintegrating Tablet of Lornoxicam [11-15]:

Oral disintegrating tablets (ODTs) are increasingly favored, particularly among elderly and young patients with difficulty swallowing. Lornoxicam (LX), a potent enolic acid (oxicam) derivative, is commonly prescribed for conditions like sciatica, osteoarthritis, inflammatory joint diseases, and post-surgical pain. However, its poor water solubility leads to suboptimal gastrointestinal absorption and bioavailability. Therefore, this study aimed to develop an oral disintegrating tablet of Lornoxicam using a mixture of croscarmellose and croscarmellose super disintegrating agent (CM).

Various weight ratios of croscarmellose were combined with Lornoxicam, ranging from 1:0.5 to 1:1.5. The ratio of Lornoxicam to CM (1:1.5) that exhibited the fastest dissolution rate was selected, and tablets were prepared using a wet granulation process. After evaluating multiple formulations, the ODT formulation with the best characteristics was chosen, featuring a disintegration time of 12 s, hardness of 3.6 kg/cm^2, friability of 0.8 %, and cumulative percent drug release of 99.62 % within 30 min.

Formulation Development and Evaluation of Osmotic Drug Delivery System for Lornoxicam [16-17]:

Osmotic drug delivery systems are reliable methods for controlled oral medication administration, functioning on the principle of osmotic pressure to release medication under controlled conditions. These systems typically consist of an osmotic pump tablet (OPT) containing the drug, osmotic agents, excipients, and a semipermeable membrane coating. This study aimed to develop an osmotic drug delivery system for Lornoxicam, employing two different formulation approaches: basic osmotic tablets and controlled porosity osmotic tablets.

Comparison between the first controlled porosity osmotic tablet and a standard osmotic tablet coated with water-soluble pore-forming polymers involved evaluating parameters such as appearance, weight uniformity, drug content, hardness, and drug release. The effects of various osmotic agents (e.g., sodium chloride, mannitol) and different concentrations of pore former (e.g., sorbitol) were also investigated. In the basic osmotic tablet, sodium chloride served as the osmotic agent, coated with a cellulose acetate semipermeable membrane containing a critical-sized orifice for drug release.

The release of Lornoxicam was found to be influenced by the concentration of the osmotic agent, the level of the pore former, and the thickness of the coating membrane. The developed formulation, the controlled porosity osmotic tablet of Lornoxicam (CPOP), exhibited zero-order release over 12 hours. This study demonstrates the potential of the Lornoxicam controlled porosity osmotic pump tablet for regulating drug release over a 12 h period.

Formulation and Evaluation of Mini-Tablets-Filled-Pulsincap Delivery of Lornoxicamin The Chronotherapeutic Treatment of Rheumatoid Arthritis [18-21]:

So far, no prior studies have explored the combination of mini- tablets and pulsincap, as developed in our research. Our aim was to optimize a pulsincap formulation to effectively treat rheumatoid arthritis with Lornoxicam, aligning with the disease's chronotherapeutic rhythm. Mini-tablets were manufactured through direct compression, following preformulation testing to assess drug-polymer compatibility and mini-tablet stability, dissolution, and physicochemical properties.

FTIR and DSC analysis revealed no interactions between the drug and polymers used. All physicochemical parameters of the mini-tablets fell within acceptable limits. Lornoxicam mini-tablets were housed in insoluble capsule bodies, with the orifice sealed by a polymer stopper. An enteric coating was applied to the entire capsule body after sealing. Various polymers and concentrations were tested to find the optimal plug, resulting in a 5 h lag time when paired with a 5 % CAP coating. Plugs containing 30 % HPMC-K100M and 40 % sodium alginate demonstrated the most suitable characteristics.

CONCLUSION

The proposed bi-layer tablets, as per Metkar Vishal*et al*., consist of an immediate-release layer and a sustained-release layer. This design aims to ensure quick drug release in the stomach for rapid symptom relief, followed by sustained release in the intestine for prolonged analgesic effects. The transdermal anti-inflammatory gels developed by the group led by Manish Mukati employed various polymers and

Lornoxicam. Their rheological properties, including viscosity and spreadability, as well as pH and drug content, were evaluated and found satisfactory. Pluronic Lecithin Organogel (PLO) gel outperformed Carbopol gel in the study.

Water-soluble and oil-soluble suppository bases were utilized for crafting Lornoxicam suppositories, as detailed by Pushkar Baviskar*et al.* and Misal, Nilesh V. *et al*. The main objective of the research on tablet for mouth dissolving, as outlined by Saitejaswi, R. *et al*., was to develop a repeatable fast-dissolving tablet formulation of Lornoxicam to enhance drug efficacy and mitigate side effects such as gastric discomfort.

Transdermal matrix patches, as discussed by Bhumi B. Patel *et al*., represent discrete dosage forms applied to intact skin to facilitate controlled drug delivery to the systemic circulation. Transfersomes, demonstrated in the study by Asim Pasha *et al*., exhibit promising stability features and offer potential as a long-term delivery method for Lornoxicam via transdermal administration.

The study led by Sonali P. Mahaparale focused on developing sustained-release matrix tablets of Lornoxicam to ensure long-term production. Likewise, the research led by Patil, Supriya C. *et al.* aimed to create a systemic Lornoxicam emulgel to minimize side effects and dosing frequency.

Oral disintegrating tablets (ODTs), increasingly popular among elderly and young patients with swallowing difficulties, were investigated by Muhammad Syed Shoaeb, *et a*l. Lastly, osmotic drug delivery systems, discussed by Abdul Hadi Mohd, *et al*., are considered reliable for controlled drug release under controlled osmotic pressure conditions.

To our knowledge, our study is the first to integrate mini-tablets and pulsincap technology, aiming to fulfill ideal pulsincap formulation specifications effectively.

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