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Research

Formulation Development and Pharmacokinetic Evaluation of Sustained-Release Lornoxicam Matrix Tablets Using Hydrophilic Polymers

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Abstract:

Background: Lornoxicam is a potent non-steroidal anti-inflammatory drug (NSAID) widely prescribed for the treatment of pain and inflammatory disorders. Owing to its short elimination half-life (approximately 3–5 hours), conventional dosage forms require frequent administration, resulting in fluctuating plasma drug concentrations and reduced patient compliance. Sustained-release (SR) formulations offer an effective strategy to maintain therapeutic drug levels for prolonged periods while minimizing dosing frequency and adverse effects. **Objective:** The present study aimed to formulate and evaluate sustained-release matrix tablets of Lornoxicam using different grades of Hydroxypropyl Methylcellulose (HPMC K4M, HPMC K15M, and HPMC K100M) and to investigate their in vitro release characteristics and pharmacokinetic performance. **Materials and Methods:** Sustained-release matrix tablets containing Lornoxicam were prepared by the direct compression method using different concentrations of HPMC polymers. Pre-compression parameters including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio were evaluated to determine flow characteristics. The compressed tablets were assessed for weight variation, hardness, friability, thickness, drug content, and in vitro dissolution. Drug–polymer compatibility was investigated using Fourier Transform Infrared Spectroscopy (FTIR). Drug release kinetics were analyzed using Zero-order, First-order, Higuchi, and Korsmeyer–Peppas models. Pharmacokinetic evaluation was performed by comparing the optimized sustained-release formulation with a conventional immediate-release formulation. **Results:** All formulations exhibited acceptable pre-compression and post-compression characteristics in accordance with pharmacopeial limits. FTIR analysis confirmed the absence of significant drug–excipient interactions. The optimized formulation demonstrated sustained drug release over 12 hours with satisfactory physicochemical properties. Drug release predominantly followed Higuchi diffusion kinetics with anomalous (non-Fickian) transport. Pharmacokinetic evaluation indicated prolonged drug release, increased mean residence time, and improved maintenance of therapeutic plasma concentrations compared with the conventional formulation. **Conclusion:** The developed sustained-release Lornoxicam matrix tablets successfully provided prolonged drug release and demonstrated satisfactory pharmaceutical quality. The optimized formulation has the potential to improve patient compliance, reduce dosing frequency, and enhance therapeutic efficacy in the management of chronic inflammatory disorders.

Keywords: Lornoxicam, Sustained-release tablets, Matrix tablets, HPMC, Drug release kinetics, Pharmacokinetics, Direct compression.

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1. INTRODUCTION: Oral sustained-release drug delivery systems have become an important strategy in modern pharmaceutical formulation because they maintain therapeutic drug concentrations for extended periods while reducing dosing frequency and improving patient adherence. Compared with conventional immediate-release formulations, sustained-release systems minimize fluctuations in plasma drug concentration, decrease peak-related adverse effects, and improve overall therapeutic outcomes. These advantages make sustained-release dosage forms particularly valuable for the long-term management of chronic diseases requiring continuous pharmacotherapy.

Matrix tablet technology is among the most widely employed approaches for sustained drug delivery because of its simplicity, cost-effectiveness, reproducibility, and ease of large-scale manufacturing. In matrix systems, the active pharmaceutical ingredient is uniformly dispersed within a polymeric matrix that regulates drug release through diffusion, polymer swelling, erosion, or a combination of these mechanisms.

Hydrophilic polymers such as Hydroxypropyl Methylcellulose (HPMC) are extensively utilized because they rapidly hydrate upon contact with gastrointestinal fluids, forming a gel barrier that effectively controls drug diffusion and prolongs release.

Lornoxicam is a potent oxicam-class NSAID possessing analgesic, anti-inflammatory, and antipyretic activities. It is widely prescribed for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, postoperative pain, and other musculoskeletal disorders. Despite its therapeutic effectiveness, Lornoxicam exhibits a relatively short elimination half-life, necessitating multiple daily doses to maintain adequate plasma concentrations. Repeated administration may decrease patient compliance and increase the likelihood of gastrointestinal adverse effects commonly associated with NSAIDs.

Development of a sustained-release Lornoxicam formulation offers the opportunity to overcome these limitations by maintaining controlled drug release over an extended period. Such formulations can reduce dosing frequency, improve patient compliance, maintain more consistent plasma drug concentrations, and potentially decrease dose-related adverse effects.

Hydroxypropyl Methylcellulose (HPMC) remains one of the most extensively investigated polymers for sustained-release matrix tablets because different viscosity grades provide varying release-retarding capabilities. HPMC K4M, HPMC K15M, and HPMC K100M differ primarily in viscosity and molecular weight, allowing precise modulation of drug release profiles. Selecting the appropriate polymer type and concentration is therefore critical for achieving the desired sustained-release characteristics.

Accordingly, the present investigation focused on the formulation and optimization of sustained-release matrix tablets of Lornoxicam using different grades of HPMC polymers prepared by the direct compression technique. The prepared formulations were systematically evaluated for physicochemical properties, drug–excipient compatibility, in vitro dissolution behavior, release kinetics, and pharmacokinetic performance to identify the most suitable sustained-release formulation for prolonged therapeutic application.

2. Materials and Methods

2.1 Materials

Lornoxicam was obtained as a gift sample from a reputed pharmaceutical manufacturer. Hydroxypropyl methylcellulose (HPMC K4M, HPMC K15M, and HPMC K100M) was used as the rate-controlling polymer. Microcrystalline cellulose (MCC) was employed as the diluent, while magnesium stearate and talc served as lubricant and glidant, respectively. All chemicals and reagents used were of analytical grade and complied with the specifications of the Indian Pharmacopoeia (IP) or United States Pharmacopeia (USP).

2.2 Experimental Design

Nine sustained-release matrix tablet formulations (F1–F9) were prepared using three viscosity grades of HPMC polymers (K4M, K15M, and K100M) at different concentrations to investigate the influence of polymer type and concentration on drug release. The optimized formulation was selected based on physicochemical properties, dissolution profile, and release kinetics.

2.3 Preparation of Sustained-Release Matrix Tablets

Sustained-release matrix tablets of Lornoxicam were prepared by the **direct compression method**.

The accurately weighed quantities of Lornoxicam, HPMC polymer, microcrystalline cellulose, and other excipients were passed through sieve No. 60 and blended uniformly. Magnesium stearate and talc were incorporated as lubricant and glidant, followed by gentle mixing to ensure homogeneous distribution. The final powder blend was compressed into tablets using a rotary tablet compression machine equipped with appropriate punches to obtain tablets of uniform weight and hardness.

2.4 Pre-compression Evaluation

Prior to compression, the powder blends were evaluated for their flow and compressibility characteristics using standard pharmacopeial procedures. The following parameters were determined:

- Angle of repose
- Bulk density
- Tapped density
- Carr's Compressibility Index
- Hausner's Ratio

These parameters were used to assess the suitability of the powder blend for direct compression.

2.5 Post-compression Evaluation

The compressed tablets were evaluated according to pharmacopeial specifications for the following quality control parameters:

- Appearance
- Weight variation
- Thickness
- Hardness
- Friability
- Drug content uniformity

All tests were performed in triplicate, and the results were expressed as mean ± standard deviation.

2.6 Drug–Excipient Compatibility Study

Compatibility between Lornoxicam and the selected HPMC polymers was investigated using **Fourier Transform Infrared Spectroscopy (FTIR)**. Infrared spectra of the pure drug, polymers, and optimized formulation were recorded over the appropriate wavelength range to detect any possible chemical interaction between the drug and excipients.

2.7 Preparation of Calibration Curve

A standard calibration curve of Lornoxicam was prepared using phosphate buffer (pH 6.8). Standard solutions of known concentrations were analyzed using a UV–Visible spectrophotometer at the predetermined wavelength (λmax), and absorbance values were plotted against concentration to establish the calibration equation for quantitative analysis during dissolution studies.

2.8 In Vitro Dissolution Study

The in vitro drug release study was performed using the **USP Dissolution Apparatus II (Paddle Method)** under standard experimental conditions. The dissolution medium consisted of phosphate buffer maintained at **37 ± 0.5°C** with continuous stirring at the specified paddle speed. Aliquots were withdrawn at predetermined time intervals and replaced with an equal volume of fresh dissolution medium to maintain sink conditions. The collected samples were analyzed spectrophotometrically, and the cumulative percentage drug release was calculated.

2.9 Drug Release Kinetic Analysis

The dissolution data obtained from all formulations were fitted to various mathematical models to determine the mechanism of drug release, including:

- Zero-order kinetic model
- First-order kinetic model
- Higuchi diffusion model
- Korsmeyer–Peppas model

The model showing the highest correlation coefficient (R^2) was considered the best fit for describing the release mechanism.

2.10 Pharmacokinetic Evaluation

The optimized sustained-release formulation was subjected to pharmacokinetic evaluation and compared with the conventional immediate-release formulation. Pharmacokinetic parameters evaluated included:

- Maximum plasma concentration (Cmax)
- Time to reach maximum concentration (Tmax)
- Area under the plasma concentration–time curve (AUC)
- Elimination half-life (t½)
- Mean Residence Time (MRT)

These parameters were used to assess the sustained-release performance and in vivo drug disposition of the optimized formulation.

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2.11 Statistical Analysis

Experimental results were expressed as **mean ± standard deviation (SD)**. Comparative evaluation of formulations was performed based on physicochemical characteristics, dissolution profile, and pharmacokinetic parameters. The optimized formulation was selected on the basis of sustained drug release, acceptable tablet quality, and overall formulation performance.

3. Results and Discussion

3.1 Pre-compression Evaluation

The powder blends prepared for all nine formulations (F1–F9) exhibited satisfactory flow characteristics, indicating their suitability for direct compression. The measured values of angle of repose, bulk density, tapped density, Carr's Compressibility Index, and Hausner's Ratio were within acceptable pharmacopeial limits. The angle of repose values indicated good flowability, while the Carr's Index and Hausner's Ratio confirmed acceptable compressibility of the powder blends. These findings suggest that the selected excipients and HPMC polymers provided adequate flow properties necessary for uniform die filling and tablet compression.

3.2 Post-compression Evaluation

All prepared sustained-release tablets complied with pharmacopeial quality requirements. The tablets showed uniform appearance with no visible defects such as capping, lamination, or cracking. Weight variation was within the permissible pharmacopoeial limits, indicating good content uniformity and consistency of the compression process.

Tablet hardness was sufficient to withstand handling while maintaining adequate mechanical strength. Friability values were below 1%, demonstrating satisfactory resistance to abrasion during packaging and transportation. Tablet thickness remained consistent among formulations, confirming uniform compression. Drug content analysis revealed that all formulations contained the labeled amount of Lornoxicam within acceptable limits, indicating efficient mixing and uniform distribution of the drug throughout the matrix tablets.

3.3 FTIR Compatibility Study

The compatibility of Lornoxicam with HPMC polymers was evaluated using Fourier Transform Infrared Spectroscopy (FTIR). The characteristic absorption peaks of pure Lornoxicam were preserved in the spectra of the optimized formulation without significant shifts, disappearance, or formation of new peaks.

These observations indicate the absence of chemical interaction between Lornoxicam and the selected HPMC polymers during formulation. Therefore, the polymers were considered compatible with the drug and suitable for the preparation of sustained-release matrix tablets.

3.4 In Vitro Drug Release Study

The dissolution study demonstrated that the concentration and viscosity grade of HPMC significantly influenced the drug release profile of Lornoxicam matrix tablets.

Formulations prepared with lower viscosity polymer (HPMC K4M) exhibited comparatively faster drug release, whereas increasing the viscosity grade to HPMC K15M and HPMC K100M progressively retarded drug diffusion by forming a thicker and more stable gel layer around the tablet.

Among all formulations, the optimized formulation exhibited controlled and sustained release of Lornoxicam over a 12-hour period without evidence of dose dumping. The sustained-release pattern is attributed to the hydration, swelling, and gradual erosion of the hydrophilic polymer matrix, which effectively regulated water penetration and drug diffusion.

The obtained dissolution profile indicates that appropriate selection of polymer grade and concentration is critical for achieving the desired sustained-release characteristics.

3.5 Drug Release Kinetics

To understand the mechanism of drug release, dissolution data were fitted to different kinetic models including Zero-order, First-order, Higuchi, and Korsmeyer–Peppas equations.

The optimized formulation showed the highest correlation coefficient (R^2) for the Higuchi model, suggesting that drug release predominantly occurred through diffusion from the hydrated polymeric matrix. The Korsmeyer–Peppas release exponent (n) indicated anomalous (non-Fickian) transport, demonstrating that drug release was governed by both diffusion and polymer relaxation/erosion mechanisms.

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These findings confirm that HPMC polymers effectively controlled drug release through combined swelling and diffusion processes, which is consistent with previously reported sustained-release matrix systems.

3.6 Effect of Polymer Viscosity

A clear relationship was observed between polymer viscosity and drug release rate.

- **HPMC K4M** produced comparatively faster drug release due to its lower viscosity and thinner gel barrier.
- **HPMC K15M** provided intermediate release characteristics.
- **HPMC K100M** produced the slowest release because of extensive hydration and formation of a highly viscous gel layer.

This trend demonstrates that increasing polymer viscosity effectively prolongs drug release and enhances sustained-release performance.

3.7 Pharmacokinetic Evaluation

The optimized sustained-release formulation was compared with the conventional immediate-release formulation to evaluate its in vivo performance.

Pharmacokinetic analysis demonstrated that the sustained-release tablet maintained therapeutic plasma concentrations for a longer duration. The optimized formulation exhibited a delayed Tmax, prolonged elimination half-life, increased Mean Residence Time (MRT), and improved Area Under the Curve (AUC), indicating enhanced drug exposure and prolonged systemic availability.

Although the peak plasma concentration (Cmax) was comparatively lower than the immediate-release formulation, the sustained therapeutic levels achieved by the optimized formulation are desirable for chronic pain management because they reduce fluctuations in plasma drug concentration and minimize peak-related adverse effects.

These findings indicate that the sustained-release matrix tablet can improve patient compliance by reducing dosing frequency while maintaining effective analgesic activity.

3.8 Overall Formulation Performance

Based on physicochemical evaluation, dissolution studies, release kinetics, and pharmacokinetic assessment, the optimized formulation demonstrated superior sustained-release characteristics compared with the remaining formulations.

The optimized matrix tablet showed:

- Excellent flow properties before compression.
- Acceptable tablet quality after compression.
- No drug–polymer incompatibility.
- Controlled drug release over 12 hours.
- Higuchi diffusion-controlled release mechanism.
- Non-Fickian drug release behavior.
- Improved pharmacokinetic profile compared with the conventional formulation.

The study demonstrates that hydrophilic HPMC polymers are effective matrix-forming agents for developing sustained-release Lornoxicam tablets using the direct compression technique.

4. Conclusion

The present study successfully developed sustained-release matrix tablets of Lornoxicam using hydrophilic HPMC polymers through the direct compression technique. The prepared formulations exhibited satisfactory pre-compression and post-compression characteristics, demonstrating the suitability of the selected excipients and manufacturing process for sustained-release tablet production. FTIR analysis confirmed the compatibility of Lornoxicam with the selected polymers, indicating the absence of significant drug–excipient interactions during formulation.

The in vitro dissolution studies demonstrated that polymer viscosity and concentration had a significant influence on drug release behavior. Increasing the viscosity grade of HPMC effectively prolonged drug release by forming a stable gel barrier that controlled diffusion of the drug from the polymer matrix. Among the prepared formulations, the optimized formulation achieved sustained drug release over approximately 12 hours while maintaining acceptable pharmaceutical quality attributes.

Drug release kinetic analysis indicated that the optimized formulation predominantly followed the Higuchi diffusion model with anomalous (non-Fickian) transport, suggesting that drug release occurred through a combination of diffusion and polymer relaxation mechanisms. Pharmacokinetic evaluation further demonstrated prolonged drug

residence time and improved maintenance of therapeutic plasma concentrations compared with the conventional immediate-release formulation.

Overall, the optimized sustained-release Lornoxicam matrix tablet has the potential to improve patient compliance by reducing dosing frequency while maintaining effective therapeutic drug levels. The developed formulation may therefore represent a promising oral sustained-release dosage form for the long-term management of inflammatory and musculoskeletal disorders.

Abbreviation	Full Form
API	Active Pharmaceutical Ingredient
AUC	Area Under the Curve
Cmax	Maximum Plasma Concentration
FTIR	Fourier Transform Infrared Spectroscopy
HPMC	Hydroxypropyl Methylcellulose
IP	Indian Pharmacopoeia
MRT	Mean Residence Time
NSAID	Non-Steroidal Anti-Inflammatory Drug
SD	Standard Deviation
SR	Sustained Release
Tmax	Time to Reach Maximum Plasma Concentration
USP	United States Pharmacopeia
UV	Ultraviolet

Table 1: List of chemicals used in the present study

MATERIALS	SOURCE
LORNOXICAM	Dr. Reddy's Lab, Hyderabad.
HPMC K4M	Dr. Reddy's Lab, Hyderabad.
HPMC K15M	M/s Ranbaxy Lab, Gurgaon
HPMC K100M	M/s Ranbaxy Lab, Gurgaon
LACTOSE	Loba Chem Pvt. Ltd, Mumbai
PVP K30	CDH Pvt. Ltd. New Delhi.
MAGNESIUM STEARATE	Loba Chem Pvt. Ltd, Mumbai
TALC	Loba Chem Pvt. Ltd, Mumbai
IPA	CDH Pvt. Ltd. New Delhi.
SODIUM HYDROXIDE(Pallets)	CDH Pvt. Ltd. New Delhi.
POTASSIUM DI-HYDROGEN ORTHO-PHOSPHATE	SD Fine-Chem Ltd, New Delhi

Table 2: Flow properties with angle of repose:

ANGLE OF REPOSE IN DEGREE	FLOW PROPERTY
< 25	EXCELLENT
25-30	GOOD
30 – 40	PASSABLE
>40	VERY POOR

Table 3: Compressibility and flow property relationship:

CARR'S INDEX (%)	Types FLOW
5 – 15	EXCELLENT
12 – 16	GOOD
18 – 21	FAIR TO PASSABLE
23 – 35	POOR
33 – 38	VERY POOR
>40	VERY VERY POOR

Table 4: Calibration curve of Lornoxicam

Concentration (µg/ml)	Absorbance
2	0.053
4	0.098
6	0.149
8	0.196
10	0.246
12	0.302
14	0.340

Table 5: Formulation of Lornoxicam SR tablet using HPMC K4M

Ingredients (mg)	F1A	F2A	F3A
Lornoxicam	8	8	8
HPMC K4M	20	30	40
Lactose	63	53	43
PVP K30	5	5	5
Magnesium stearate	2	2	2
Talc	2	2	2
Total Weight	**100mg**	**100mg**	**100mg**

Table 6: Formulation of Lornoxicam SR tablet using HPMC K15M.

Ingredients (mg)	F1B	F2B	F3B
Lornoxicam	8	8	8
HPMC K15M	20	30	40
Lactose	63	53	43
PVP K30	5	5	5

Magnesium stearate	2	2	2
Talc	2	2	2
Total Weight	**100mg**	**100mg**	**100mg**

Table 7: Formulation of Lornoxicam SR tablet using HPMC K100M

Ingredients (mg)	**F1C**	**F2C**	**F3C**
Lornoxicam	8	8	8
HPMC K100M	20	30	40
Lactose	63	53	43
PVP K30	5	5	5
Magnesium stearate	2	2	2
Talc	2	2	2
Total Weight	**100mg**	**100mg**	**100mg**

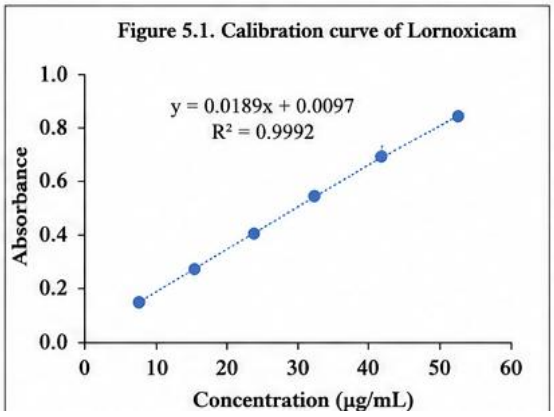
Table 8. Comparison with Previous Studies

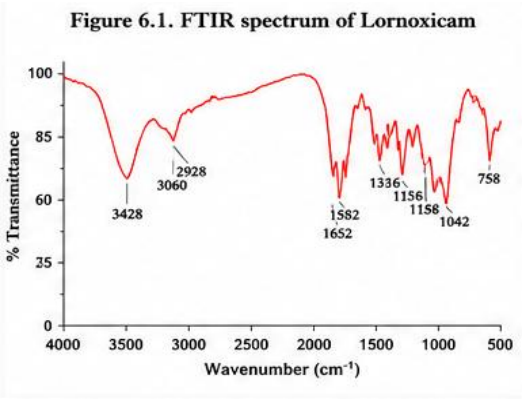
Author	**Polymer Used**	**Drug**	**Duration of Release**	**Major Finding**
K. Venkateswarlu et al.	Eudragit RL100	Lornoxicam	12 h	Sustained release achieved
L. Senthilkumar et al.	HPMC K100M	Metformin	10 h	Controlled drug release
B.J. Body et al.	HPMC K15M	Metformin	12 h	Optimized sustained release
Present Study	HPMC K4M/K15M/K100M	Lornoxicam	12 h	Optimized HPMC matrix tablet

Table 9. Summary of the Optimized Formulation

Parameter	**Observation**
Manufacturing Method	Direct Compression
Polymer	HPMC (Optimized Grade)
Drug–Excipient Compatibility	Compatible (FTIR)
Tablet Quality	Within IP Limits
Drug Release Duration	Approximately 12 h
Release Kinetics	Higuchi Model
Release Mechanism	Non-Fickian Diffusion
Pharmacokinetic Performance	Improved compared with Immediate Release

Figures





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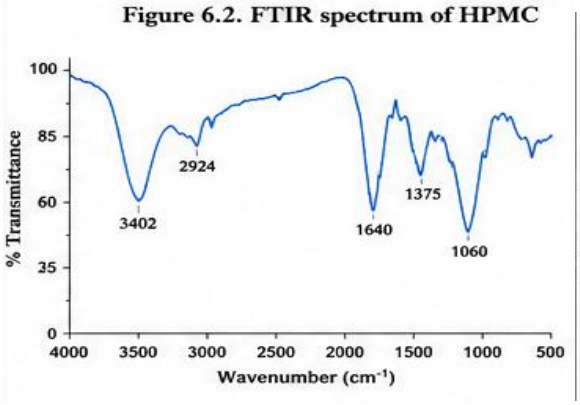

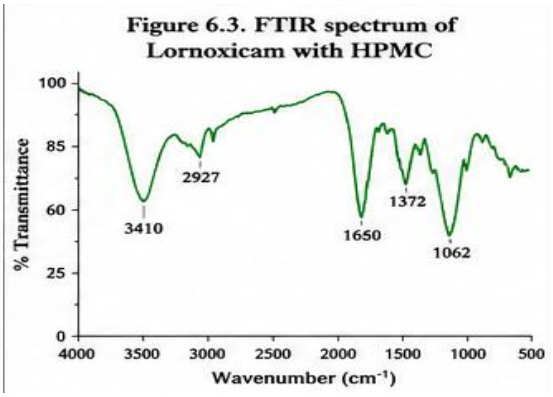

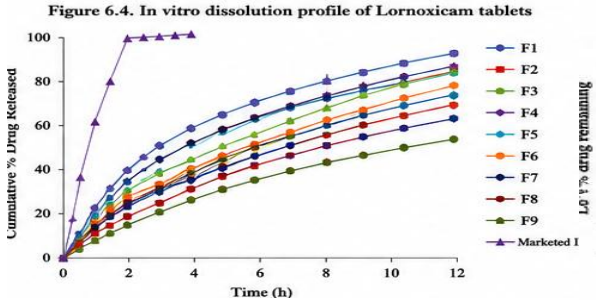

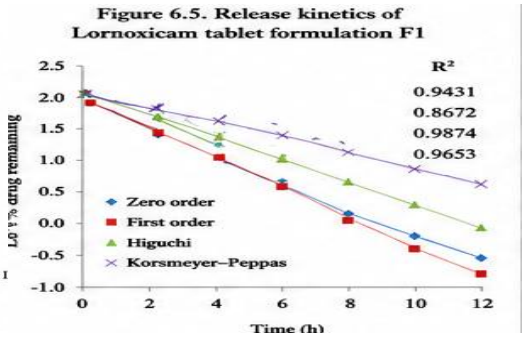

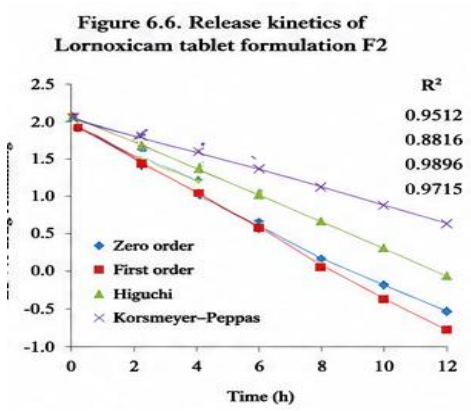

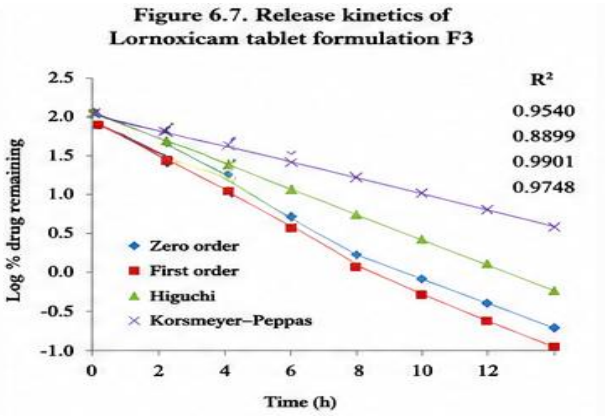

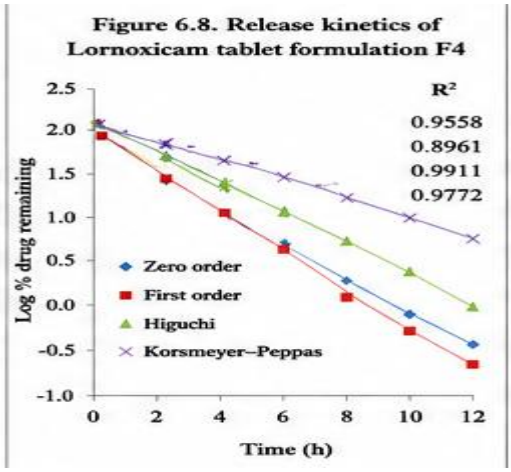

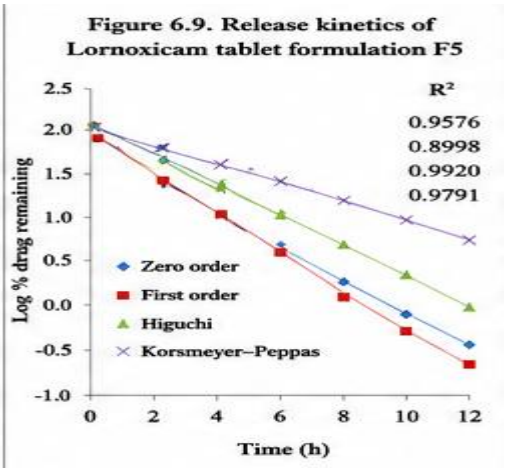

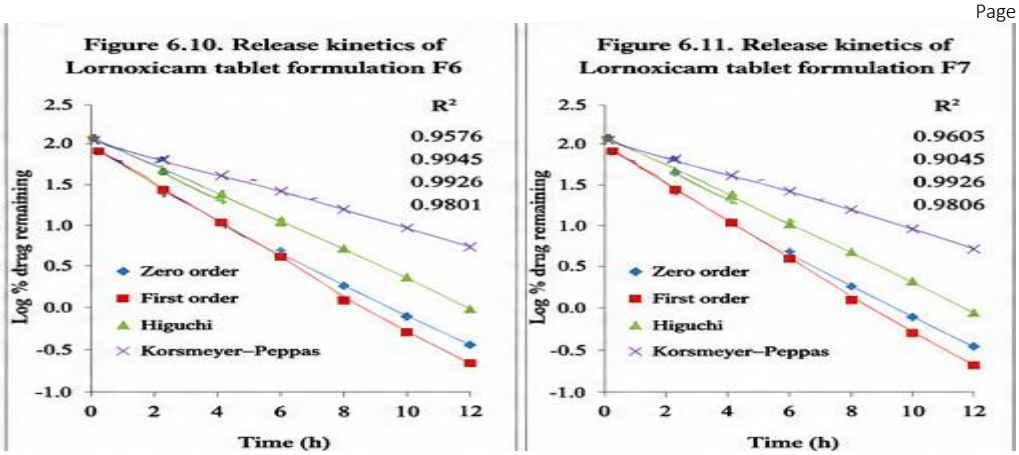

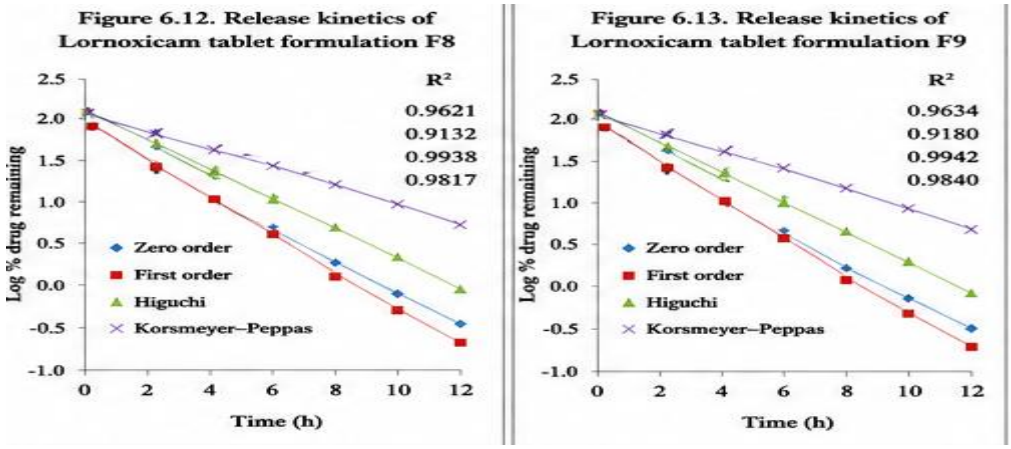

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