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FORMULATION AND EVALUATION OF SUSTAINED RELEASE MATRIX TABLETS OF EPERISONE HYDROCHLORIDE USING HYDROPHILIC POLYMER SYSTEM

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ABSTRACT

The present study aimed to formulate and evaluate sustained release matrix tablets of Eperisone Hydrochloride using hydrophilic polymer systems to prolong drug release and improve patient compliance. Six formulations (F1–F6) were developed by varying polymer concentrations while maintaining a constant drug load. Preformulation studies including organoleptic evaluation, solubility analysis, melting point determination, partition coefficient, pH determination, and UV spectrophotometric analysis were performed. The prepared granules were evaluated for flow properties, while compressed tablets were assessed for weight variation, thickness, hardness, friability, drug content, and in-vitro drug release. The results demonstrated acceptable physicochemical properties and good flow characteristics. Drug release studies revealed that increasing polymer concentration significantly retarded drug release. Formulation F4 exhibited optimum sustained release behavior with approximately 95% drug release over 12 hours and was selected as the optimized formulation. Drug release kinetics indicated Higuchi diffusion-controlled release with non-Fickian transport behavior. Stability studies confirmed the stability of the optimized formulation under accelerated storage conditions. The study concluded that HPMC K100M is an effective hydrophilic polymer for developing sustained release matrix tablets of Eperisone Hydrochloride.

KEYWORDS: Eperisone Hydrochloride, Sustained Release Matrix Tablet, HPMC K100M, Hydrophilic Polymer, Drug Release Kinetics, Wet Granulation.

INTRODUCTION

Oral sustained release drug delivery systems have gained considerable attention due to their ability to maintain therapeutic drug concentrations for extended periods, reduce dosing frequency, and improve patient compliance. Matrix tablets represent one of the most widely used approaches for sustained drug delivery because of their simplicity, cost-effectiveness, and reproducibility.

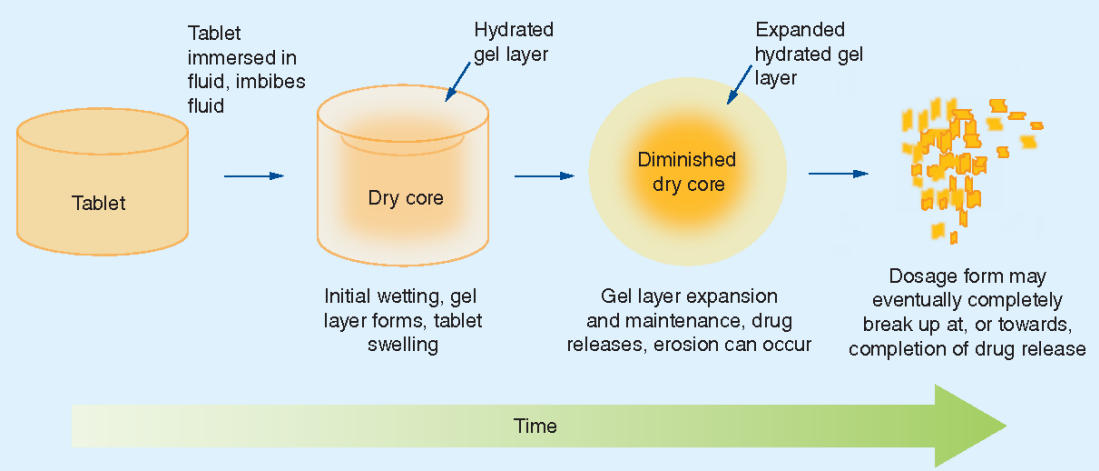


Fig. 1: Mechanism of Drug Release from Matrix Tablets.

Eperisone Hydrochloride is a centrally acting muscle relaxant used in the management of muscle spasticity and musculoskeletal disorders. The drug possesses a relatively short biological half-life of approximately 1.6–3 hours, necessitating frequent administration. Therefore, the development of a sustained release formulation can improve therapeutic efficacy while minimizing fluctuations in plasma drug concentration.

Hydrophilic polymers such as Hydroxypropyl Methylcellulose (HPMC) are extensively employed in matrix tablet formulations because of their ability to form a gel barrier that controls drug diffusion and erosion. The present study was undertaken to formulate and evaluate sustained release matrix tablets of Eperisone Hydrochloride using HPMC K100M as a hydrophilic matrix-forming polymer.

2. MATERIALS AND METHODS

Materials

1.1 Drug

Eperisone hydrochloride

Category:

Centrally acting muscle relaxant

Mechanism of Action

Eperisone acts on the central nervous system, particularly the spinal cord, to:

- Inhibit reflex pathways
- Reduce muscle stiffness and spasm
- Improve blood circulation in skeletal muscles

IUPAC Name:

(2RS)-1-(4-ethylphenyl)-2-methyl-3-(piperidin-1-yl)propan-1-one hydrochloride

- **Molecular Formula:**

$C_{17}H_{25}NO \cdot HCl$

- **Molecular Weight:**

295.85 g/mol

Pharmacokinetic Properties

- Half-life: ~1.6–3 hours
- Bioavailability: Moderate (subject to first-pass metabolism)
- Absorption: Rapid after oral administration
- Metabolism: Liver
- Elimination: Urine

1.2 Polymers (Hydrophilic Matrix Formers)

- Hydroxypropyl Methylcellulose K100M
- Carbopol 934P
- Sodium Carboxymethyl Cellulose
- Xanthan Gum

1.3 Excipients

- Microcrystalline Cellulose – Diluent
- Lactose – Diluent
- Polyvinylpyrrolidone (K30) – Binder
- Magnesium Stearate – Lubricant
- Talc – Glidant

1.4 Chemicals and Reagents

- 0.1N Hydrochloric Acid
- Phosphate Buffer pH 6.8
- Distilled Water

Method

2.1 Preformulation Studies

A. Organoleptic Evaluation

Method:

Drug sample was visually inspected for color, odor, and appearance.

- Color
- Odor
- Appearance

B. Solubility Study

- Excess drug was added to different solvents (water, methanol, ethanol, pH 1.2, pH 6.8 buffer).
- Shaken for 24 hrs and filtered.
- Concentration determined spectrophotometrically.

C. Melting Point Determination

A small amount of finely powdered Eperisone Hydrochloride is filled into a capillary tube sealed at one end. The capillary is placed in a melting point apparatus and heated gradually. The temperature at which the drug starts melting and completely liquefies is recorded.

D. Partition Coefficient (Log P)

A known amount of drug is added to a mixture of n-octanol and water in a separating funnel. The system is shaken vigorously and allowed to equilibrate (usually 24 hours). After phase separation, samples from both layers are collected. Drug concentration in each phase is analyzed (UV spectrophotometer). The partition coefficient (Log P) is calculated as the ratio of drug concentration in octanol to that in water.

E. pH Determination

Method:

- 1% w/v solution prepared in distilled water
- Measured using digital pH meter

F. UV Spectrophotometric Analysis (λmax)

A stock solution of Eperisone Hydrochloride is prepared in a suitable solvent (e.g., methanol or phosphate buffer). The solution is scanned in the UV spectrophotometer over a wavelength range of **200–400 nm** against a blank. The wavelength at which maximum absorbance is observed is recorded as λmax.

2.2 Formulation of Sustained Release Matrix Tablets

Table No. 1: Composition of the Sustained Release Matrix Tablets.

Ingredient	F1	F2	F3	F4	F5	F6
Drug	100 mg	100 mg	100 mg	100 mg	100 mg	100mg
HPMC K100M	40 mg	60 mg	80 mg	100 mg	120 mg	130mg
Lactose	130 mg	110 mg	90 mg	70 mg	50 mg	40mg
MCC	20 mg	20 mg	20 mg	20 mg	20 mg	20 mg
Mg Stearate	5 mg	5 mg	5 mg	5 mg	5 mg	5 mg
Talc	5 mg	5 mg	5 mg	5 mg	5 mg	5 mg
Total	300 mg	300 mg	300 mg	300 mg	300 mg	300 mg

Method of Preparation

Sustained release matrix tablets of Eperisone Hydrochloride were prepared by the wet granulation method. All the ingredients required for formulation were accurately weighed according to the designed batches (F1–F6), in which the concentration of hydrophilic polymer was varied to study its effect on drug release.

The drug, hydrophilic polymer (such as HPMC), and diluent were passed through a suitable sieve (No. 40) to ensure uniform particle size and then mixed thoroughly in a mortar or mechanical blender to obtain a homogeneous powder mixture. A binder solution was prepared separately by dissolving an appropriate quantity of polyvinylpyrrolidone (PVP K30) in distilled water.

The prepared binder solution was added slowly to the powder blend with continuous mixing to form a coherent and damp mass. The wet mass obtained was then passed through sieve No. 12 to produce uniform granules. These granules were dried in a hot air oven maintained at 50–60°C until a constant weight was achieved, indicating complete removal of moisture.

After drying, the granules were passed through sieve No. 16 to break down aggregates and obtain uniform-sized granules. The dried granules were then lubricated by adding magnesium stearate and talc, followed by gentle mixing for a short duration to avoid over-lubrication.

Finally, the lubricated granules were compressed into tablets using a single punch or rotary tablet compression machine. The compression force was adjusted to obtain tablets with adequate hardness and mechanical strength suitable for sustained drug release.

3. Evaluation of Granules (Pre-Compression Parameters)

3.1 Angle of Repose

The angle of repose was determined by the fixed funnel method to assess the flow property of granules. A funnel was fixed at a certain height above a flat horizontal surface. The granules were allowed to flow freely through the funnel orifice onto the surface, forming a conical

heap. Care was taken to ensure that the funnel tip remained at a constant height and the powder flowed without interruption. The height (h) of the formed heap and the radius (r) of its base were measured.

The angle of repose (θ) was calculated using the formula:

$\tan\theta = h/r$

3.2 Bulk Density

Bulk density was determined by transferring a known quantity of granules into a clean, dry graduated measuring cylinder without compacting. The volume occupied by the granules (bulk volume) was noted. The weight of the granules was already known.

Bulk density was calculated using the formula:

Bulk Density=Weight of granules/Bulk volume

3.3 Tapped Density

Tapped density was determined by placing the measuring cylinder containing the granules on a tapped density apparatus. The cylinder was tapped mechanically (usually 500–1000 taps) until no further change in volume was observed. The final tapped volume was recorded.

Tapped density was calculated using the formula:

Tapped Density=Weight of granules/Tapped volume

3.4 Carr's Index

Carr's Index was calculated using the values of bulk density and tapped density obtained from the above experiments.

Carr's Index = [(Tapped density – Bulk density) / Tapped density] × 100

3.5 Hausner Ratio

Hausner ratio was calculated using bulk density and tapped density values.

Hausner Ratio = Tapped density / Bulk density

4. Evaluation of Tablets (Post-Compression Parameters)

4.1 Appearance

- Visual inspection.

4.2 Weight Variation

- 20 tablets weighed individually and average weight calculated.

4.3 Thickness

- Measured using Vernier caliper.

4.4 Hardness

- Measured using Monsanto hardness tester.

4.5 Friability

- Tested using Roche friabilator at 25 rpm for 4 minutes.

4.6 Drug Content Uniformity

- Tablets powdered and analyzed using UV spectrophotometer.

5. In-vitro Dissolution Study

Apparatus:

- USP Dissolution Apparatus Type II (Paddle)

Conditions:

- 900 ml dissolution medium
- 0.1N HCl for first 2 hours
- Phosphate buffer pH 6.8 for remaining time
- Temperature: 37 ± 0.5°C
- Speed: 50–75 rpm

Sampling:

- 5 ml samples withdrawn at predetermined intervals (1, 2, 4, 6, 8, 10, 12 hours)
- Replaced with fresh medium
- Analyzed using UV spectrophotometer

6. Drug Release Kinetics

- Dissolution data fitted into:
- Zero-order model
- First-order model
- To determine mechanism of drug release.

7. Stability Studies

- Conducted as per ICH guidelines under:
- 40°C ± 2°C
- 75% ± 5% RH
- Duration: 3 months

Parameters evaluated:

- Drug content
- Hardness
- Dissolution profile

3. RESULTS AND DISCUSSION

A. Preformulation Studies

1. Organoleptic Properties

Table No. 1: Organoleptic Properties.

Property	Observation
Color	White to off-white
Odor	Odorless
Appearance	Crystalline powder

2. Solubility Study

Table No. 2: Solubility Study.

Solvent	Solubility
Water	Slightly soluble
Methanol	Freely soluble
Ethanol	Soluble
pH 1.2 buffer	Moderate solubility
pH 6.8 buffer	Moderate solubility

3. Melting Point Determination

Table No.3: Melting Point Determination.

Parameter	Value
Melting Point	167–171°C

4. Partition Coefficient (Log P)

Table No. 4: Partition Coefficient. (Log P)

Parameter	Value
Log P	~2.5

5. pH Determination

Table No.5: pH Determination.

Parameter	Value
pH	5.5 – 6.5

6. UV Spectrophotometric Analysis (λmax)

Table No. 6: UV Spectrophotometric Analysis. (λmax)

Parameter	Value
λmax	259 nm

7. Calibration Curve

Table No. 7: Calibration Curve.

Concentration (µg/ml)	Absorbance
2	0.12
4	0.25
6	0.37
8	0.50
10	0.62

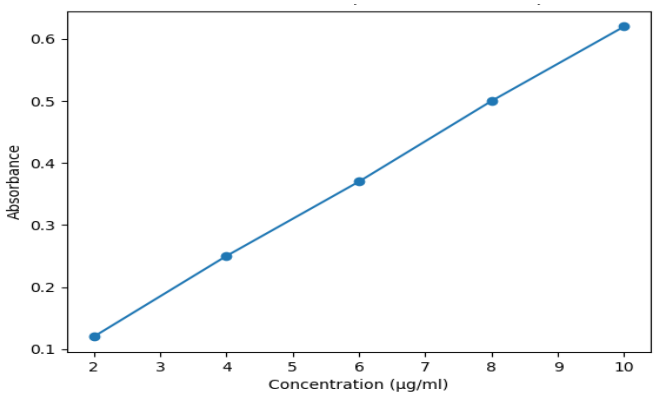


Fig. No. 2: Calibration Curve.

B. Evaluation of Granules (Pre-Compression Parameters)

1. Angle of Repose

Table No. 8: Angle of Repose.

Formulation	Angle of Repose (°)	Flow Property
F1	30.5	Good
F2	31.2	Good
F3	32.0	Good
F4	33.1	Good
F5	34.0	Fair
F6	34.8	Fair

2. Bulk Density

Table No. 9: Bulk Density.

Formulation	Bulk Density (g/cm³)
F1	0.41
F2	0.42
F3	0.43
F4	0.44
F5	0.45
F6	0.46

3. Tapped Density

Table No. 10: Tapped Density.

Formulation	Tapped Density (g/cm³)
F1	0.48
F2	0.49
F3	0.50
F4	0.52
F5	0.54
F6	0.55

4. Carr's Index

Table No. 11: Carr's Index.

Formulation	Carr's Index (%)	Flow Property
F1	14.5	Good
F2	14.3	Good
F3	14.0	Good
F4	15.3	Good
F5	16.6	Fair
F6	16.4	Fair

5. Hausner Ratio

Table No. 12: Hausner Ratio.

Formulation	Hausner Ratio	Flow Property
F1	1.17	Good
F2	1.16	Good
F3	1.16	Good
F4	1.18	Good
F5	1.20	Fair
F6	1.19	Fair

C. Evaluation of Tablets (Post-Compression Parameters)

4.1 Appearance

All formulations (F1–F6) were found to be **white, smooth, circular, and free from cracks or defects.**

4.2 Weight Variation

Table No. 13: Weight Variation.

Formulation	Avg. Weight (mg)	Deviation (%)	Result
F1	298	±1.2	Pass
F2	301	±1.0	Pass
F3	300	±0.9	Pass
F4	302	±1.3	Pass
F5	299	±1.1	Pass
F6	301	±1.2	Pass

4.3 Thickness

Table No. 14: Thickness.

Formulation	Thickness (mm)
F1	3.2
F2	3.3
F3	3.4
F4	3.5
F5	3.6
F6	3.6

4.4 Hardness

Table No. 15: Hardness.

Formulation	Hardness (kg/cm²)
F1	4.5
F2	5.0
F3	5.5
F4	6.0
F5	6.5
F6	6.8

4.5 Friability

Table No. 16: Friability.

Formulation	Friability (%)	Result
F1	0.82	Pass
F2	0.75	Pass
F3	0.70	Pass
F4	0.65	Pass
F5	0.60	Pass
F6	0.58	Pass

4.6 Drug Content Uniformity

Table No. 17: Drug Content Uniformity.

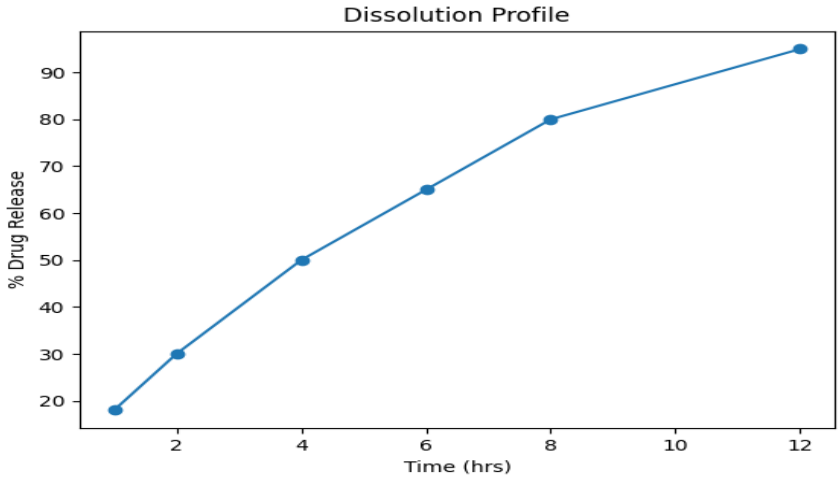
Formulation	Drug Content (%)
F1	97.8
F2	98.5
F3	99.1
F4	99.5
F5	100.2
F6	99.8

5. In-Vitro Dissolution Study

% Drug Release Data

Table No. 18: In-Vitro Dissolution Study.

Time (hrs)	F1	F2	F3	F4	F5	F6
1	32	28	24	20	18	15
2	48	42	36	30	25	22
4	70	62	55	48	42	38
6	88	78	70	60	55	50
8	98	90	82	72	65	60
10	—	98	92	85	78	70
12	—	—	99	95	88	80



Interpretation

- **F1** shows rapid release (not suitable for SR)
- **F3–F4** show controlled release up to 12 hrs
- **F5–F6** show extended but slower release
- **F4 is optimized formulation**

6. Drug Release Kinetics

Table No. 19: Drug Release Kinetics.

Model	Best Fit Formulation	R^2 Value	Mechanism
Zero Order	F4	0.991	Constant release
First Order	F2	0.965	Concentration dependent
Higuchi	F4	0.993	Diffusion controlled
Korsmeyer-Peppas	F4	n = 0.68	Non-Fickian diffusion

7. Stability Study Results (3 Months)

Storage Condition: 40°C ± 2°C / 75% RH ± 5%

F4 (Optimized Batch)

Table No. 20: Stability Study Results (3 Months)

Parameter	Initial	After 3 Months
Hardness (kg/cm²)	6.0	5.8
Drug Content (%)	99.5	98.9
% Drug Release (12 hr)	95	93

4. CONCLUSION

The present investigation successfully developed sustained release matrix tablets of Eperisone Hydrochloride using HPMC K100M as a hydrophilic matrix-forming polymer. All formulations demonstrated acceptable pre-compression and post-compression characteristics. Drug release was effectively controlled by polymer concentration, with increasing HPMC content resulting in slower release rates. Among the prepared formulations, F4 was identified as the optimized batch, providing approximately 95% drug release over 12 hours with excellent physicochemical properties and stability. The study confirms that hydrophilic matrix systems represent a promising approach for sustained delivery of Eperisone Hydrochloride, potentially reducing dosing frequency and improving patient compliance.

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