

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES

[ISSN: 0975-4725; CODEN(USA): IJPS00] Journal Homepage: https://www.ijpsjournal.com



Research Article

Solubility Enhancement, Formulation & Evaluation of Hydrogel of Aceclofenac

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ARTICLE INFO

Published: 06 Oct 2025

Keywords:

Aceclofenac, Hydrogel, Gaur gum, Carbopol-934, HPMC, anti-inflammatory, solubility enhacement, NSAIDs, Rheumatoid Arthritis, Osteoarthritis, Mixed Hydrotropy, Solid Dispersion Technique DOI:

10.5281/zenodo.17278731

ABSTRACT

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), such as Aceclofenac, possess strong anti-inflammatory and analgesic properties. However, their oral use is associated with gastrointestinal (GIT) irritation and ulceration. Aceclofenac, commonly used for conditions like rheumatoid arthritis and osteoarthritis, has limited solubility and bioavailability due to its classification as a BCS Class II drug. To address these issues, Aceclofenac hydrogel formulations were developed using hydrophilic polymers (e.g., Carbopol-934, HPMC, guar gum) to improve drug delivery by avoiding first-pass metabolism, enhancing local action, and reducing gastric ulcerogenic effects. Aceclofenac hydrogel formulations were evaluated for physical characteristics, pH, viscosity, drug content, spreadability, extrudability, and in vitro drug release. The use of mixed hydrotropy (urea and sodium tri-citrate in a 1:3 ratio) was found to maximize solubility. Formulating the hydrogel through solid dispersion techniques improved Aceclofenac's bioavailability. The optimized hydrogel demonstrated enhanced solubility and effective drug release properties. The development of Aceclofenac hydrogel using hydrophilic polymers and mixed hydrotropy technique effectively addressed challenges related to GIT irritation, solubility, and bioavailability. These formulations hold potential for improved therapeutic outcomes, offering a safer and more effective alternative for the treatment of joint diseases and related conditions.

INTRODUCTION

Topical gel formulation is one of the most widely used dosage types to minimise systemic side effects. NSAIDs (non-steroidal anti-inflammatory drugs) are commonly utilised to treat

inflammatory conditions like rheumatoid arthritis. When used orally they produce stomach discomfort dur to irritation.

It acts as analgesic and anti-inflammatory actions by inhibition of enzyme cyclooxygenase. The cyclooxygenase is irradiated in synthesis of

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



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prostaglandin from archidonic acid. Osteoarthritis, rheumatoid arthritis, and other joint conditions are usually treated with it.

The aceclofenac (ACF) is used orally in the treatment of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis.^{5,6} and But administration of ACF causes gastrointestinal ulcers and gastrointestinal bleeding. 7 the half-life is 3-4 yrs which requires oral of ACF administration at regular intervals. Topical administration of ACF would be a possible alternative offering distinct advantages such as elimination of the absorption variable rate, first pass intestinal and hepatic metabolism inherent with oral dosing and delivering the drug directly to the inflamed site and thereby, producing high local concentrations and avoiding the side effects.8 The hydrogel has the potential to trap a significant amount of water in its network structure while remaining impermeable to water. A appropriate hydrophilic polymer and solvent utilised aling with drug release the drug gently from the core.9,10

Hydrotropy is a term used to describe the process of increasing the solubility of a substance in water due to the presence of a significant amount of additives. The mechanism by which it improves solubility is more closely related to complexation comprising a mild interaction between the hydrotrophic substances like sodium benzoate, sodium acetate, sodium alginate, urea and the poorly water soluble drugs. 11,12 Solid dispersion is the most effective technique for enhancing the release of poorly soluble drugs. The API in solid dispersions may be distributed as separate molecules, amorphous particles, or crystalline particles, whereas the carrier may be in a crystalline or amorphous state.¹³ Solid dispersion is that polymers used in solid dispersion may be stabilizing drugs in amorphous state and retarding

crystallization after ingestion and dispersion. Solid dispersion of water insoluble drugs is the increase of chemical stability and shelf life compared to liquid formulations. Water-soluble polymers such as PVP and HPMC have a particular benefit in the science that they are known to prolong crystallization and stabilize the amorphous state or the solubilized state of the drug in the matrix.

MATERIALS AND METHODS

Aceclofenac was obtained as a gift sample from Arti pharmaceutical ltd Mumbai. Carbopol 934, HPMC, Guar gum, Propylene glycol, Glycerin, Triethanolamine, Methyl paraben, Urea, Sodium tricitrate (Modern Lab. Nashik) (AR grade)were used in this investigation. Preparation of Hydrotropic solid dispersion was done by Solvent Evaporation method. It is a relatively new technique in which the drug and selected hydrotropes are used in various ratios in beaker, with distilled water being applied at a temperature between 80-85 ° C. The selected hydrotrope is then taken and added to the distilled water. Then slowly add the drug to the beaker and the teflon-coated magnetic bead is lowered in the beaker, the temperature is maintained for optimal stirring and the stirring is continued until the semi-solid mass is produced. This semi-solid mass is distributed over several watch glasses and is put in the oven at a temperature of 60-65 ° C. Then the crushing is done with the pestle and mortar and, after drying, it passes through the sieve no.100 and is held in the desiccators for 6 day.

Hydrotropic solid dispersion of Aceclofenac:

Urea, 3gm, sodium citrate 9 gm and 10 ml of warm distilled were placed in beaker. It was stirred well with magnetic stirrer, 1.2gm of Aceclofenac (drug to carrier ratio was 1:3) was added in the above solution and temperature maintained in the range 55-56°c. The water evaporated after 30 min,



the wet solid dispersion was spread on watch glass which was kept in hot air oven at 50°c for 24 hrs. The hydrotropic solid dispersion were crushed using mortar and pestle and passed through sieve no.60 and finally stored in air tight glass bottle.

Determination of λ max of ACF:

Determination of λ max of Aceclofenac in phosphate buffer pH 7.4-The UV spectrum of Aceclofenac was determined in phosphate buffer pH 7.4 and maximum absorbance was recorded.

Solubility:

The solubility of Aceclofenac in water, ethanol and Hydrotopic Blend was determined.

FTIR Spectroscopy:

The IR spectrum of Aceclofenac in potassium bromide was recorded by scanning in the

wavelength region of 4000-400 cm using FTIR spectrophotometer.

Accuracy:

Accuracy was calculated in terms of % recovery for (80%, 100% and 120%V/V solutions)

Intra- day and inter-day precision:

A standard solution containing (0.4, 1.2, 2.0 μ g/mL) were analyzed three times on the same day for the determination of intra-day precision and on three different days for the determination of interday precision and % RSD was calculated.

Formula Design

Formulation and Development topical hydrogel of Aceclofenac: 1% w/w

Table 1 Formula for préparation of Hydrogel of Aceclofenac

Ingrédient	F1	F2	F3	F4-solid dispersion batch
Aceclofenac	0.1 g	0.1 g	0.1 g	1.2 g
Carbopol-934	0.5 g	0.5 g	0.5 g	1.2 g
HPMC	0.3 g	0.6 g	1.2 g	1.2 g
Guar-gum	0.1 g	0.1 g	0.1 g	1.2 g
Propylene glycol	2ml	2ml	2ml	2ml
Methyl paraben	0.2 g	0.2 g	0.2 g	0.2 g
Glycérine	2ml	2ml	2ml	2ml
Triethanolamine	0.2ml	0.2ml	0.2ml	0.2ml
Purified Water	q.s to 10ml	q.s to 10ml	q.s to 10ml	q.s to 10ml

Formulation of Acelcofenac topical hydrogel

Preparation of ACF solution:

The propylene glycol 2ml was warmed in water bath to 55 -60 °C in this Aceclofenac was dispersed with constant stirring.

Water phase:

Carbopol 934 was soaked in water for 24 hours. Separately, guar gum and HPMC powder were

soaked in water for 24 hours. Then the soaked HPMC and guar gum were transferred to the Carbopol mixture and stirred for 20 minutes.

Preparation of Hydrogel:

The solution of Aceclofenac in propylene glycol was neutralized with triethanolamine, the water phase, glycerine, methyl paraben was added while stirring and volume was made to 10ml with purified water.



Evaluation of hydrogel

Physical characteristics:

The prepared hydrogel formulation was evaluated for colour, homogeneity, consistency, grittiness, texture and phase separation.

Determination of pH:

The pH of hydrogel formulation was determined .One gram of gel was dissolved in 25 ml of distilled water and pH was determined.

Viscosity:

The viscosity of hydrogel was determined by using Brookfield viscometer at 20rpm and 28°c.

Spreadability:

The spreadability was determined using spreadability glass apparatus.

Drug content:

Accurately weighed hydrogel was dissolved in 100ml of phosphate buffer pH 7.4. It was filtered using Whatman filter paper. Suitable dilutions were done and drug content was determined at λ max 273nm using UV spectophotometer.

Extrudability:

The extrudability was determined by calculating weight in grams required to extrude at least 0.5cm

ribbon of hydrogel in 10sec from the collapsible aluminium tube.

In-vitro drug release:

In vitro drug release study of aceclofenac was carried out in a Franz diffusion call, by using cellophane membrane. The membrane was soaked in media for 12hrs, and placed in the space between the donor and receiver compartment of the Farnaz diffusion cell. 1gm of hydrogel was applied on donor side. phosphate buffer pH 7.4 was used as diffusion media. the temperature of cell was maintained constant 37 + 0.5°c by using circulating jacket. The solution was stirred continuously using magnetic bead. 2ml sample were withdrawn after 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330, 360, 390, 420min and replaced with equal amount of fresh media. similar procedure was carried out for formulation F1 to F4. Sample analysed was by spectrophotometrically at 273nm and % CDR was calculated.

RESULT AND DISCUSSION

UV spectroscopic analysis for the Aceclofenac was performed in phosphate buffer pH 7.4 and in spectrum Aceclofenac showed absorbance maximum at 273nm.

Accuracy:

Table 2 Results for Accuracy determination of Aceclofenac

Conc. Level	Sample amount	Amount of Standard	Aceclofenac		
(%)	(μg/mL)	Added (μg/mL)	Mean	Amount	% Mean
				recovered	Recovery
80%	8	10	0.504	16.66	92.58%
	8	10			
	8	10			
100%	10	10	0.538	17.73	98.54%
	10	10			
	10	10			
120%	12	10	0.550	25.01	100.64%



12	10	
12	10	

Precision:

Precision of intra-day and inter-day

Intra-day precision

Table 3 Results for Intraday precision determination of Aceclofenac

Time	Conc. (µg/mL)	± SD	% RSD
9.00	4	0.0016	1.39
am	12	0.00115	0.41
	20	0.0005	0.11
12 pm	4	0.0025	2.00
	12	0.0023	0.64
	20	0.524	0.38
4 pm	4	0.0028	2.00
	12	0.0021	0.64
	20	0.529	0.39

Inter-day precision

Table 4 Results for Inter day precision determination of Aceclofenac

Time	Conc. (µg/mL)	± SD	% RSD
	4	0.0013	1.31
9 am	12	0.0030	0.30
	20	0.0119	1.19
	4	0.0088	0.80
12 pm	12	0.0030	0.30
	20	0.0041	0.41
	4	0.0090	0.82
4 pm	12	0.0033	0.32
	20	0.0044	0.43

Solubility Enchancement: Hydrotropic Blend has shown 60.21% solubility enhancement as compared to Aceclofenac in water

Compatability Study: To study compatibility between accelophenac and exciepients used for formulation compatibility study was performed using FTIR.

FTIR of Accelophenac pure drug and Aceclofenac drug and excipients was performed and checked for the peaks obtained.

EVALUATION OF ACECLOFENAC HYDROGEL USING GELLING AGENT:

Physical appearance:

The result of physical appearance i.e. colour, odour, homogeneity, phase separation, consistency, texture, grittiness of all batches are in shown in table. All batches of hydrogel were found to be transparent, characteristics odour with good homogeneity, consistency and texture. All formulation was non-gritty and without phase separation.

Physical appearance of hydrogel:

Table 5 Physical appearance of hydrogel of Aceclofenac

Parameter	F1	F2	F3	F4
Colour	Transparent	Transparent	Transparent	Transparent
Odour	Characteristics	Characteristics	Characteristics	Characteristics
Homogeneity	Good	good	good	Good
Consistency	Good	good	good	Good
Phase separation	None	None	None	None
Texture	Good	Good	Good	Good
Grittiness	Non-gritty	Non-gritty	Non-gritty	Non-gritty

pH determination:



The pH value of hydrogel batches were found in the range of 5.7-6.2 which is similar to skin pH.

Table 6 pH of hydrogel formulation

-	F1	F2	F3	F4	
	6.26	6.33	5.7	6.28	

Viscosity:

The tests were performed by using Brook-field viscometer. Highest viscosity was found in formulation F3 and F4. It may be due to low concentration of gelling agent. The viscosity range observed for all formulation was 10102-15057Cps.

Table 7 viscosity of hydrogel formulation

F1	F2	F3	F4
10102cps	10213cps	11519cps	15057cps

Viscosity of F4 found have significant viscosity.

Spreadability:

The spreading coefficient of various hydrogel formulation are given below. It was concluded 'that all the developed formulation showed acceptable spreadability, F3 and F4 formulation has more spreadability as compare to other formulation i.e. 14.30 and 12.93 respectively.

Table 8 Spreading coefficient of the formulation

F1	F2	F3	F4
11.12	12.83	12.80	12.93
gm/sec	gm/sec	gm/sec	gm/sec

Spreadability of F4 found to have significant spreadability.

Drug content:

The drug content of different hydrogel formulation was estimated by using UV spectrophotometer at 200-400 nm rang. The release of drug through prepared formulation was to be 99.25, 83.83,88,99.25 respectively. The result was found to be satisfactory.

Table 9 Drug content of F1 and F4 batch

F1	F1 F2		F4
99.25%	83.83%	88%	99.25%

Drug content of F1 and F4 batch found to have significant drug content

In-vitro diffusion study:

Table 10 In-vitro diffusion study of three batches F1,F2,F3

	Cumulative % of drug release				
Time (min)	F1	F2	F3		
30	1.77	1.26	1.12		
60	2.91	2.50	2.8		
90	9.47	4.96	3.75		
120	22.55	5.17	3.75		
150	24.10	8.98	8.05		
180	33.77	12.25	12.3		
210	51.11	18	14.9		
240	71.82	21	22.25		

The drug release through the hydrogel formulation without solid-dispersion batches F1,F2,F3 was shown in above table ,F1 could up to 71.82 % at the end of 4hr.

Table 11 Cumulative % drug release of F1,F3 batch and marketed preparation

Daten and marketed preparation					
	Cum	ulative % of d	rug release		
Time	F1	F4- solid	Marketed		
(min)		dispersion			
30	0.84	5	6.3		
60	4.65	9.37	7		
90	8.25	13.77	13.61		
120	23.47	27.39	19.3		
150	24.6	30.17	29.35		
180	32.5	36.22	32.43		
210	48.87	54	48.89		
240	59.35	78.1	81.20		
270	69.95	91.17	92.21		
300	75.5	100	92.62		
330	81.6	-	-		
360	88.4	-	-		
390	92.72	-	-		
420	93.5	-	-		

The drug release through the hydrogel formulation without solid dispersion (batch F1) was slower and



could reach up to 93.5% at the end of 7 hr. Hydrogel batch (F4) with solid dispersion showed 100% in 5hr. Drug release which higher than batch F1 without solid dispersion. F4 batch was

compared to marketed gel product, it reached up to 92.62% in 5hr. Optimize formulation F4 showed significantly improved drug release rate compared to marketed preparation.

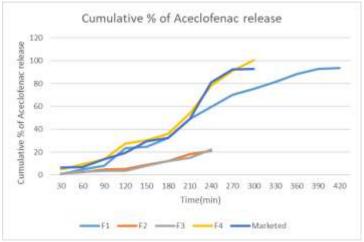


Fig.1 Cumulative % of Aceclofenac release

Extrudability:

The extrusion of the hydrogel from the tube is important during its application its application and in patient acceptance. The extrudability results of formulation was found to be excellent and satisfactory. Extrudability of hydrogel batches. Extrudability of F4 batches found to have significant extrudability.

Extrudability of hydrogel batches

Table 12 Extrudability of hydrogel batches

- 1	ttore re es		or my arroger successes	
	F1	F2	F3	F4
Ī	96.89%	96.84%	94.7%	96.90%

CONCLUSION

Applying mixed hydrotropic technique (Urea: Sodium Citrate,1:3) solubility of the acceclofenac was improved, the solid dispersion was utilized for formulation of hydrogel, which resulted in improved drug release rate.

Aceclofenac hydrogel with gelling agent and using mixed hydrotropic technique was formulated and evaluated physicochemical properties.

Concentration of gelling agent lower, higher the drug release rate in case of F1 batch such as 93.5%. By using mix hydrotropic method of solid dispersion, solubility of the drug was improved and also increased drug release rate. Batch F4 showed good result as compare to other batches.

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HOW TO CITE: Suvarna Katti, Anuja Bhosale, Dayali Pagare, Solubility Enhancement, Formulation & Evaluation of Hydrogel of Aceclofenac, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 10, 571-579. https://doi.org/10.5281/zenodo.17278731

