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FORMULATION AND EVALUATION OF ACECLOFENAC SODIUM GEL - USING CARBOPOL 934 AND 940

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ABSTRACT

Gels are getting popularity nowadays when compared with other semisolid dosage form like ointments, creams, lotion and pastes due to their stability and controlled release. Gels formulations are substitute for oral route of administration and to avoid first pass metabolism. The present research has been undertaken with the aim to develop the formulation of Aceclofenac sodium Gel using different grades of gelling agents such as Carbopol 934p and Carbopol 940 in different concentration. Aceclofenac Sodium is recommended in long term use of rheumatoid arthritis and osteoarthritis. Gels are evaluated by following parameter such as pH, homogeneity, grittiness, drug content, viscosity, spreadability, extrudability, skin irritation studies. FTIR studies showed that no interaction between drug, polymer and excipients. The study concluded that the Carbopol 934p was suitable for gel preparation when compared to Carbopol 940.

INTRODUCTION[1,2]

Gels are getting nowadays when compared with other semisolid dosage form like ointments, creams, lotions and pastes due to their stability and controlled release. Stability of drug and better absorption can improve by gel formulations are substitute for oral route of administration and avoid first pass metabolism. Topical gels are intented for skin application, to certain mucosal surfaces for local action or percutaneous penetration of medicament, for their emollient or protective action. Topical drug delivery has advantage such as applying the drug directly into the skin and it also provides prolonged action on the targeted site. Gels are evaluated by following parameter such as PH, homogenicity, grittiness, drug content, vicosity, spread ability, extrudability, invitro and stability study.

MATERIALS AND METHOD

Gels are getting nowadays when compared with other semisolid dosage form like ointments, creams, lotions and pastes due to their stability and controlled release. Stability of drug and better absorption can improve by gel formulations are substitute for oral route of administration and avoid first pass metabolism. Topical gels are intented for skin application, to certain mucosal surfaces for local action or percutaneous penetration of medicament, for their emollient or protective action. Topical drug delivery has advantage such as applying the drug directly into the skin and it also provides prolonged action on the targeted site. Gels are evaluated by following parameter such as PH, homogenicity, grittiness, drug content, vicosity, spread ability, extrudability, invitro and stability st.

Table No 1: List Of Materials.

Materials	Manufacturer
Carbopol 934p	Kemphasol, Mumbai
Carbopol 940	Kemphasol, Mumbai.
Triethanolamine	Emplura® merck life science private limited.
Propylene glycol	Nice® chemicals (p)LTD
Methanol	Changshu Hongsheng fine chemicals co., Ltd.
Aceclofenac sodium	Medistark biotech PVT LTD
Methyl paraben sodium	BRM chemicals
Distilled water	lonil® signifies ultra pure desonized water

Table No. 2: List Of Equipments.

EQUIPMENTS	companyNAME
PHmeter	Elico
UV spectrophotometry	Merck
Brookfield DV -II+pro	Brook field viscometer
Electronic weighing balance	Shimadzu
Water bath	Vani

FORMULATION OF ACECLOFENAC SODIUM GEL

PREPARATION METHOD

Carbopol was soak in a sufficient amount of water and kept it few hours for swelling of polymer. Then methyl paraben sodium was dissolved in a given quantity of water heat it until it reaches 70°c. Dissolve the methanol in minimum amount of propylene glycol this was added to the formed when it reaches 50°c dissolve the drug in propylene glycol and this was added to the formulated when it comes 40°c.when the formulation comes under 40°c now we can add the soaked Carbopol and drop add the triethanolamine until the clear, transparent gel was formed.

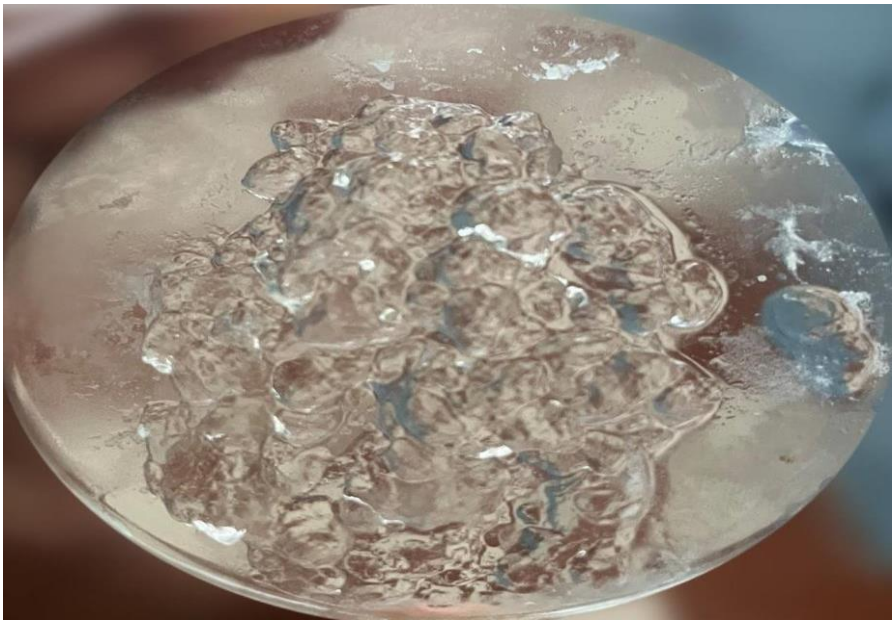


Table No. 3: List of Ingredients & Their Uses.

INGREDIENTS	USE
Aceclofenac sodium	Osteoarthrit is Rheumatoid arthrit is
Carbopol 934&940	Gelling Thickener
Triethanolamine	Neutralizer & PH Adjuster
Methyl paraben sodium	Anti-Microbial agent
Propylene glycol	Moisturising agent
Methanol	Provide an acidic environment

Table No. 4: Formulation of Gel –Carbopol 940.

Ingredients	F1	F2	F3	F4	F5
Drug	116mg	116mg	116mg	116mg	116mg
Carbopol940	80mg	100mg	120mg	140mg	160mg
Propylene glycol	1.5ml	1.5ml	1.5ml	2ml	2ml
Ethanol	0.03ml	0.03ml	0.03ml	0.03ml	0.03ml
Triethanolamine	q.s	q.s	q.s	q.s	q.s
Methyl paraben Sodium	0.20mg	0.20mg	0.20mg	0.20mg	0.20mg
Water	q.s	q.s	q.s	q.s	q.s

Table No. 5: Formulation Table For Carbopol 934p.

Ingredient	F6	F7	F8	F9	F10
Drug	116mg	116mg	116mg	116mg	116mg
Carbopol 934p	80mg	100mg	120mg	140mg	160mg
Propylene glycol	1.5ml	1.5ml	2ml	2ml	2ml
Ethanol	0.03ml	0.03ml	0.03ml	0.03ml	0.003ml
Triethanolamine	q.s	q.s	q.s	q.s	q.s
Methyl paraben sodium	0.20mg	0.20mg	0.20mg	0.20mg	0.20mg
Water	q.s	q.s	q.s	q.s	q.s

EVALUATION PARAMETERS

The formulated gel was subjected to follow evaluation parameters.

pH (3, 7)

The pH of the gel formulations was determined by using digital pH meter by placing the glass electrode completely into the gel system and measure pH of the gel.

Spread ability (3)

It was determined by wooden block and glass slide apparatus. Weights 20g were added to pan and the time was noted for upper slide to separate completely from the fixed slides. Spreadability was then calculated by using the formula:

S=MXL/T

S=Spread ability,

M-weight tide to upper slide, L=length of glass slide,

T-time taken to separate the slide completely from each other.

Viscosity (3)

Viscosity measures the flow characteristics of gel formulation. Change in viscosity of the product is indicative of change in stability and effectiveness of product. The viscosity of gel was determined by using Brookfield DV-II+Pro.

Homogeneity (3)

All formulated gels were tested for homogeneity by visual inspection after the gels have been set in the container. They were tested for their appearance and presence of any aggregates.

Grittiness (6)

All the formulations were evaluated microscopically for the presence of particles if any no appreciable particular matter was seen under light microscope. Hence obviously the gel preparation fulfils the requirement of freedom from particular matter and from grittiness as desired for any topical preparation.

Drug Content (4)

A quantity (100mg) of the gel was dissolved in 100 ml of Phosphate buffer of pH 6.8. The volumetric flask containing gel solution was shaken for 2h on a mechanical shaker to allow the drug to dissolve completely. The solution was filtered and drug content determined spectrophotometrically at 276 nm using Phosphate buffer (pH 6.8) as blank.

Table No. 6: Evaluation Parameters F1-F5.

Formulation Code	F1	F2	F3	F4	F5
Homogensity	++	++	+++	+++	++
Grittiness	-	-	-	-	-
Spreadability	20.00	23.05	21.66	20.22	20.00
PH	6.1	6.5	6.8	6.7	6.12
Physical appearance	Clear	Clear	Clear	Clear	Clear
Viscosity	3045.31±1.12	3189.28±1.09	3369.34±1.09	3424.89± 1.13	3518.92± 1.17
Drug content	91%	93.2%	96.2%	92.8%	93.5%

Table No.7: Evaluation Parameters F6-F10.

Formulation Code	F6	F7	F8	F9	F10
Homogeneity	+++	+++	+++	++	+++
Grittiness	-	-	-	-	-
Spread ablity	15.09	21.55	20.51	19.04	17.02
Ph	6.67	3.56	6.48	6.82	6.71
Physical appearance	Clear	Clear	Clear	Clear	Clear
Viscosity	3056.7± 1.05	3010.76± 1.08	3128.67± 1.15	3237.56± 1.19	3327.87± 1.07
Drug content	92.1%	95.8%	96.4%	91.8%	93.7%

++ - GOOD, +++ - EXCELLENT

(-) = Absence of appreciable particular matter

RESULTS AND DISCUSSION

Ten different formulations of Gels (F1-F10) were prepared by using cartopol 934p and 940 in different polymer concentration. Preformulation studies are also done in order to select the optimized formulation various evaluation parameters like Homogeneity, Viscosity, Spread ability, pH, Physical appearance, and drug content were done.

PRE FORMULATION STUDY

CHARACTERISTIC OF ACECLOFENAC SODIUM

The following are done according to British Pharmacopoeia. **DESCRIPTION**: A White or almost white powder **SOLUBILITY:** Methanol and Ethanol completely soluble **MELTING POINT:** 296.149°c.

Homogeneity

Among all the formulations from FI to F10, F2 &F7 showed good homogeneity with absence of Jumps. The developed gel preparations were much clear and transparent.

Spreadability

The value of spreadability indicates that the gel is easily spreadable by small amount of shear in formulation F1 to F5 spreadability of Carbopol 934p gel was range 20.00 to 30.00 gem/sec.

In formulation F6 to F10 spreadability of Carbopol 940 was range 15.09 to 20.51gcm/sec. indicating spreadability of gel formulation for F2 and F7 was good as compared to other formulation.

pH

The pH value of all developed formulations of Carbopol 934p were in the range 6.1 to 6.12. Carbopol 940 gel were in the range of 6.48 to 6.82 Which is well within the limits of skin pH is 56 to 7.5 F2 and F7 was good as compared to other formulation.

Physical appearance

Carbopol 934p and 940 gels Physical appearance were found to be sparkling and transparent, FI to F10 all gel formulation were free from presence of particles.

Viscosity

The viscosity of the formulation F1 to F5 containing Carbopol 934p were in range 3045.311.12 to 3518.92±1.17 cps whereas the formulation F6 to F10 containing drug and Carbopol 940 were in the range of 3056.7 ±1.05 to 3327.87 ±1.07 cps from the results it was found that viscosity is an important physical property of topical formulation which affects the rate of drug release, in general an increase of viscosity vehicle would cause a more rigid structure with a consequent decrease of the rate of drug release.

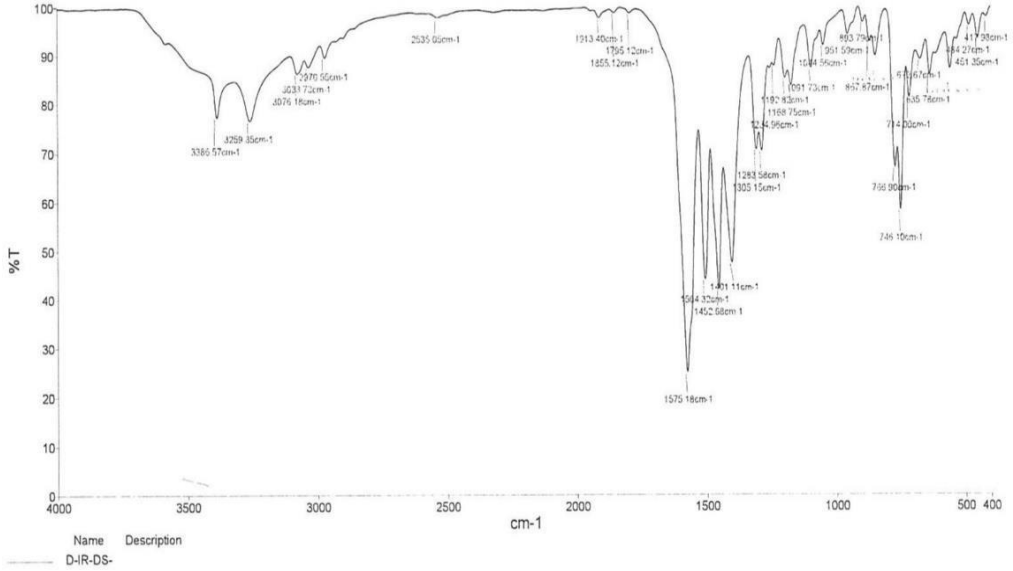
DRUG CONTENT

The percentage drug content of all prepared gel formulation F1 to F 10 were found to be in the range 91 to 96.4% The percentage drug content of formulations was found to be within the I.P limits. Hence the methods adopted for gels formulations were found to be suitable.

COMPATIBILITY STUDIES

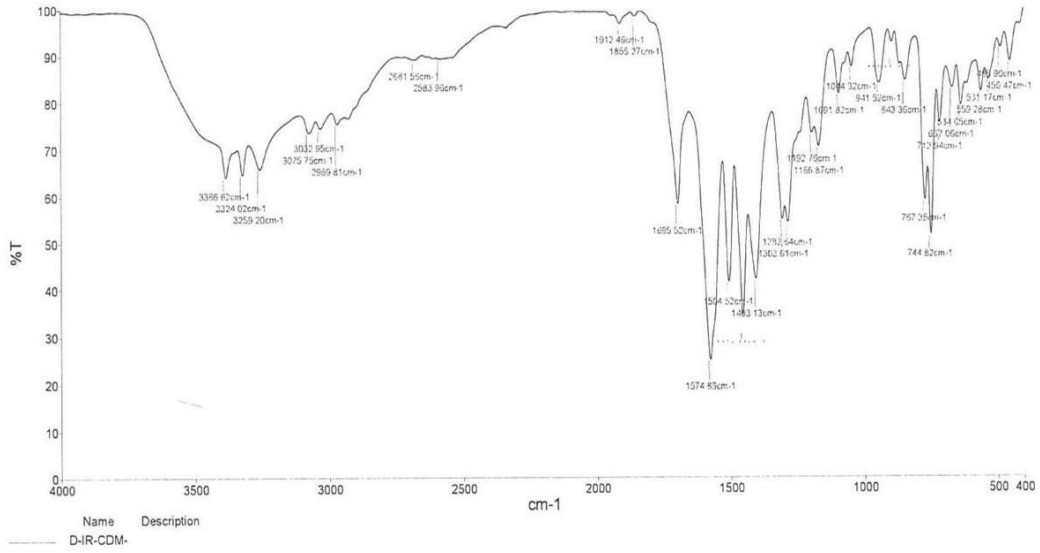
The incompatibility between the drug and excipients were studied by FT-IR spectroscopy. The results indicate that there was no chemical incompatibility between drug and excipients used in the formulation.

FTIR STUDIES FOR AECLOFENAC SODIUM



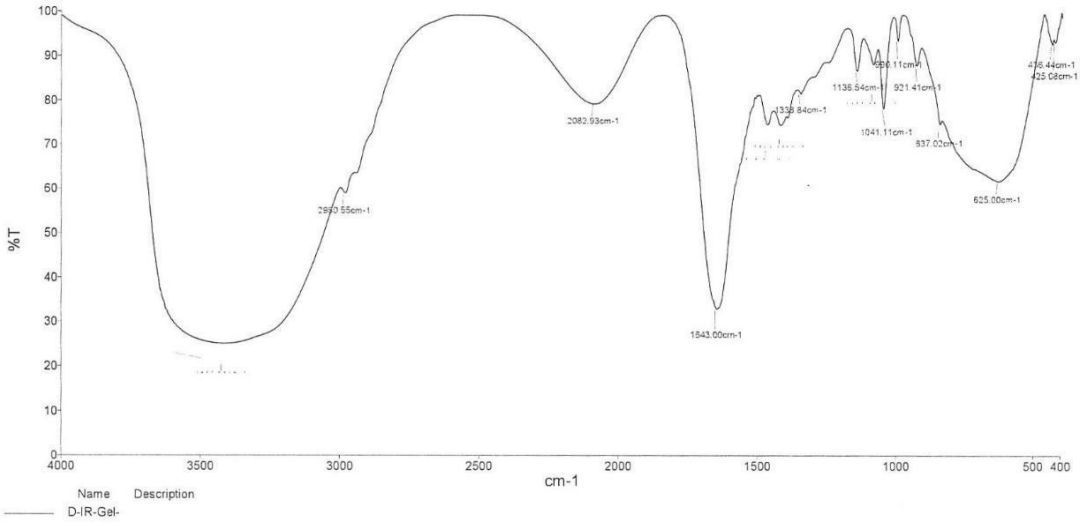
S.NO	WAVE NUMBER Cm^{-1}	FUNCTIONAL GROUP
1	3387.0 Cm^{-1}	NH Stretching
2	3203.76 Cm^{-1}	COOH Stretching
3	3076.18 Cm^{-1}	=CH Stretching
4	2970.55 Cm^{-1}	CH Stretching
5	1602.85 Cm^{-1}	C=C Stretching

FTIR STUDIES FOR DRUG MIXTURE WITH CARBOPOL 934p or 940



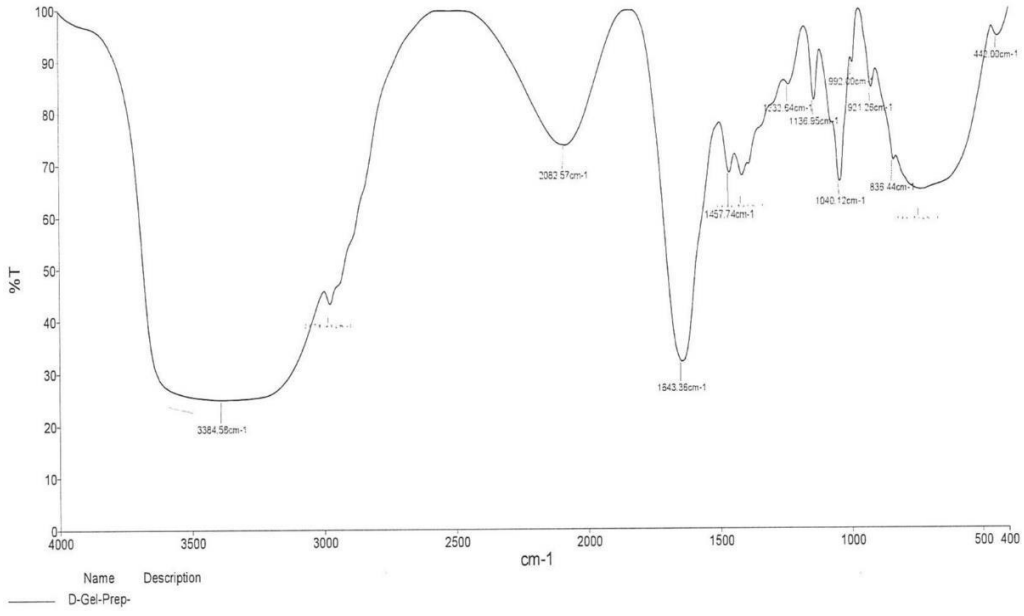
S.NO	WAVE NUMBER Cm^{-1}	JNCTIONAL GROUP
1	3387.62 Cm^{-1}	NH Stretching
2	3324.02 Cm^{-1}	-OH Stetching
3	3259.20 Cm^{-1}	-OH Stretching
4	3032.95 Cm^{-1}	=CH Stretching
5	3075.75 Cm^{-1}	=CH Stretching

FTIR STUDIES FOR GEL WITH CARBOPOL 934P



S. NO	WAVE NUMBER Cm^{-1}	FUNCTIONAL GROUP
1	3417.89 Cm^{-1}	NH Stretching
2	2980.55 Cm^{-1}	-OH Stretching
3	1643.00 Cm^{-1}	C=C Stretching
4	1338.84 Cm^{-1}	C-N Stretching
5	1136.54 Cm^{-1}	C-O Stretching

FTIR STUDIES FOR GEL PREPERATION WITH CARBOPOL 940



S.NO	WAVE NUMBER Cm^{-1}	FUNCTIONAL GROUP
1	3387.58 Cm^{-1}	NH Stretching
2	2978.41 Cm^{-1}	-OH Stetching
3	1643.36Cm^{-1}	C=C- Stretching
4	3032.95 Cm^{-1}	-C-O Stretching
5	1136.95 Cm^{-1}	-C-O Stretching

CONCLUSION

Aceclofenac Sodium is recommended in long term use of rheumatoid arthritis and osteoarthritis. To overcome the disadvantage in oral route the Aceclofenac was formulated as gel. The formulated Gels are evaluated for pH, homogeneity, grittiness, drug content, viscosity, spreadability, extrudability, skin irritation studies and FTIR incompatibility studies. FTIR studies showed that no interaction between drug, polymer and excipients used in the formulation. The study concluded that the Carbopol 934p was suitable for gel preparation when compared to Carbopol 940.

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