RESEARCH PAPER

Design and Development of Solid-Lipid Nanoparticles (Sln) Based Topical Gel

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ABSTRACT

Solid lipid nanoparticles (SLNs) have emerged as a promising nanocarrier system for topical drug delivery due to their excellent biocompatibility, controlled drug release, and enhanced skin permeation. The present study aimed to design and develop an SLN-based topical gel to improve the stability, bioavailability, and therapeutic efficacy of a poorly water-soluble drug. SLNs were prepared using the hot homogenization followed by ultrasonication technique employing a solid lipid, surfactant, and co-surfactant. The optimized SLN formulation was incorporated into a carbopol-based gel and evaluated for its physicochemical and pharmaceutical characteristics. The prepared formulations were characterized for particle size, polydispersity index (PDI), zeta potential, drug entrapment efficiency, morphology, and compatibility using Fourier-transform infrared spectroscopy (FTIR). The topical gel was further evaluated for pH, viscosity, spreadability, drug content, in vitro drug release, and stability under accelerated storage conditions. The optimized SLN formulation exhibited nanosized particles with a narrow size distribution, high entrapment efficiency, and good physical stability. The SLN-loaded gel demonstrated suitable pH, satisfactory viscosity, excellent spreadability, and uniform drug content, making it appropriate for topical application. In vitro drug release studies revealed a sustained release profile compared with the conventional gel, indicating the ability of SLNs to prolong drug availability at the site of application. Stability studies confirmed that the optimized formulation remained physically and chemically stable throughout the study period. Overall, the developed SLN-based topical gel represents a promising platform for localized drug delivery, offering enhanced skin retention, sustained drug release, improved patient compliance, and potential therapeutic benefits over conventional topical formulations

Keywords: Solid lipid nanoparticles (SLNs); Topical gel; Nanocarrier drug delivery; Controlled drug release; Skin permeation; Entrapment efficiency.

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Conflict of interest: None

1. INTRODUCTION

Advanced drug delivery systems have been developed to reduce dosing frequency, improve therapeutic efficacy, and provide site-specific drug delivery while minimizing systemic side effects.[1]Polymeric carriers play a central role in these systems by enabling controlled and sustained drug release.[2] Among them, in situ gels and topical gel formulations have gained considerable attention because they improve patient compliance, prolong drug residence time, and enhance localized drug action. However, conventional topical dosage forms such as creams, ointments, and lotions often suffer from poor skin penetration, inadequate drug retention, instability of active pharmaceutical ingredients, and the need for frequent application. [3]Nanotechnology has significantly advanced topical drug delivery through the development of nanoscale carriers with superior drug-loading capacity, enhanced skin permeation, and controlled drug release. Among these carriers, Solid Lipid Nanoparticles (SLNs) have emerged as promising lipid-based nanocarriers due to their excellent biocompatibility, biodegradability, and physical stability.[4] Typically ranging from 50–1000 nm, SLNs consist of physiologically compatible solid lipids stabilized with surfactants, providing protection against oxidation, hydrolysis, and photodegradation while enabling sustained drug release.[5] SLNs are particularly advantageous for topical administration because their nanosized particles increase surface contact with the skin, enhance adhesion to the stratum corneum, and form an occlusive film that reduces transepidermal water loss (TEWL). This occlusive effect improves skin hydration, thereby facilitating greater drug permeation and retention within the target tissue.[6] Consequently, SLNs have been extensively investigated for the delivery of anti-inflammatory, antifungal, antibacterial, analgesic, anticancer, and herbal bioactive compounds.[7] Despite these advantages, SLN dispersions alone possess low viscosity and limited residence time on the skin, restricting their clinical application. Incorporating SLNs into hydrogel systems prepared with polymers such as Carbopol 934P, Hydroxypropyl Methylcellulose (HPMC), or Poloxamer 407 overcomes these limitations by improving viscosity, spreadability, bioadhesion, and formulation stability. The hydrogel matrix also prevents nanoparticle aggregation while providing prolonged contact with the skin and sustained drug release.[11] The

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successful development of an SLN-based topical gel depends on careful optimization of formulation variables, including lipid type, surfactant concentration, preparation method, and polymer composition. These factors significantly influence particle size, polydispersity index, zeta potential, encapsulation efficiency, rheological properties, drug release behaviour, and storage stability. Comprehensive characterization involving FTIR, DSC, XRD, SEM, particle size analysis, pH, viscosity, spreadability, in vitro drug release, ex vivo skin permeation, and stability studies is essential to ensure formulation quality and therapeutic performance.[12] Therefore, the present study focuses on the design, development, optimization, and evaluation of a Solid Lipid Nanoparticle (SLN)-based topical gel to achieve enhanced drug stability, improved skin permeation, controlled drug release, prolonged therapeutic action, and improved patient compliance for effective topical drug delivery.[13]

2. MATERIALS AND METHODS

Drugs/ Chemicals

List of Drugs/ Chemicals

LIST OF EQUIPMENTS:

Table 1: Equipments used and their manufacturers

Sr. No.	Equipments	Model /Company
1	Digital pH meter	Model- 111E, EI products, Parwanoo.
2	Peristaltic Pump	V. J. Instrument
3	Brookfield DV-E viscometer	Model-LV DVE230, Brookfield Engineering Laboratories, Inc., USA
4	Magnetic stirrer with hot plate	Hicon
5	Weighing balance	Shimadzu Corporation, Japan.
6	Sonicator (Ultrasonic)	Model-1.5L50H, PCi^{TM} Analytics
7	UV Spectrophotometer UV 1800	Shimadzu Corporation, Japan.
8	Thermostatic waterbath	Hicon

EXPERIMENTAL DETAILS

A standard calibration curve was prepared by dissolving the reference drug in phosphate buffer (pH 7.4) at different concentrations. [14]The solutions were scanned between 200–400 nm using a UV–Visible spectrophotometer to determine the λmax, and calibration curves were constructed to evaluate linearity. Preformulation studies included determination of the melting point, pH, solubility, and drug–excipient compatibility. The melting point was measured to assess drug purity and compared with reported values.[15] The pH of a 1% w/v drug solution was determined using a calibrated digital pH meter in triplicate. Solubility was evaluated in different solvents to identify a suitable formulation medium. Drug–excipient compatibility was investigated by FT-IR spectroscopy using the KBr pellet method (4000–600 cm^{-1}). Physical mixtures containing drug, polymer, and surfactant (1:1:1) were stored at room temperature, 30°C/65% RH, and 40°C/75% RH to evaluate stability. Phase diagrams of catanionic drug–surfactant systems were constructed by preparing mixtures with different drug-to-surfactant ratios in sodium chloride solution. Samples were equilibrated for one week before characterization by visual observation, rheological analysis, and cryo-transmission electron microscopy (Cryo-TEM) to identify micelles, vesicles, precipitation, and phase behavior.[16] Polymer solutions were prepared by dissolving Poloxamer 407 in cold distilled water (4°C) with continuous stirring until clear. Carbopol 934P was dispersed separately in distilled water, allowed to swell, and stirred until homogeneous.[17] Both polymer solutions were stored at 4°C before use. The gelation temperature was determined using the tube inversion method by gradually heating the formulations from 15°C to 80°C at 2°C intervals.[18] The temperature at which the formulation ceased flowing upon inversion was recorded as the gelation temperature. The pH of polymer solutions was measured using a calibrated pH meter, with all experiments performed in triplicate to ensure reproducibility.[19]

FORMULATION EXPANSION:

1. Preparation Of Gels

All gels in this thesis were prepared with a final concentration of 1% w/v for Carbopol 934P and 20% w/v for Poloxamer 407 to examine gelation temperature, viscosity, pH, and other gel properties.[20]

Table .3 Composition of *In*-situ gel formulation containing Thermosensitive & Mucoadhesive Polymer

Ingredients	B1	B2	B3	B4	B5	B6
Carbopol 934 P *In*-situ gel						
Carbopol 934 P	1	1	1	--	--	--
Ondansetron HCL	0.8	--	0.8	--	--	--
Ketorolac Trimethamine	--	0.5	0.5	--	--	--
Sodium Dodecyl Sulfate	0.5	0.5	0.5	--	--	--
Nacl	0.9	0.9	0.9	--	--	--

Poloxomer 407 *In*-situ gel						
Poloxomer 407	--	--	--	20	20	20
Zolmitriptan	--	--	--	2.5	--	2.5
Dexamethosone	--	--	--	--	0.1	0.1
Lauryl Pyridinium Chloride	--	--	--	--	1.5	1.5
Trimethylammonium Bromide	--	--	--	2	--	2
Distill Water	--	--	--	5	5	5

Carbopol 934P gels were prepared by either direct dispersion or a double-strength mixing method.[21] In the first method, the drug or catanionic mixture was dissolved in saline, followed by gradual Carbopol addition, neutralization, hydration, and pH adjustment (7.4 ± 0.1). In the second method, concentrated drug solution and 2% Carbopol gel were prepared separately and mixed equally to obtain 1% gel.[22] The reference catanionic mixture was incorporated into a Poloxamer 407–Carbopol 934P gel with continuous stirring. Gels were stored at 4°C for 24 hours, while entrapped air bubbles were removed by refrigeration, sonication, or antifoaming agents.

RESULTS AND DISCUSSION

DETERMINATION OF UV ABSORPTION MAXIMA

Table 9.1: UV Absorption Maxima and R^2 (Medium: Phosphate Buffer pH 7.4)

Sr. No.	Drugs	Concentration Range	UV Absorption Maxima	R^2 (Standard Calibration Curve)
1	Dexamethosone	1-30 µg/mL	241 nm	0.998
2	Ketorolac	2-20 µg/mL	215 nm	0.996
3	Zolmitriptan	5-100 µg/mL	283 nm	0.996
4	Ondansetron	5-50 µg/mL	246 nm	0.998

CHARACTERISATION AND IDENTIFICATION OF DRUGS

Table. 4: Characterization of Zolmitriptan:

Sr. No.	Characterization	Specifications	Result
1	Description	White Powder	Complies
2	Solubility	Water: soluble	Complies
3	Assay	98-102 %	Complies

Table 5: Characterization of Dexamethasone Sodium Phosphate:

Sr. No.	Characterization	Specifications	Result
1	Description	A crystalline powder that is white or slightly yellow, nearly odorless, and highly hygroscopic.	White Crystalline Powder
2	pH (in 1%w/v solution)	5.7 to 6.7	Complies
3	Solubility	Water: Freely Soluble	Complies
		Methanol: Freely soluble	
		Ether: Slightly insoluble	
		Chloroform: Very slightly soluble	
4	Specific Optical Rotation (1% w/v solution)	$+75^0$ and $+83^0$	Complies
5	Assay	97 to 103 %	Complies

Table 6: Characterization of Ondansetron Hydrochloride

Sr. No.	Characterization	Specifications	Result
1	Description	White to off-white powder	Complies

2	Solubility	Freely Soluble in Water and Normal Saline	Complies
3	Assay	98-102 %	Complies

Table 7: Characterization of Ketorolac Tromethamine:

Sr. No.	Characterization	Specifications	Result
1	Description	White or almost white, crystalline powder	Almost white, crystalline powder
2	pH (in 1%w/v solution)	5.7 to 6.7	Complies
3	Solubility	Water: Freely Soluble	Complies
		Methanol: Freely soluble	
		Ether: Slightly insoluble	
		Methylene chloride: Practically Insoluble	
4	Assay	98.5 to 101.5 %	Complies

DRUGS- EXCIPIENTS COMPATIBILITY STUDY

Table 8: Compatibility study of Dexamethasone with Excipients

Conditions	Physical Observations		FTIR Study	
	Initial	Final	Initial	Final
Room Temperature	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard
At 300 °C & 65% RH	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard
At 400 °C & 75% RH	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard

Table.9: Compatibility study of Ketorolac with Excipients

Conditions	Physical Observations		FTIR Study	
	Initial	Final	Initial	Final
Room Temperature	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard
At 300 °C & 65% RH	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard
At 400 °C & 75% RH	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard

Table. 10: Compatibility study of Zolmitriptan with Excipients[23]

Conditions	Physical Observations		FTIR Study	
	Initial	Final	Initial	Final
Room Temperature	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard
At 300 °C & 65% RH	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard
At 400 °C & 75% RH	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard

Table 11. Compatibility study of Ondansetron with Excipients.

Conditions	Physical Observations		FTIR Study	
	Initial	Final	Initial	Final
Room Temperature	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard
At 300 °C & 65% RH	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard
At 400 °C & 75% RH	White	White	No changes in the main Peak and Match with the Standard	No changes in the main Peak and Match with the Standard

DEXAMETHASONE

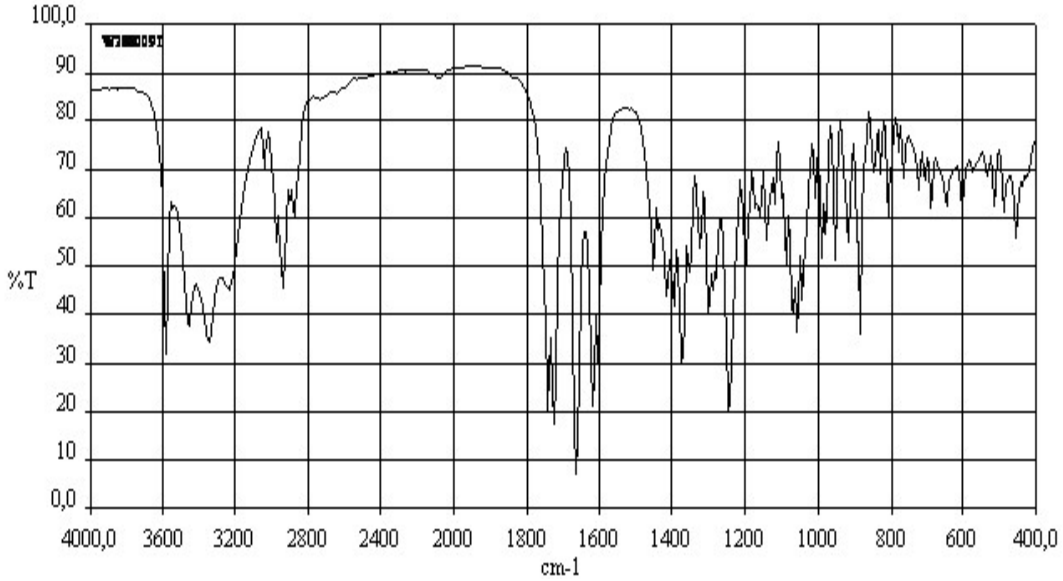

FIG.1 - I.R.GRAPH OF DEXAMETHOSONE SODIUM PHOSPHATE

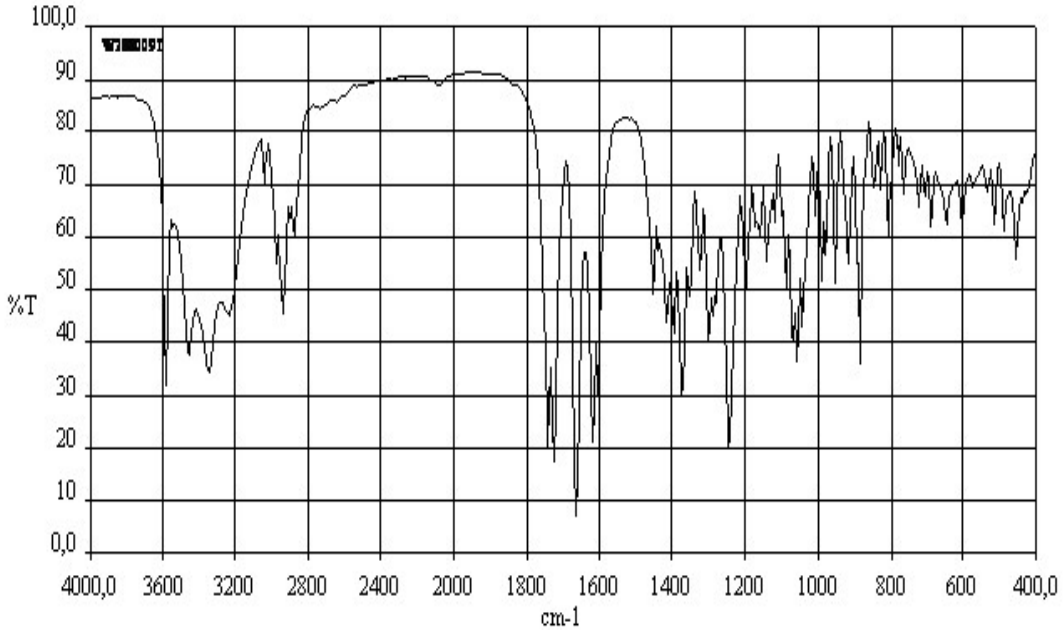

FIG.2 - I.R.GRAPH OF DEXAMETHOSONE SODIUM PHOSPHATE ***(Room temperature, after 6 months)***

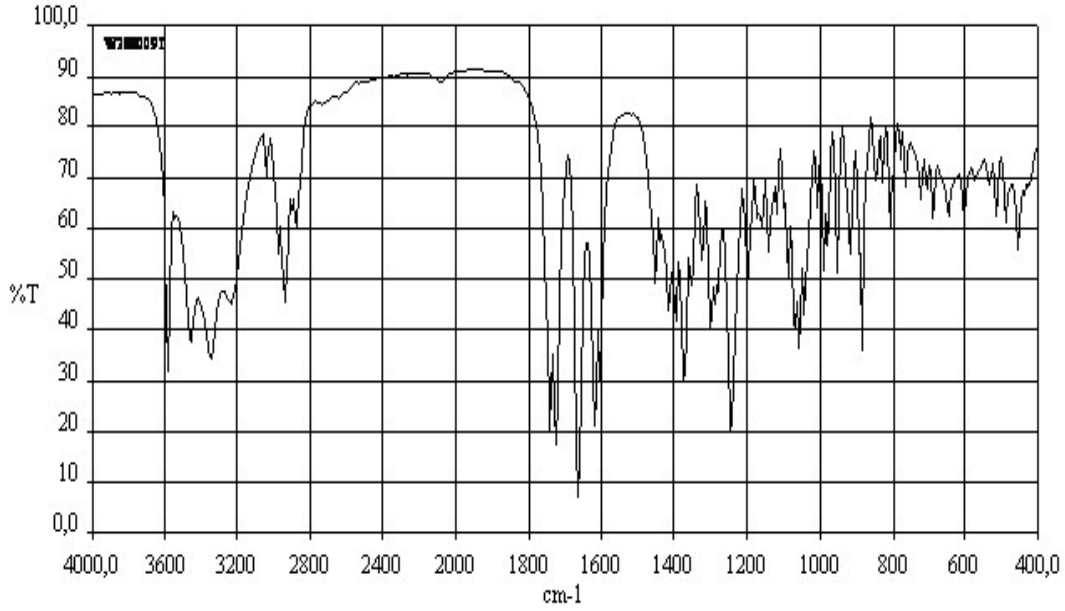

FIG.3 - I.R.GRAPH OF DEXAMETHOSONE SODIUM PHOSPHATE

(300 °C and at 65% relative humidity (RH), after 6 months)

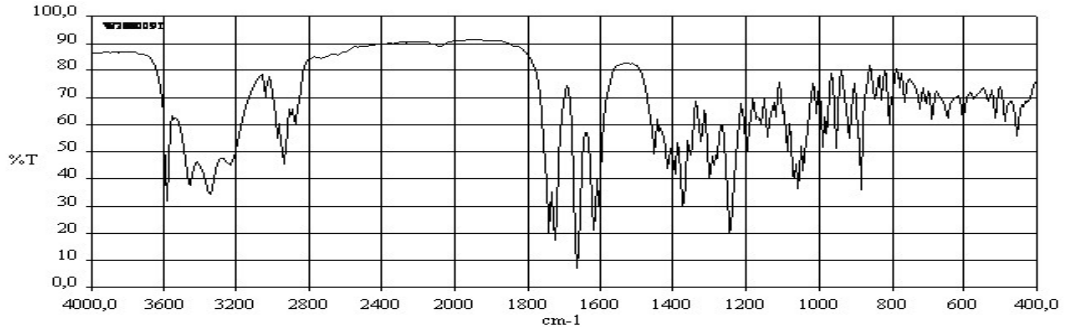

FIG.4 - I.R.GRAPH OF DEXAMETHOSONE SODIUM PHOSPHATE
(40^0C and at 75% RH, after 6 months) **KETOROLAC**

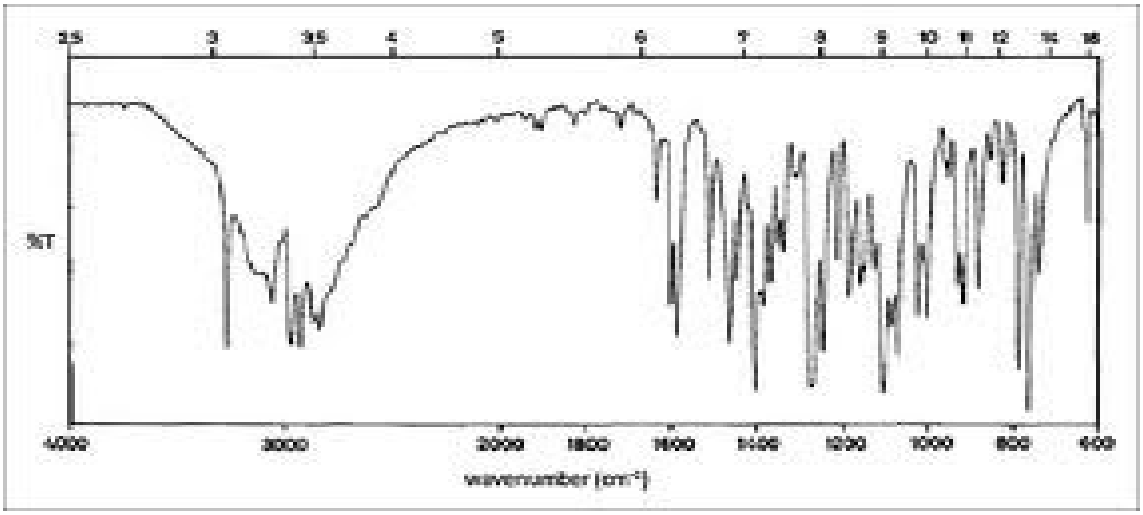

FIG.5- I.R.GRAPH OF KETOROLAC TROMETHAMINE (INITIAL)

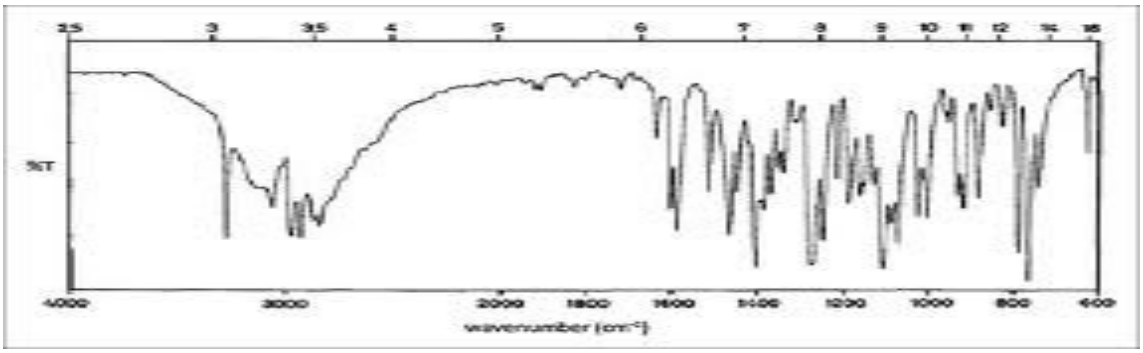

FIG.6- I.R.GRAPH OF KETOROLAC TROMETHAMINE ***(Room temperature, after 6 months)***

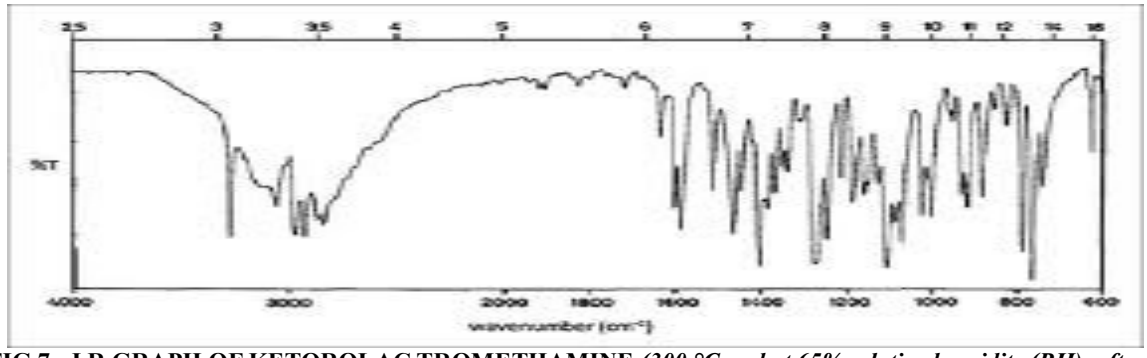

FIG.7 - I.R.GRAPH OF KETOROLAC TROMETHAMINE ***(300 °C and at 65% relative humidity (RH), after 6 months)***

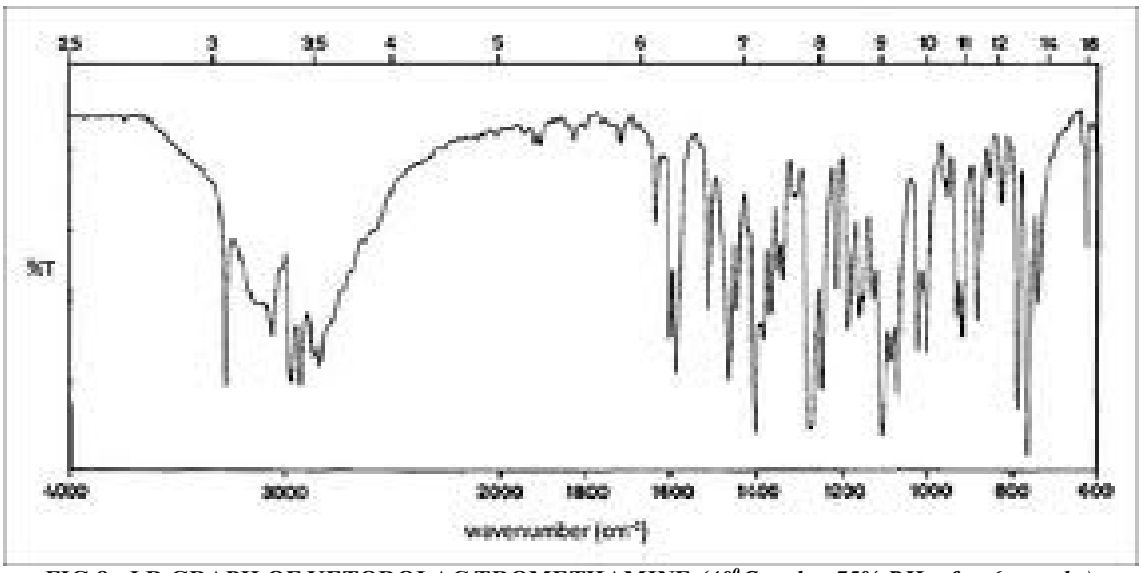

FIG.8 - I.R.GRAPH OF KETOROLAC TROMETHAMINE ***(40^0C and at 75% RH, after 6 months)***

ZOLMITRIPTAN

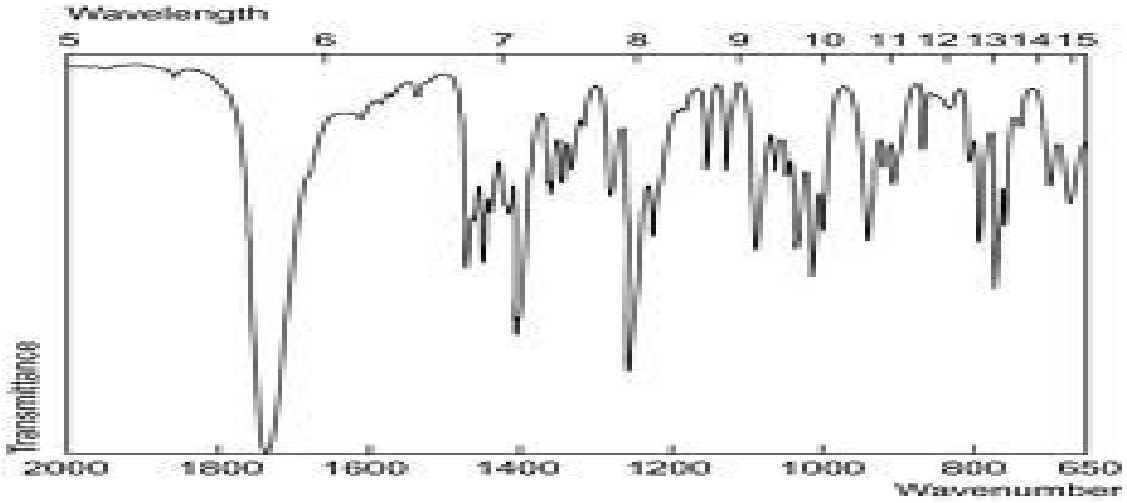

FIG.9- I.R.GRAPH OF ZOLMITRIPTAN (INITIAL)

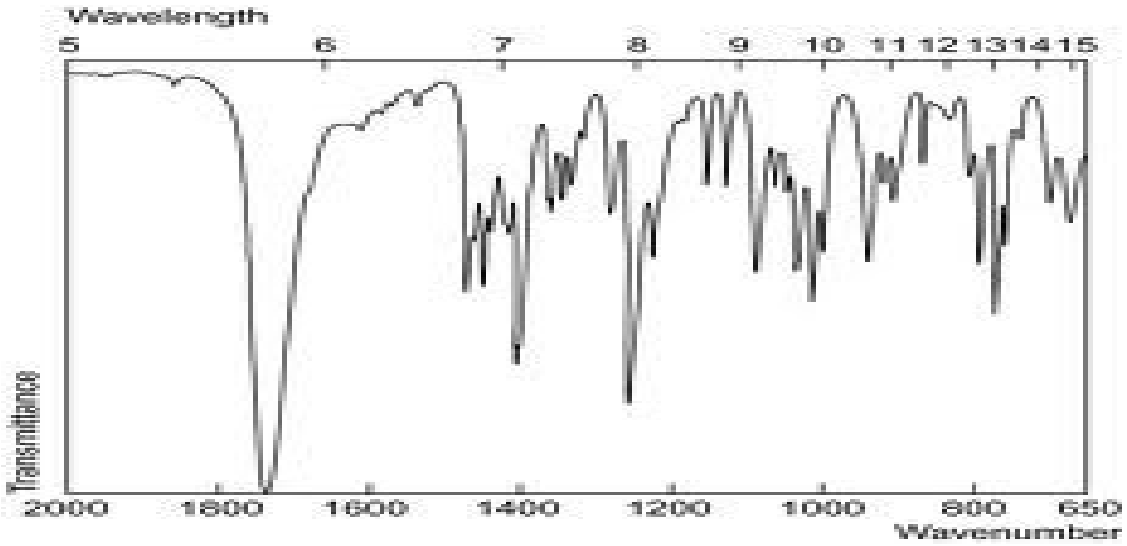

FIG.10- I.R.GRAPH OF ZOLMITRIPTAN ***(Room temperature, after 6 months)***

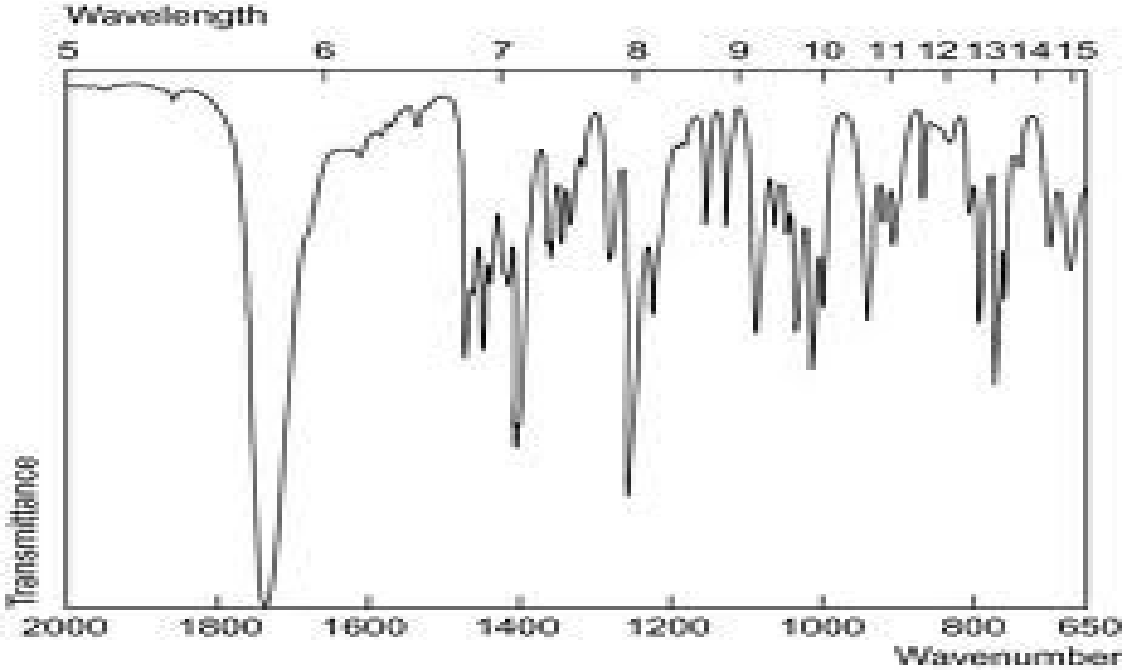

FIG.11- I.R.GRAPH OF ZOLMITRIPTAN ***(300 ℃ and at 65% relative humidity (RH), after 6 months)***

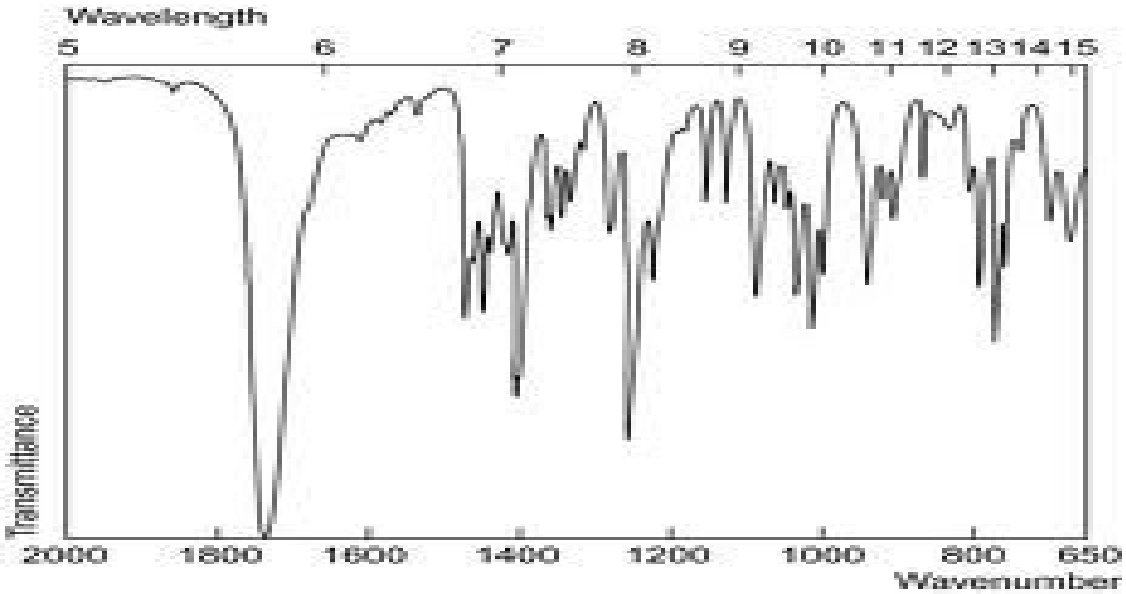

FIG.12- I.R.GRAPH OF ZOLMITRIPTAN ***(400 ℃ and at 75% RH, after 6 month)*** **ONDANSETRON HYDROCHLORIDE**

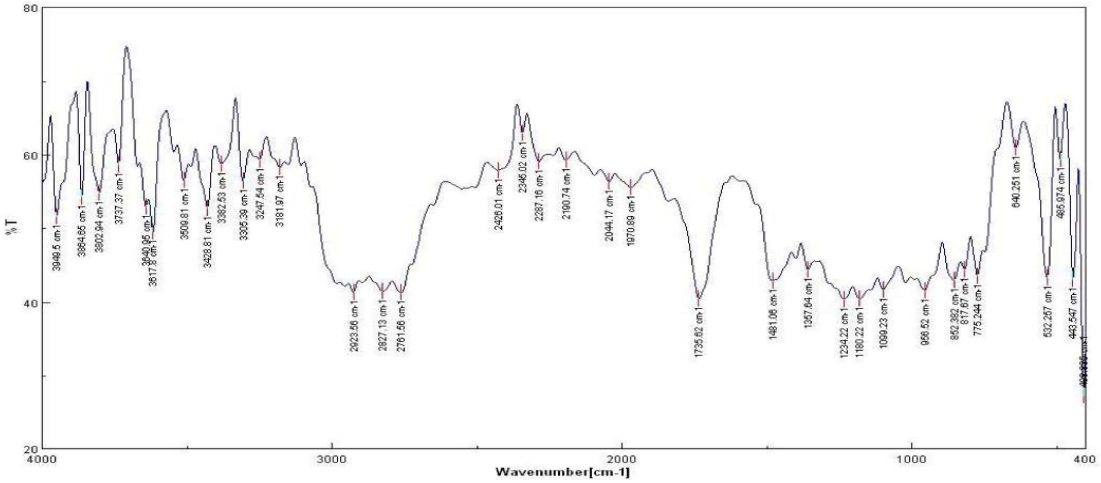

FIG.13 - I.R.GRAPH OF ONDANSETRON HYDROCHLORIDE (INITIAL)

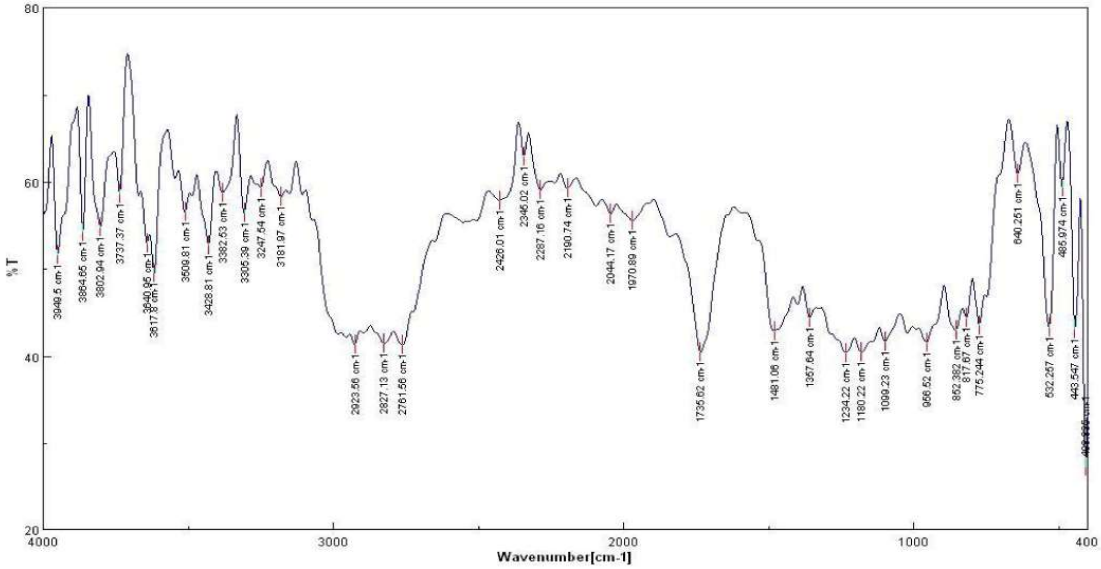

FIG.14 - I.R.GRAPH OF ONDANSETRON HYDROCHLORIDE *(Room temperature, after 6 month)*

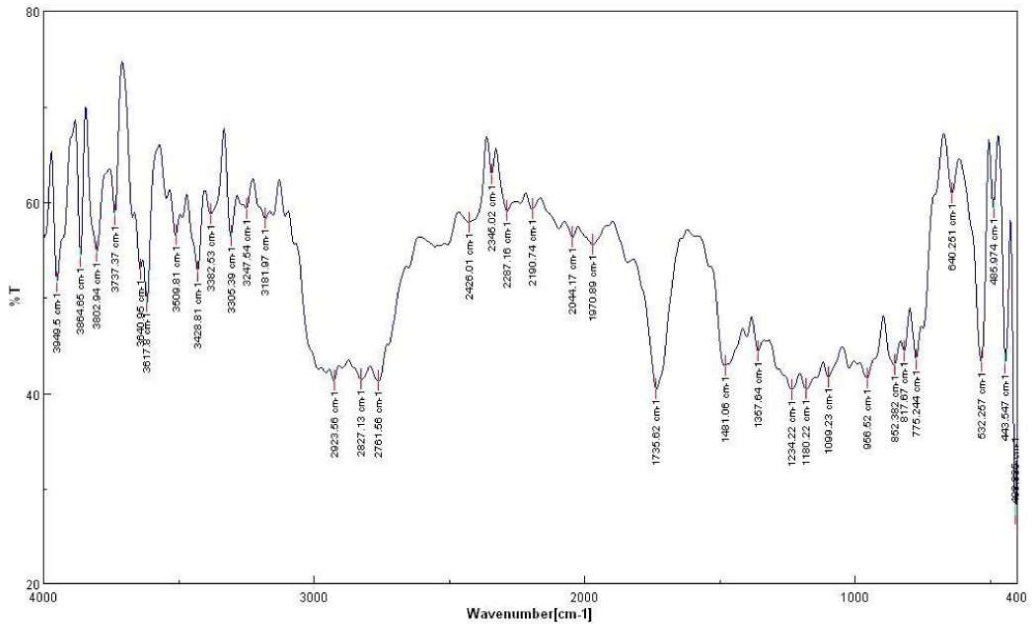

FIG.15 - I.R.GRAPH OF ONDANSETRON HYDROCHLORIDE (*30^{0}C and at 65% relative humidity (RH), after 6 month)*

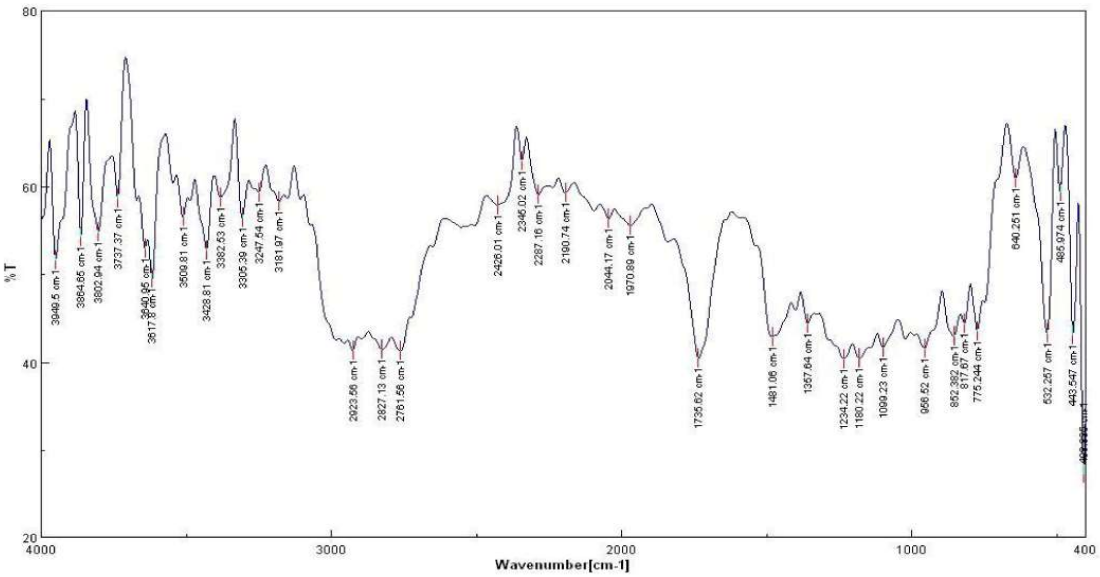

FIG.16 - I.R. GRAPH OF ONDANSETRON HYDROCHLORIDE *(40^{0}C and at 75% RH, after 6 month)*

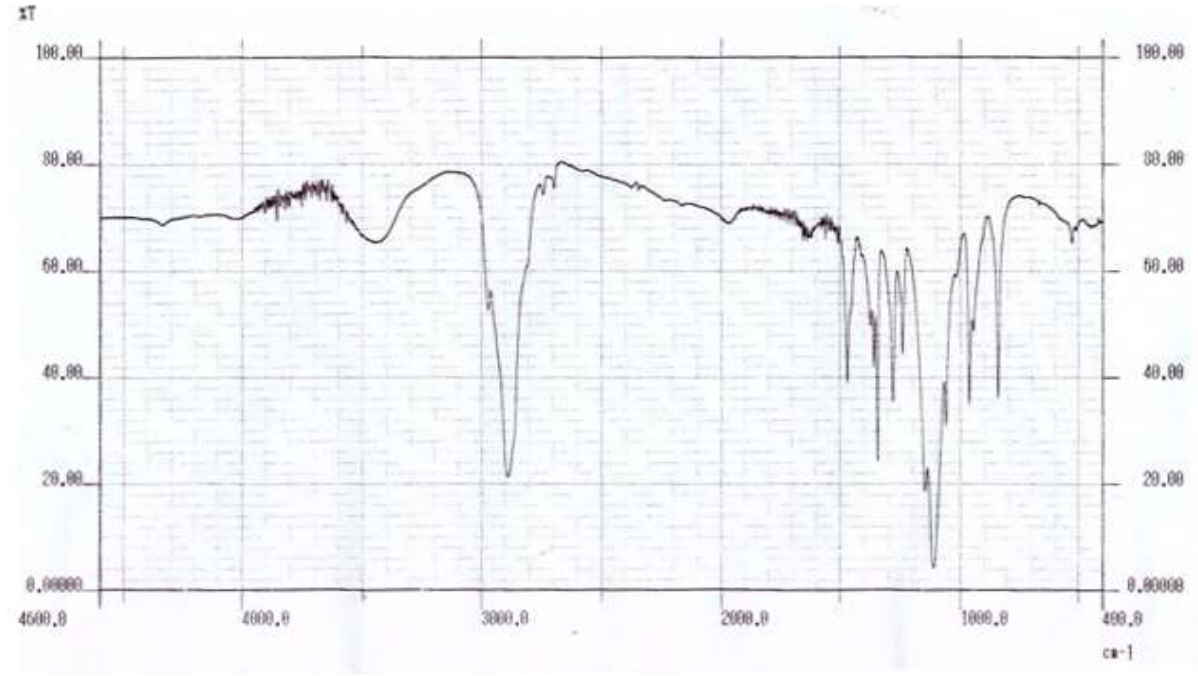

Figure 17: FT-IR of Poloxamer 407

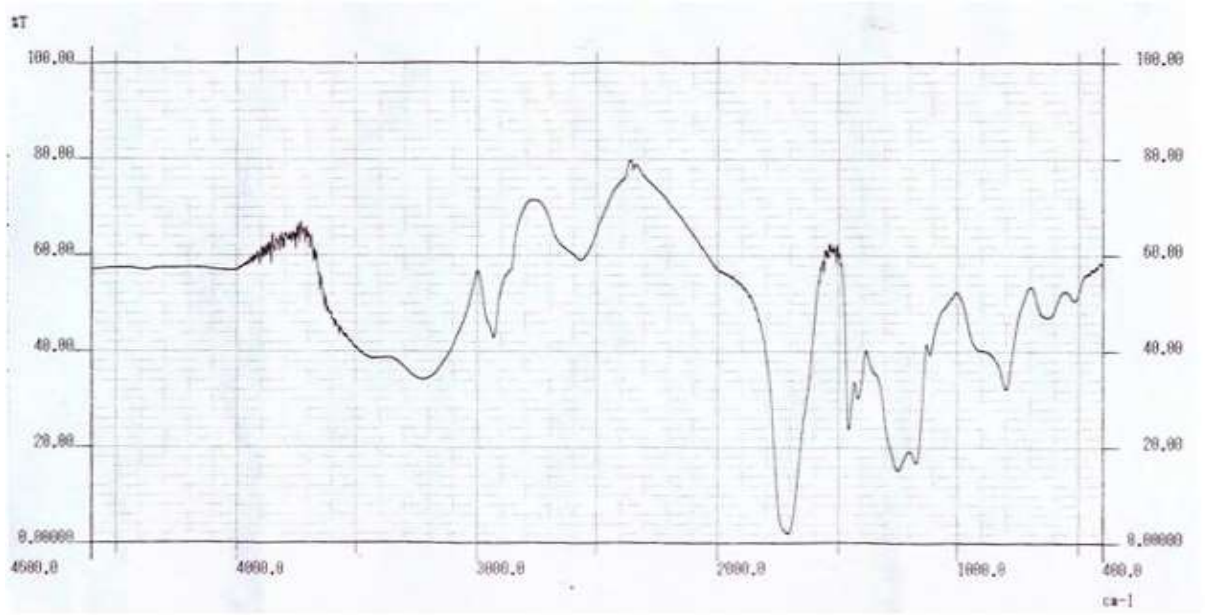

Figure 18: FT-IR of Carbopol 934P

PRELIMINARY EVALUATION PARAMETERS:

Gelation temperature of polymer solution:

Gelation temperature is the temperature at which the liquid phase makes a transition to gel. The formulated gel (Plain, Drug, and with catanionic mixture) was evaluated for Gelation temperature.

pH of polymer solution and Effect of Drugs and Catanionic Mixture on pH and gelation temperature:

Table. 12: Gelation Temperature and pH of Formulated Carbopol Gel

Sr. No	Gel Formulations	Gelation Temperature (°C)	pH	Gelation Time (Sec)
1	Plain Carbopol (C)	26.33±0.55	5.36±0.04	56±0.14
2	C+ Dex (C1)	24.32±0.43	5.42±0.14	58±0.16
3	C+Ket (C2)	25.36±0.32	5.34±0.24	60±0.20

4	C+Zolm (C3)	26.10±0.23	5.36±0.42	62±0.18
5	C + Ond (C4)	26.45±0.67	5.29±0.23	57±0.17
6	C + Ket/SDS (C5)	26.55±0.56	5.45±0.56	59±0.17
7	C + Ond/SDS (C6)	27.38±0.44	5.26±0.45	58±0.14
8	C + LPC/Dex (C7)	26.33±0.39	5.67±0.75	57±0.16
9	C + TTAB/Dex (C8)	27.10±0.56	5.23±0.26	58±0.16
10	C + BAC/Zolm (C9)	26.22±0.63	5.65±0.54	62±0.18
11	C + LPC/Zolm (C10)	26.76±0.22	5.25±0.10	63±0.18
12	C + BAC/Dex (C11)	26.57±0.70	5.23±0.18	58±0.16
13	C + Ket/Dex (C12)	25.88±0.45	5.53±0.17	62±0.18
14	C + Ket/Zolm (C13)	24.90±0.75	5.77±0.38	63±0.18
15	C + TTAB/Zolm (C14)	25.10±0.27	5.56±0.08	58±0.16
16	C + BAC/SDS (C15)	25.23±0.84	5.96±0.27	62±0.18

Table.13: Gelation Temperature and pH of formulated Poloxamer gel

Sr. No	Gel Formualtions	Gelation Temperature (°C)	pH	Gelation Time (Sec)
1	Plain Carbopol (P)	26.76±0.22	5.36±0.04	74.33±4.50
2	P + Dex(P1)	26.57±0.70	5.42±0.14	75.33±4.38
3	P + Ketc (P2)	25.88±0.45	5.34±0.24	77.44±3.36
4	P + Zolm (P3)	26.10±0.23	5.36±0.42	76.33±3.56
5	P + Ond (P4)	26.45±0.67	5.29±0.23	79.23±4.23
6	P + Ket/SDS (P5)	26.55±0.56	5.52±0.04	76.63±5.23
7	P + Ond/SDS (P6)	24.90±0.75	5.77±0.38	74.43±5.30
8	P + LPC/Dex (P7)	25.10±0.27	5.56±0.08	76.33±3.70
9	P + TTAB/Dex (P8)	25.23±0.84	5.96±0.27	78.33±3.80
10	P + BAC/Zolm (P9)	26.33±0.55	5.36±0.04	75.43±3.75
11	P + LPC/Zolm (P10)	24.32±0.43	5.42±0.14	72.33±4.50
12	P + BAC/Dex (P11)	25.36±0.32	5.34±0.24	79.63±4.56
13	P + Ket/Dex (C12)	26.10±0.23	5.36±0.42	76.43±4.50
14	P + Ket/Zolm (P13)	26.45±0.67	5.29±0.23	77.53±4.80
15	P + TTAB/Zolm (P14)	26.67±0.70	5.23±0.28	74.33±4.33
16	P + BAC/SDS (P15)	23.89±0.79	5.83±0.70	75.33±4.57

Each value is expressed as mean±S.D. (n=3).

The thermosensitive gel maintained stable gelation temperature, gelation time, viscosity, and pH regardless of component concentrations. Previous studies demonstrated that amphiphilic drugs with oppositely charged surfactants form vesicles, which effectively prolong drug release from gels, providing the basis for this formulation strategy.

***In vitro* drug Release**:

RELEASE STUDY OF DRUGS FROM CATANIONIC AGGREGATES FROM GEL

Four catanionic drug–surfactant systems were evaluated for sustained drug release, and all demonstrated effective release prolongation. Ketorolac/SDS formulations included both vesicular and micellar systems, while ondansetron/SDS vesicles from both sides of the equimolar ratio were investigated. Due to incompatibility of drug-rich vesicles with Carbopol, Poloxamer was used as an alternative gel base in selected formulations.

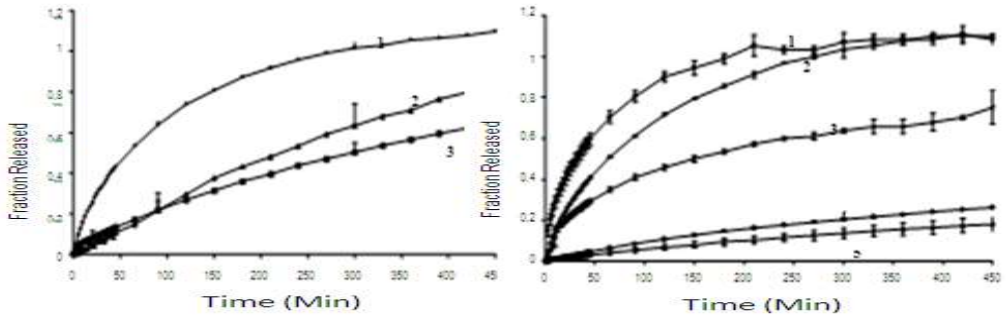

Figure 14. demonstrates that catanionic micelles and vesicles markedly prolonged the release of ketorolac and ondansetron compared with drug-only gels. Ketorolac diffusion coefficients decreased by at least tenfold, with no significant difference between micellar and vesicular systems. Ondansetron exhibited even greater sustained release, particularly with SDS-rich vesicles, showing diffusion coefficients nearly 60-fold lower than the reference formulation. Rheological studies revealed only minor changes after incorporating catanionic systems into Carbopol or Poloxamer gels, indicating minimal polymer interactions. Cryo-TEM confirmed that both micelles

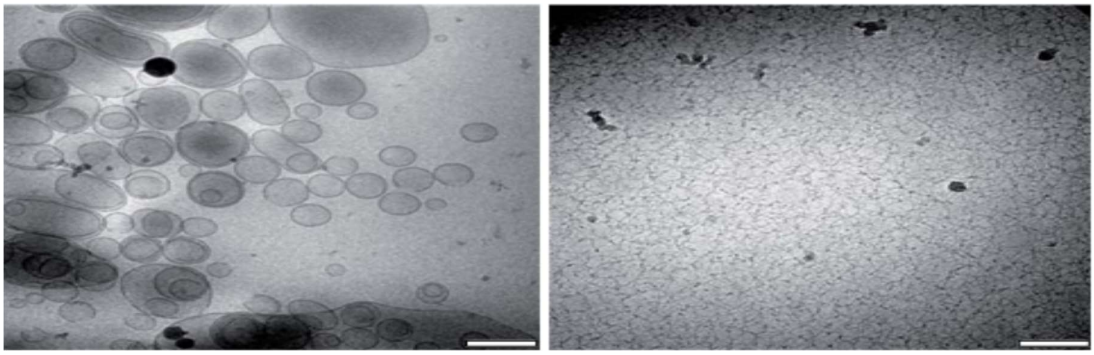

Figure 15. Cryo-TEM confirms intact vesicles and micelles within the Carbopol gel matrix.

The zolmitriptan/TTAB catanionic system demonstrated significantly sustained drug release, with diffusion coefficients approximately 10–100 times lower than those of the reference gel containing zolmitriptan alone. Variations in total concentration (40–160 mM) or drug-to-surfactant ratio had no significant effect on drug diffusion, indicating that the sustained-release behavior was independent of micellar concentration or composition and was primarily governed by the catanionic complex formation.

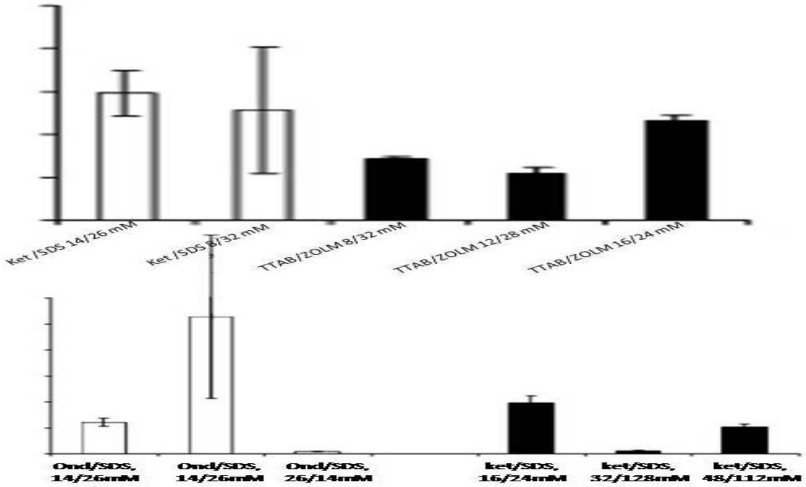

Figure 16. illustrates the degree to which drug release could be slowed in the presence of various The bar chart compares the diffusion coefficient of the reference drug formulation with those of various catanionic formulations, demonstrating their sustained-release potential. Error bars represent confidence intervals. Rheological studies confirmed that compatible

catanionic mixtures did not significantly alter the Carbopol gel network. Therefore, the reduced drug diffusion and sustained release are primarily attributed to the catanionic delivery system rather than changes in the gel's rheological properties.

SUMMARY & CONCLUSION

The study demonstrated that thermosensitive gels containing poloxamer 407 and carbopol 934P exhibited suitable gelation temperature, gelation time, viscosity, and pH, with no significant physicochemical incompatibility between drugs, polymers, and surfactants as confirmed by FTIR analysis. Catanionic aggregates formed in systems containing oppositely charged surfactants, highlighting their relevance in pharmaceutical formulations while indicating a potential risk of precipitation. Incorporation of drugs into catanionic systems markedly enhanced and prolonged drug release, extending release from 30 minutes to 12 hours. Release behavior was governed mainly by free monomer concentration because the large catanionic aggregates remained largely immobile within the gel matrix.

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