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Formulation and Charecterization and Evaluation Gentamicin Sulphate and Loratadine Emulgel for Treatment as Anti-Bacterial and Anti-Allergic

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ABSTRACT

This research focuses on developing a topical **emulgel system formulation combining Gentamicin sulphate aminoglycoside (an antibiotic** and **allergic agent)** to enhance the better treatment of localized skin infections and allergic reactions. **Loratadine H1 receptor (an anti-allergic).** Emulgel, a hybrid novel system of emulsion and gel, allows for effective delivery of both hydrophilic waters loving nature and hydrophobic drugs while bypassing the gastrointestinal tract and first-pass metabolism in the formulation offers several many type advantages, including improved patient compliance, enhanced skin penetration, better stability, thixotropy, High Spredaability, and non-greasy texture. Pre-formulation studies assessed the compatibility and solubility of both drugs, Gentamicin Sulphate and Loratadine along with physicochemical properties like pH, melting point, TLC, Particle size, flowability, as angle of repose, bulk tapped density and FTIR analysis. Emulgel was prepared using Carbopol grade as a gelling agent, Span 20 and Tween 20 as emulsifiers, and preservatives like methyl and propyl parabens. Triethanolamine pH adjuster, Evaluation studies included organoleptic assessment, rheology, in vitro drug release, zeta potential, SEM imaging, skin irritation tests, and stability studies. The dual-drug combination aims to provide desired therapeutic effects against bacterial infections and allergic inflammation, overcoming solubility limitations and ensuring better topical absorption. This research supports the development of an effective dermatological treatment with improved clinical outcomes and patient convenience. This research demonstrates that combining Gentamicin and Loratadine in an emulgel base not only enhances their individual therapeutic potentials but also ensures **patient compliance, localized action,** and **reduction of systemic side effects.** The findings support the potential of this dual-drug emulgel as a promising alternative in **dermatological therapy**, offering improved outcomes for patients with concurrent skin infections and allergic responses.

Keywords: *Dual combination formulation, Emulgel system, Gel and Emulsion in Incorporating Method, Preformulation study of drugs and also Evaluation of Formulation.*

1. INTRODUCTION

Gel and Emulsion incorporating to form emulgel, together in emulsion and gel, either form water-in-oil or oil-in-water emulsified gel stable effective carrier for hydrophilic and hydrophobic drug substance, oil in water is lipophilic and water in oil for hydrophobic drug content. In recent years, researchers and industrial scientists have shown growing interest in semisolid formulations especially emulgels. These systems are designed for topical and systemic drug delivery via the skin, offering improved patient compliance by facilitating drug absorption with minimal side effects. Emulgels are three-dimensional semisolid systems combining the characteristics of gels and emulsions, making them suitable for both hydrophilic and lipophilic drugs. A newly development is the combination of antibiotic and anti-allergic agents in emulgels. Since infections can trigger allergic reactions and delivering these therapeutic agents locally enhances effectiveness, increases drug bioavailability, and reduces systemic adverse effects. Topical drug delivery systems remain a key focus for treating both localized and systemic conditions, thanks to their advantages over conventional dosage forms. Common applications include treating skin infections, wounds, and allergies. Effective topical administration depends on several factors that influence percutaneous absorption:

- Cross the intact stratum corneum site
- Via sweat ducts site
- Through sebaceous follicles site

The stratum corneum is the primary barrier, covering over 99% of the skin's surface area and acting as the rate-limiting membrane for drug permeation. Successful percutaneous delivery involves three major steps:

- Maintaining a concentration gradient between the vehicle and target tissue
- Delivery the active ingredient from the formulation
- Diffusing the drug through the skin's layers.

Criteria Choice for Emulgel Formulation

- Optimal pH for Skin suitability, non- irritating, and contagious free, Stable drug and permeability also good.
- Low molecular weight and Dalton is low.
- Choice of drug is not interaction show and full compatibility show
- In emulsion use suitable emulsifying agent emulsion make a micro based.
- In gel Carbopol interaction show but use pH adjuster to maintained pH.

Emugel Composition

In emulgel composition is used to medicated formulation in emulgel to create is use the firstly is Drug, Emulsifying agent, Gelling agent, Preservatives, Solubilizing agent, Aqueous phase substance, and pH maintaining agent, Viscosity enhancer, Penetration activators, etc.

Advantage of Emulgel

- Emulgel formulation improved the across the skin barrier support deep diffusion suitable the local and systemic action.
- Emulgel delivery of drug enhanced the stability by double methodology preparation so improved the stability of formulation.
- Emulgel formulation Increases the patient complacency smooth texture easily spread and non- greasy.
- Emulgel is dual strength incorporating novel technology based deeper topical release and also controlled release manner.

Disadvantage of Emulgel

- Emulgel Preparation is complicated manufacturing process many stages and mixing technology chance of Un-Uniformity and Phase separation.
- Emulgel is many steps and many instruments required so emulgel production cost is high.
- Emulgel preparation drug loading method is complicated and also incorporating, gel in emulsion.
- Emulgel Preparation heating step also chances of degradation of drug substance and also pH issue faced.

Emulgel Preparation

Gentamicin Sulphate + Loratadine+ Oil Phase System+ Water Phase System + Combining Emulsification +O/W or O/W+ Mixing Incorporating to gelling mixture +Emulgel

In Emulgel Emulsion Preparation

- 10ml of purified water are used to soluble 0.5% w/w tween 20 create an water aqueous phase and mix the 250mg drug.
- Methyl paraben+ propylparaben combined with Propylene glycol and then mix also aqueous phase.
- Liquid paraffin is as oil phase with Span20 of 1% was mixed with 10mg drug with dissolved in di-chloro-methane
- Oil and Aqueous phase separately heat in water bath as more than 80°C and cool as room temperature and separated mixture mixed using by Mechanical Stirrer for 20-30 minute

In Emulgel Gel Preparation

- 40ml of purified water in 100ml clean Beaker Stir around 800rpm speed.
- Measure Weighted amount of Carbopol was added small pinch small pinch with continuous stirrer about 15min. gel texture show.

Incorporating as Emulgel Preparation

- Emulsion Solution added in Gel mixture drop by drop, continuously stirring as required speed and pH was measured.
- Triethanolamine added to adjust the pH and make Viscous.
- Continued Stirred emulgel make more consistent and stable.

Emulgel Formulation Chart

Drug/Ingredient	EF1	EF2	EF3	EF4	EF5
Gentamicin sulphate	250mg	250mg	250mg	250mg	250mg
Loratadine	10mg	10mg	10mg	10mg	10mg
Carbopol 934	0.30gm	0.50gm	0.75gm	1gm	1.5gm
Span 20	0.5ml	0.75ml	0.5ml	0.5ml	0.5ml
Tween 20	0.5ml	0.5ml	0.5ml	0.5ml	0.5ml
Propylene glycol	3ml	3ml	3ml	3ml	3ml
Methyl paraben	0.02g	0.02g	0.02g	0.02g	0.02g
Propyl paraben	0.02g	0.02g	0.02g	0.02g	0.02g
Triethanolamine	q. s	q. s	q. s	q. s	q. s
Liquid paraffin	3ml	3.5ml	4ml	4.5ml	5ml
Distilled water	q. s	q. s	q. s	q. s	q. s

2. RESULT AND DISCUSSION

PRE-FORMULATION:

Organoleptic Properties:

Organoleptic senses study by human by visualize and touch taste and other to determine character

Organoleptic Character of Gentamicin Sulphate

S. No	Properties	Consequence
1.	Color	White buff yellow
2.	Shape	Powder
3.	Oduor	Odourless
4.	Texture	Fine and milky
5.	Taste	Metallic taste

Organoleptic Character of Loratadine

S. No	Properties	Consequences
1.	Color	White
2.	Shape	Powder
3.	Oduor	Odourless
4.	Texture	Fine granules
5.	Taste	Slight bitter

Solubility Studies:

Weighted amount of gentamicin sulphate and loratadine fill in test tube and stand with holder. Followed 1ml of chemical used to solubility methanol, ethanol, Dichloromethane, water, DMSO, chloroform

Gentamicin Sulphate Solubility in different Solvents

S.No	Solvents	Solubility Parameter
1.	DMSO	Insoluble
2.	Chloroform	Slightly Soluble
3.	Ethanol	Moderately Soluble
4.	Methanol	Moderately Soluble
5.	Distilled Water	Very Soluble
6.	DMF	Freely Soluble

Loratadine Solubility with Different Solvents

S. No	Solvents	Solubility Parameter
1.	Dichloromethane (DCM)	Very Soluble
2.	Distilled Water	Insoluble
3.	Chloroform	Sparingly Soluble
4.	Ethanol	Sparingly Soluble
5.	Methanol	Sparingly Soluble
6.	Dimethyl sulfoxide (DMSO)	Soluble

pH Studies:

Study of the pH of gentamicin sulphate and loratadine using the automatic or digital pH meter. Measure amount of 50mg/drug dissolved in suitable solvent. Distilled water used to clean the electrode and reading zero and put the solution electrode dip in solution and value in noted

pH determination of Gentamcin Sulphate

Drug	pH range	pH
Gentamicin Sulphate	3.5-5.5	4.86

pH determination of Loratadine

Drug	pH range	pH
Loratadine	5-7.5	7.25

Melting in Point:

Weight 50-50 mg both separate drug gentamicin sulphate and loratadine and use the capillary tube filling method, 1 dimeter end closed by heat and flex downward. The drug takes placed in watch glass and fill the drug using sample technique and after filling powder in capillary put in melting point apparatus hole and second hole put thermometer and seen in apparatus through the glass between tube and apparatus point of drug in melt noted**.**

Determination of Melt-in-Point Gentamicin Sulphate

Drug	Melt Point Range	Melt-in-point

Gentamicin Sulphate	200-220	200

Determination of Melt-in-Point Loratadine

Drug	Melt Point Range	Melt-in-point
Loratadine	130-137℃	134℃

Lamda max and calibration curve determination

- **Preparation Standard solution**

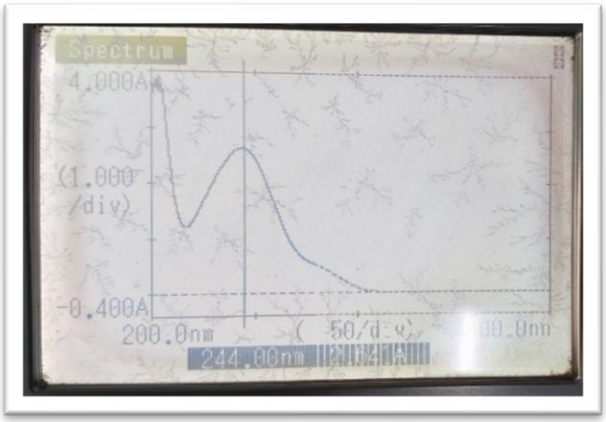
10-10 mg both separate quantities put in into volumetric flask. And suitable solvent make-up the volume resulting as the 1000µg/ml solution

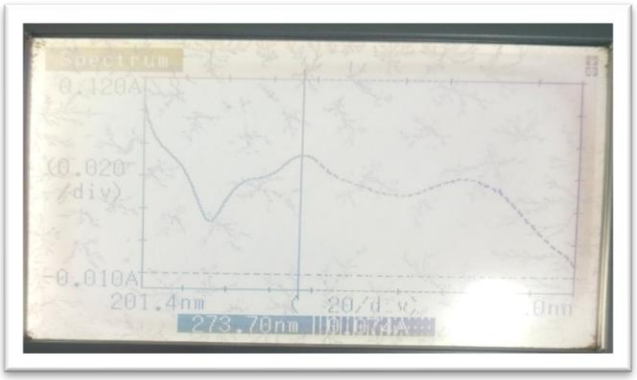
- **Lamda max**

1ml of standard solution removed in 10ml volumetric flask then make-up volume to solvent in 10ml. the sample was scanned by using UV spectroscopy within wavelength range of 200-400, with solvent as reference solution. The peak is show in UV and noted.

- **Calibration curve**

The both separated sample (1mg/ml) was utilized to prepare various concentration (0,10,15,20,25,30 µg/ml) at respectively 275,244 nm by spectrophotometer.





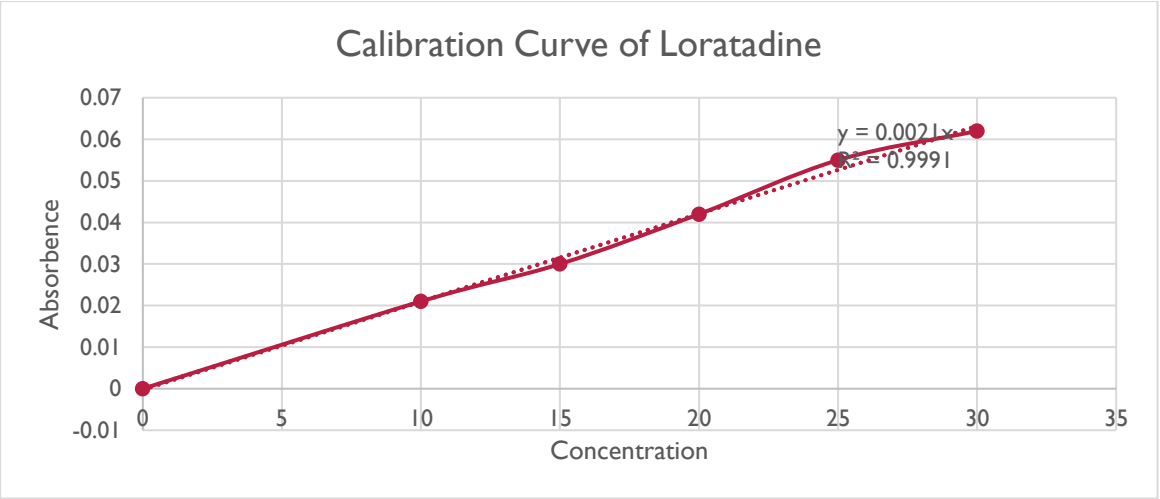
Lamda max Loratadine and Gentamicin sulphate

Drug	Lamda max
Loratadine	275nm
Gentamicin Sulphate	244nm

Absorbence of Loratadine Different Concentraion

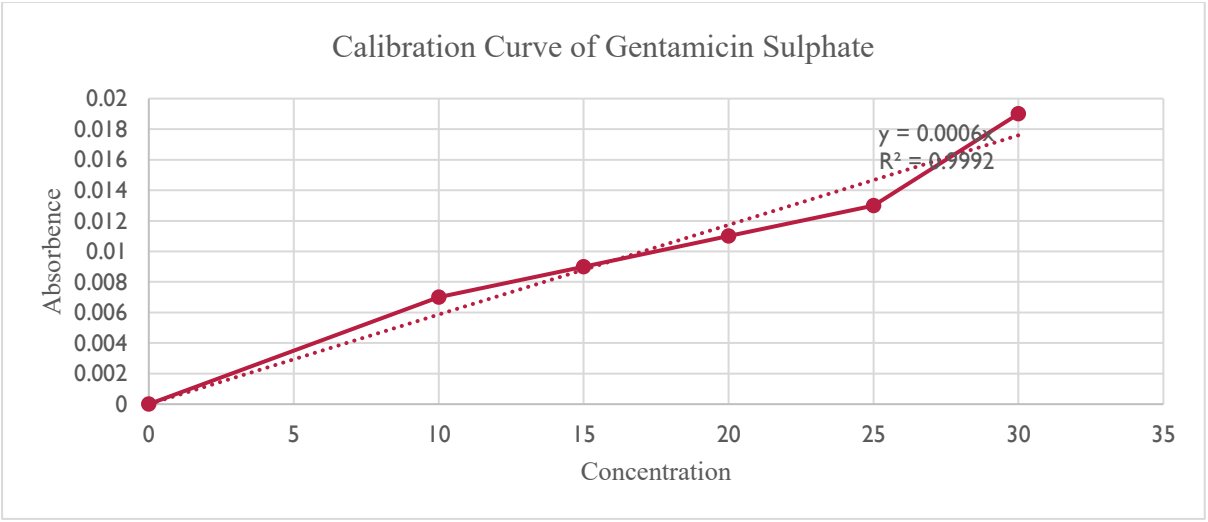
S.No	Concentrations (µg/ml)	Absorbence
1.	0	0
2.	10	0.21
3.	15	0.30
4.	20	0.42

5.	25	0.55
6.	30	0.62



Absorbence of Gentamicin Sulphate Different Concentration

S.No	Concentratation (µg/ml)	Absorbence
1.	0	0
2.	10	0.007
3.	15	0.009
4.	20	0.011
5.	25	0.013
6.	30	0.019



Partition Coefficient Determination:

Partition coefficient is studies of drug lipophilic or hydrophilic its nature. The partition coefficient used to equal amount of

lipophilic immiscible solvent n-octenol or n-butanol and hydrophilic used water. Separating funnel is used to separate both phase water and octenol. This procedure equal amount of octenol and water added in separating funnel and added drug amount of 1mg/ml dissolved by movement. After dissolving drug separating funnel with help of tripod stand placed for 24 hrs. after complete 24hrs remove solvent in separate suitable flask. the concentration amount of drug dissolved which solvent determine by UV spectroscopy.

Partition coefficient=conc of drug in aqueous phase/ conc of drug in oil or organic phase

Partition coefficient of Gentamicin Sulphate

Concentration of Gentamicin sulphate in water	**Concentration of Gentamicin sulphate in organic solvent**
0.076	0.037

Partition Coefficient = $\frac{concentration\ of\ drug\ in\ organic\ solvent}{concentration\ of\ drug\ in\ aqueous\ solvent}$

Partition Coefficient = $\frac{0.037}{0.076}$ = 0.486=0.4

Partition coefficient of Loratadine

Concentration of Loratadine in water	**Concentration of Loratadine in organic solvent**
0.207	0.87

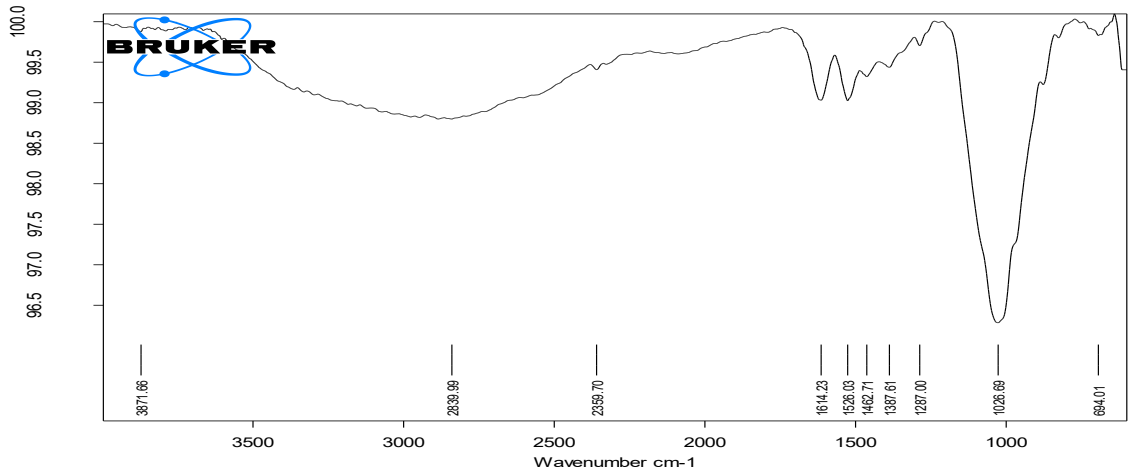
Partition Coefficient=$\frac{Concentration\ of\ drug\ in\ organic\ solvent}{concentration\ of\ drug\ in\ aqueous\ Solvent}$

Partition Coefficient = $\frac{\mathbf{0.87}}{\mathbf{0.207}}$ **= 4.2**

FTIR (Fourier Transform Infrared Spectroscopy):

The FTIR spectra is technique obtained infrared spectrum emission of sample absorption of an infrared in sample. Placed the sample in FTIR sample holder the path of light IR source and detector signal and convert to spectrum and a system setup analyze spectrum. This study is based on spectrum chemical group, and compatibility of both drug- drug and drug-excipient.

FTIR Peak of Gentamicin Sulphate



FTIR Peak of Loratadine

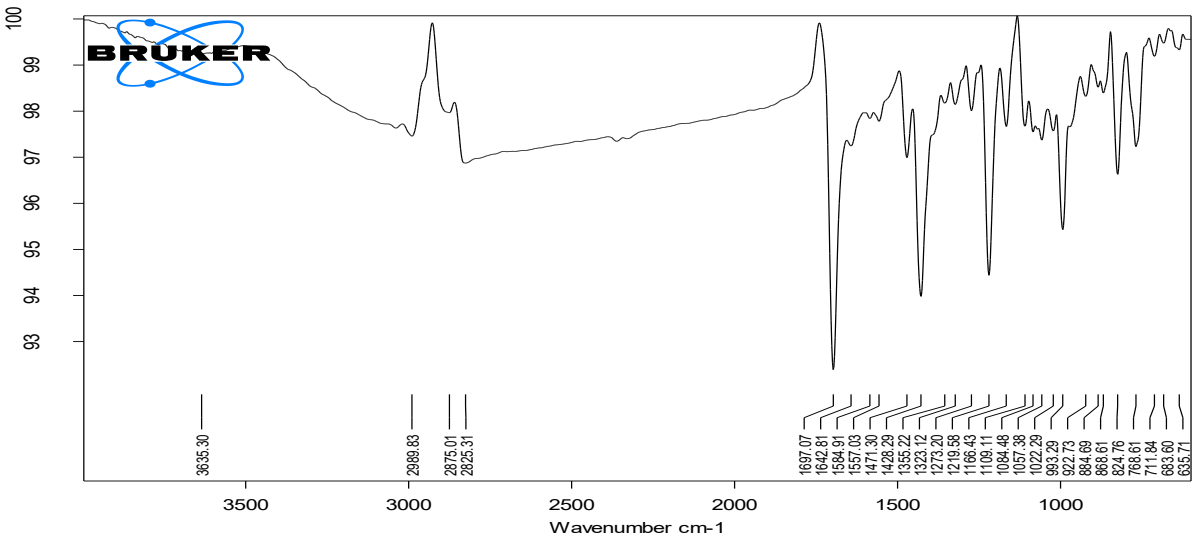
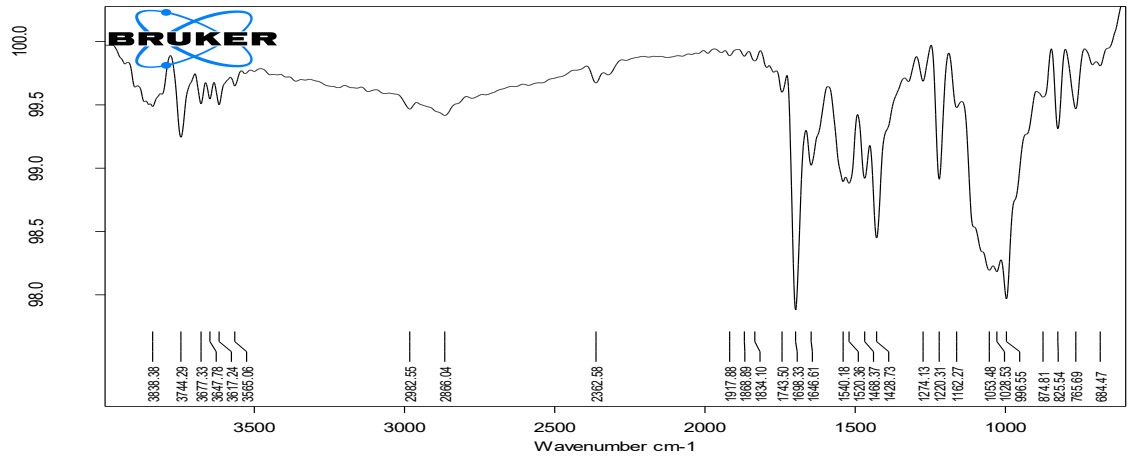
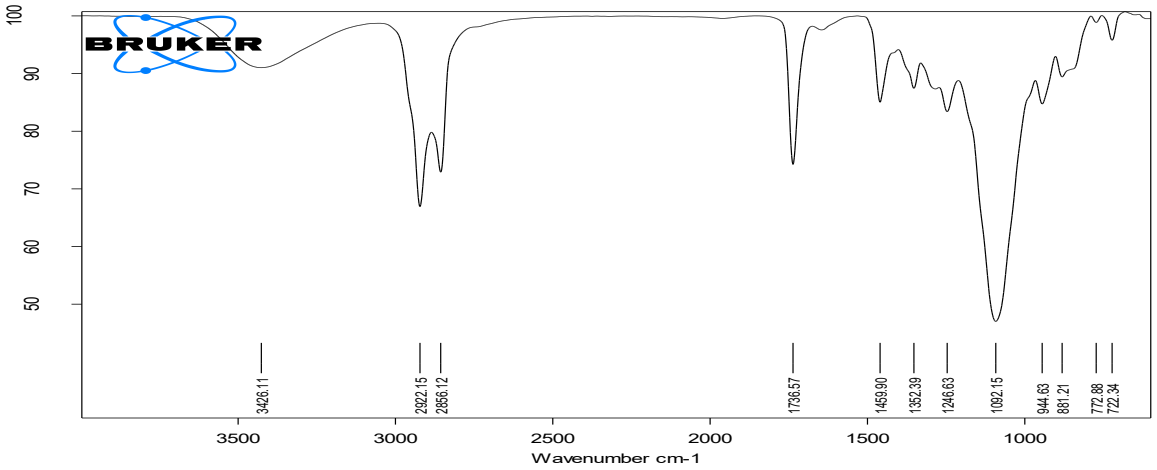


Figure FTIR Peak of Gentamicin sulphate with Loratadine



FTIR Peak of Gentamicin sulphate+ Loratadine+ Carbopol934+ Span20 +Tween 20+ Methylparaben



LOD (loss od Drying):

The loss of dryness is simple weighing method to determine the moisture content in sample its simple procedure follow firstly weight China disc is empty is (W1). second strep drug weight with disc (W2).and then sample with disc keep in hot air oven for (10min) temperature rise 100-110℃. After 10-minute sample transfer in desiccator for 10minute. Then re keep the oven 5min in temperature at 100-110℃. Finally measured weight of (W3).

- ✓ **Loss of dryness%=weight loss/weight of sample*100**

Gentamicin Sulphate

$$\textbf{\% loss of drying} = \frac{weight\ loss}{weight\ of\ drug} \times 100$$

$$= \frac{0.08}{2} \times 100$$

$$= 4\ \%.$$

Loratadine

$$\textbf{\% loss of drying} = \frac{weight\ loss}{weight\ of\ drug} \times 100$$

$$= \frac{0.05}{2} \times 100$$

$$= 2.5\%.$$

Drugs	% Loss of Drying
Gentamicin Sulphate	4%
Loratadine	2.5%

Particle size:

Powder substance is placed over the stage and observed trough the lens. The microscope eye piece with micrometer size of particle to estimated.take the microscope and measurement scale clean and placed in microscope sample placed in the scale slide and one is closed and second eye seen the diameter range used the computer system for graph of diameter.

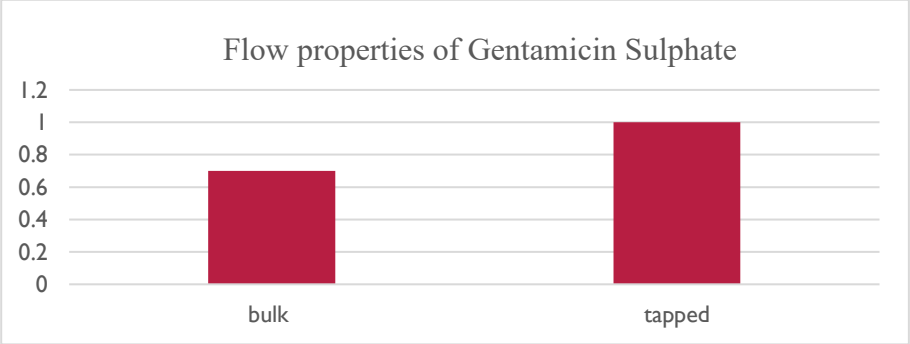
Particle Size of Gentamicin Sulphate and Loratadine

S.No	Drug Name	Particle Size
1	Gentamicin Sulphate	15µ
2	Loratadine	10µ

Flow Properties:

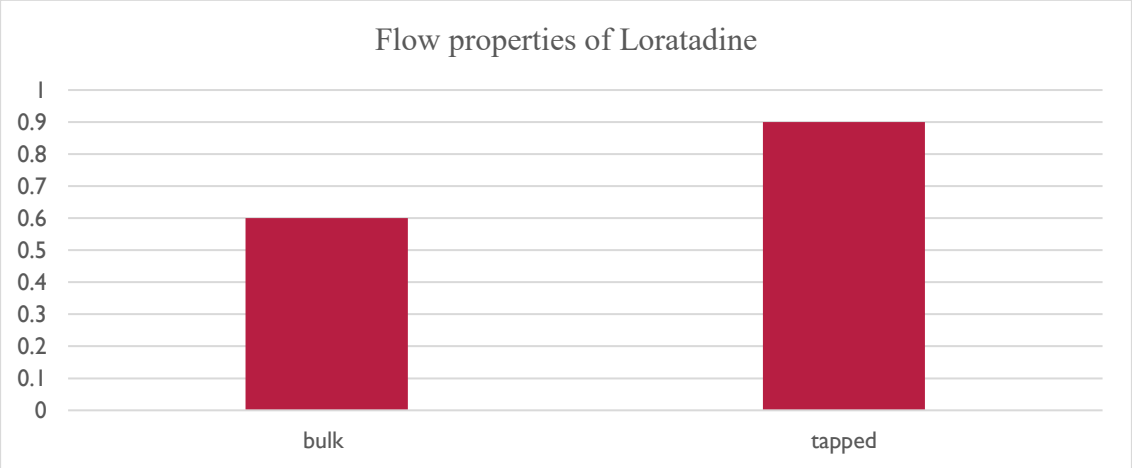
Flow Properties of Gentamicin Sulphate

Parameters	Result
Bulk density	0.7g/ml
Tapped density	1 g/ml g/cm^3



Flow properties of Loratadine

Parameters	Result
Bulk density	0.6g/ml
Tapped density	0.9g/ml



Bulk density: Measure the amount of powder drug sample in transferred into graduated cylinder material up down measure the initial volume. Determine the bulk density using formula.

- ✓
- ✓ **Bulk density=weight of drug/ bulk volume**

Tapped density: Tapped density weigh the known amount of drug powder pour the graduated cylinder, tap the specified number of times. Measure the volume. Determine tap density with formula**.**

- ✓
- ✓ **Tapped density=weight of drug powder/ tapped volume**

Carr's index: its measurement of compressibility index of flow ability of drug powder it is calculated using both bulk density and tapped density value is measured.

- ✓
- ✓ **Carr's index =tapped density-bulk density/tapped density*100**

Flow prperties different ratio of Gentamicin Sulphate

Parameters	Result
Carr's index	25% poor flow
Hausners ratio	1.33 very poor flow
Angle of repose	33.37 degree

Flow prperties different ratio of Loratadine

Parameters	Result
Carr's index	33.33% very poor
Hausners ratio	1.5 poor flow
Angle of repose	40 degree poor flow

Angle of repose: Setup position a level surface sheet or bord with funnel hold the funnel a certain height above the surface. Powder of flow slowly from funnel forming conical on surface. Determine the vertical distance (h) from bottom of powder to highest point. Determine the radius (r) of powder base. Use the trigonometric calculation of angle of repose.

- ✓
- ✓ **Angle of repose (Θ) =$\tan^{-1}$(h/r)**
- ✓

Hausner's ratio: The flowability of the powder also determined by Hausner's ratio. Its measurement density of the compressed material to the density of bulk material.

- ✓
- ✓ **Hausner's ratio= tapped density/ bulk density**

3. EVALUATION OF GENTAMICIN SULPHATE AND LORATADINE EMULGEL

Physical Evaluation

The physical evaluation of appreance of Gentamicin Sulphate and Loratadine Emulgel formulation evaluation of significent aspects including color, consistency ,uniformeity, homogeneity immisibility or phase sepration

Physical Evaluation of Formulation

Formulation	Color	Consistency	Homogeneity	Phase Sepration
EF1	Icy-White	Creamy Gel	Homogeneous	Phase- Seprate
EF2	White	Thick Gel	Homogeneous	None
EF3	Creamy White	Viscous, Gel-like	Homogeneous	None
EF4	Off - White	Viscous, Gel-like	Homogeneous	None
EF5	White	Smooth, Gel-like	Homogeneous	None

pH Evaluation

The pH evaluation of both drug formulation ensure the product described pH range for safety and stability. pH monitoring helps in maintaning the quality and efficency. The pH is important for topical formulation due to skin irritation and absorbence of formulation via topical route, Gentamicin Sulphate and Loratadine emulgel pH rannge is around 5.0 to 7.0, favorable pH for skin .

pH of Emulgel Formulation

Formulation of Emulgel	pH				Average (n=4)
EF1	6.7	6.5	6.9	7.0	6.7
EF2	6.4	6.6	5.8	6.0	6.2
EF3	6.0	7.0	6.3	5.9	6.3

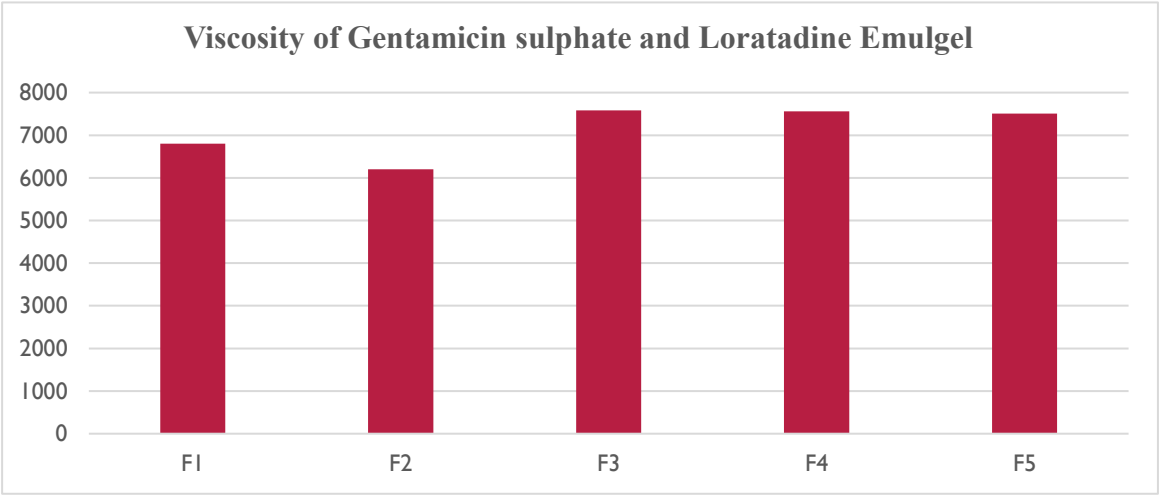
EF4	5.4	6.8	5.9	5.7	5.9
EF5	6.4	6.5	5.7	6.0	6.1

Rhenological Studies

Viscosity of Gentamicin Sulphate and Loratadine Emulgel is an important mesurement parametr determine the design and effect of formulation. Viscosity measurement a Brookfiled viscometer machine used to measure the rhenology of Emulgel formulation. Emulgel at room temprature with spindle number 64 with rpm set.

Rheological Studies of formulations

Formulation	Viscosity(cP)	RPM	Spindle number	% torque
EF1	6800	10 rpm	S64	53.6%
EF2	6200	10 rpm	S64	52.2%
EF3	7582	10 rpm	S64	63.3%
EF4	7560	10 rpm	S64	62.3%
EF5	7510	10 rpm	S64	62%



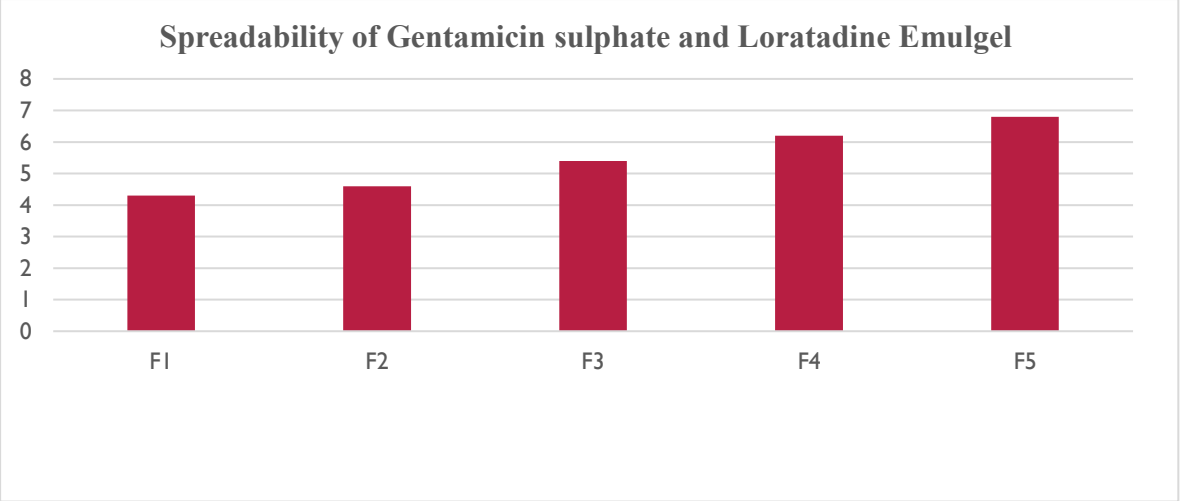
Spreadability

Spreadability measurement of emulgel determination spread over surface. Emulgel Formulation F1 to F5 denote spreadability values range from 4.3 to 6.8 g.cm/sec. spreadabaility values indicate that Emulgel can spread over skin more easily, uniform spread skin damage area or affected area.

Spreadability of Gentamicin sulphate and Loratadine Emulgel

Formulation	Emulgel in gram	Average Spread
EF1	1gm	4.3
EF2	1gm	4.6
EF3	1gm	5.4
EF4	1gm	6.2
EF5	1gm	6.8

✓



Skin irritation Evaluation

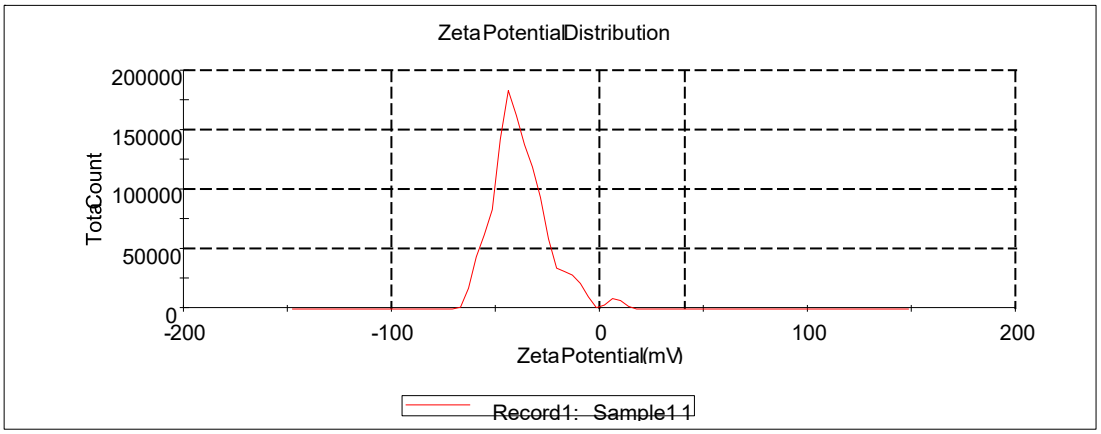
Skin irritation test evaluation by human valunteers, in this method , apply formulation direct to skin and denote problems during apply and after some minute, mostly hand skin result show that emulgel prepration not cause any skin irritation, redness and itching.

Skin irritation Evaluation

Formulation	Time	Result
Gentamicin sulphate and Loratadine Emulgel	10, 20, 30,40,50,60 minute	No irritation

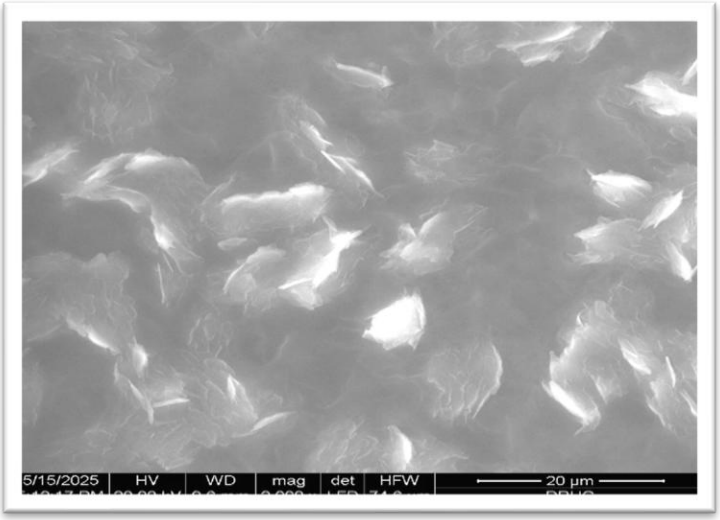
Zeta Potential

Zeta Potential is electrostatic mobility to determine the colloidal dispersion attraction between particles it parameter know about stability of colloidal particles. The emulgel formulation exhibit zeta potential -38.0(Mv) and zeta Deviation to be 13.4(Mv) and the conductivity 0.207 (mS/cm). thease value is indicate that emulgel formulation is propotaional to good particle stabilit y and suitable to topical use . -38.0(Mv) suggested strong repulsive force in particles



SEM Microscopy

A scanning electron microscope scan a focoused steam of sample detected by spacialized beam, the beam intract the sample atoms produced various signals and these signals information about surface morphology of sample and a detailed information without changing or destroying sample also information distribution and intraction of emulgel.



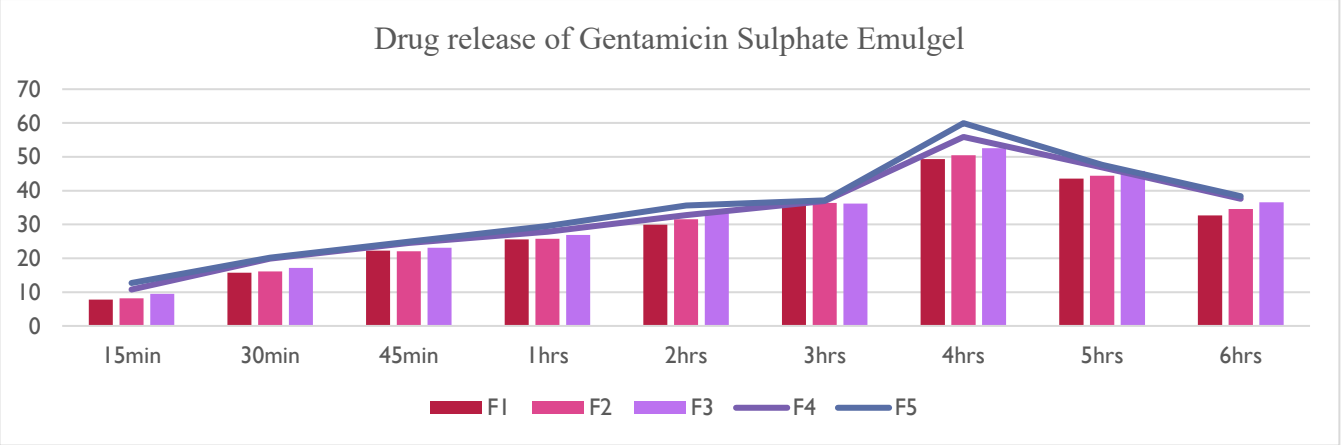
In-vitro Drug release study

The proper setup of release of drugs with chamber of Franz diffusion cell and egg cell membrane is releasing study by using UV spectroscopy with absorbence method.

Gentamicin Sulphate:

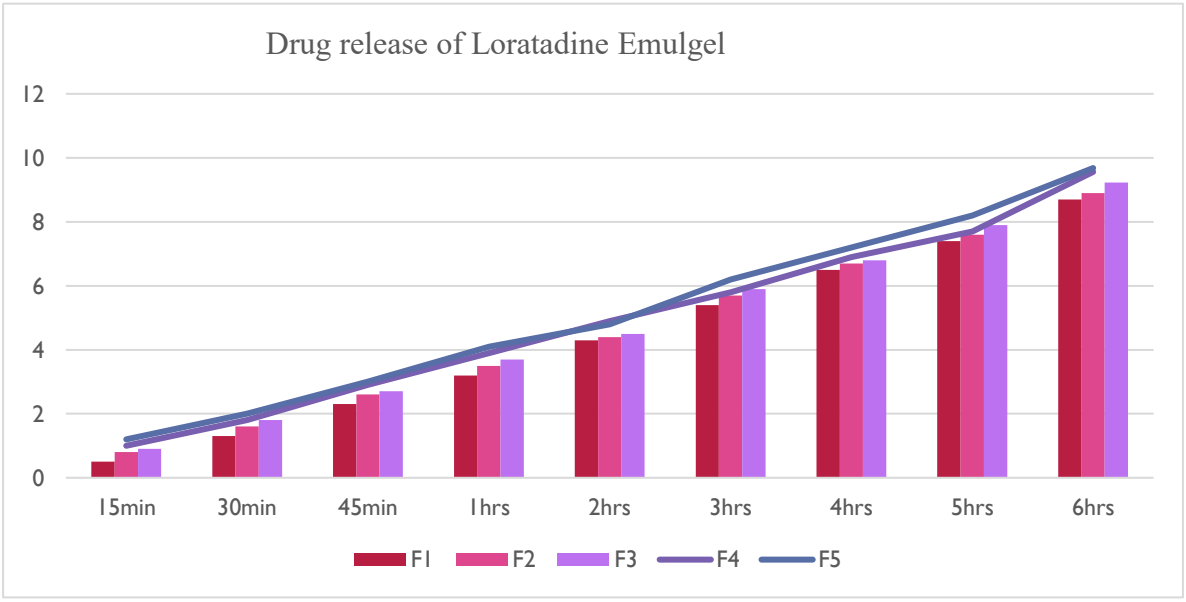
Result In-vitro release

Time(Min/hrs)	EF1	EF2	EF3	EF4	EF5
15min	7.8	8.2	9.5	10.76	12.7
30min	15.75	16.10	17.11	19.9	20.21
45min	22.3	22.11	23.10	24.5	24.88
1hrs	25.6	25.77	26.9	27.88	29.56
2hrs	29.95	31.5	33.3	32.8	35.6
3hrs	35.52	36.4	36.22	36.89	37.10
4hrs	49.32	50.43	52.6	55.88	59.96
5hrs	43.55	44.39	45.8	46.9	47.66
6hrs	32.69	34.6	36.55	37.6	38.33



In-Vitro drug release of Loratadine Emulgel

Time(Min/hrs)	EF1	EF2	EF3	EF4	EF5
15min	0.5	0.8	0.9	1	1.2
30min	1.3	1.6	1.8	1.8	2
45min	2.3	2.6	2.7	2.9	3
1hrs	3.2	3.5	3.7	3.9	4.1
2hrs	4.3	4.4	4.5	4.9	4.8
3hrs	5.4	5.7	5.9	5.8	6.2
4hrs	6.5	6.7	6.8	6.9	7.2
5hrs	7.4	7.6	7.9	7.7	8.2
6hrs	8.7	8.9	9.23	9.56	9.68



Stability Studies

Stability studies conduct at different temprature and humidity, the stability study at room temprature 27°C± 2°C temprature and 60± 10% Humidity. It to be formulation stable physically and chemically also, there no alteration in evaluation parameter, such as pH and Viscosity.

Table 7.28 Stability studies of Emulgel formulation, based on pH and Viscosity

pH study

Time (Days)	EF1	EF2	EF3	EF4	EF5
0	6.7	6.4	6.0	5.4	6.4
15	6.5	6.2	5.9	5.3	6.5
30	6.6	6.0	5.7	5.7	5.7
45	6.4	5.9	5.5	5.2	6.0

Viscosity study (27°C±2°C and 60±10%RH)

Time (Days)	EF1	EF2	EF3	EF4	EF5
0	6800	6200	7582	7560	7510
15	6750	6185	7550	7550	7450
30	6730	6150	7530	7530	7440
45	6745	6125	7520	7510	7415

4. CONCLUSION

The Gentamicin Sulphate is anti-bacterial drug but not absorbable by the oral route so potent antibiotic release by topical route and Loratadine release by GI route but is not proper release by the topical route so combination formulation of medication and also combination formulation of methodology Emulsion with gel, solve the problem of route of administration and also combination need therapies, Emulgel formulation use the many types of excipients to make the emulgel trial and final formulation in this Gentamicin sulphate and loratadine emulgel use the Gelling agents as Carbopol 934, Emulsifying agent Span and Tween 20, oil phase for liquid paraffin, Humectant and other properties use Propylene glycol, for pH adjust as Triethanolamine, Preservatives as Methyl paraben and Propyl paraben. The medicament pre-evaluation as Micrometrics, Flow properties, Organoleptic Properties, pH, Melting point, TLC, UV calibration Curve λmax, FTIR, and other Purity and Identification test, and after the Emulgel Formulation Evaluation is important of Emulgel so Firstly Physical Apparency, Formulation pH, SEM, Zeta, In-vitro release drug, Spredaability, Skin Irritation, Stability Storage and need test for Emulgel.

So Emulgel of Gentamicin Sulphate and Loratadine Combination is Anti-bacterial and Anti-allergic and Delivery by Emulgel Methodology also Combination or Incorporation Emulsion and Gel Topical Drug Delivery and Better Release and Effective.

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