



A Review: Gentamicin sulphate and Loratadine Emulgel for Treatment Skin Anti-bacterial and Anti-allergic.

Abdul Haque Ansari¹, Ankit Kumar Mishra², Dr jai Narayan Mishra³

¹ Research Scholar, Kailash Institute of Pharmacy and Management, GIDA, Gorakhpur Affiliated to Dr. APJ Abdul Kalam Technical University, Lucknow, UP, India

² Associate Professor, Kailash Institute of Pharmacy and Management, GIDA, Gorakhpur Affiliated to Dr. APJ Abdul Kalam Technical University, Lucknow, UP, India

³ Professor, Kailash Institute of Pharmacy and Management, GIDA, Gorakhpur Affiliated to Dr. APJ Abdul Kalam Technical University, Lucknow, UP, India

OPEN ACCESS

Corresponding Author

Abdul Haque Ansari

Research Scholar, Kailash Institute of Pharmacy and Management, GIDA, Gorakhpur Affiliated to Dr. APJ Abdul Kalam Technical University, Lucknow, UP, India

Received: 24-03-2025

Accepted: 05-04-2025

Available online: 28-04-2025



©Copyright: IJMPS Journal

ABSTRACT

The topical administration of Anti-biotic with Anti-allergic Emulgel to enhance the activity of both preparations. Topical Loratadine in the treatment of localised skin allergy and Gentamicin sulphate is cure the localized Anti-bacterial activity and Emulgel have both properties deliver the Hydrophobic and Hydrophilic drug properties and have Emulsion and Gel combination to fast delivery. Both combination drugs used through skin by-pass delivery GI and First-pass metabolism alteration. There are various compatible properties like being thixotropic, emollient, greaseless, readily spreadable. Longer shelf life, to other conventional market product. Emulgel are commonly used for the delivery of anti-bacterial, anti-fungal, analgesic, anti-inflammatory, anti-allergic preparations with cosmetic product. The measurement of physical and rheological assessment, pH, Spredability, Stability studies, skin irritation test, other properties are evaluated. They also have high ability to penetrate the skin easily. The formulation is based on the emulsion gel as well as gelling agent Carbopol emulsifying agent span and tween preservative as methyl paraben propyl paraben used pH adjuster use in formulation are triethylamine and some chemicals are used in formulation.

Key Words: *Emulgel, combination drugs*

INTRODUCTION [123]

Last few years scientist and vocational researcher have more interested in semisolid preparation. Particularly Emulgel. The skin is major site for systemic and local drug delivery. Skin easily delivery of drug and low side effect and patient compliance. Emulgel preparation have three-dimensional nature gel, emulsion, emulgel. Combination of anti-biotic and anti-allergic emulgel to enhance the action with preparation also need to patient because bacterial infection causes allergic activity and allergic activity causes bacterial activity. Local administration delivers to target site which enhance the drug bioavailability and minimize side effect. The topical delivery system ahead a large-scale consideration for research due to its capability both local and systemic illness compared other dosage form. Topical administration is common local skin infection wound, and allergic. Attempt to cure disease has been leading in the discovery of various drug, medicament and delivery system to get

clinical responses of drug required for treatment of diseases different route of administration are followed. Use of topical agent requires a valuable of the factor that influences precautions absorption.

- Through intact stratum-corneum
- Through sweat duct
- Through the sebaceous follicle

The base of the stratum corneum present major than 99% of the total skin surface available for circulatory drug absorption passage through this outer most layer is rate limiting step for precautions absorption. The main step includes in precautions absorption included the establishment of a concentration gradient, which providing the driving forces of drug movement across the skin, release of drug from the vehicle and drug diffusion across the layer of the skin.

Rational of Emulgel as Transdermal drug delivery system [4,5]

Serval medicines product used to the skin or mucosa membrane that either enhance basic function of skin pharmacologically alter the action in the underline tissues. Many mostly used topical agents like, ointment, cream, linements, lotion have very sticky causing problems during applied exhibit the stability also. Emulgel preparation all these factors of major semisolid preparation overcome and mixture of two method formulation, gel and emulsion delivery hydrophilic and lipophilic therapeutic moiety can successfully incorporated through Emulgel.

EMULGEL [7,8]

Emulsion and gel combined to create emulgel, emulgel are emulsion have been mixed with gelling agent to build gel, either from water-in-oil or oil-in-water emulsified gel is stable and effective carrier in hydrophilic medicine. The oil-in-water type is used for lipophilic medication, whereas the water-in-oil type is used for hydrophobic pharmaceutical emulgel is capable delivering both.

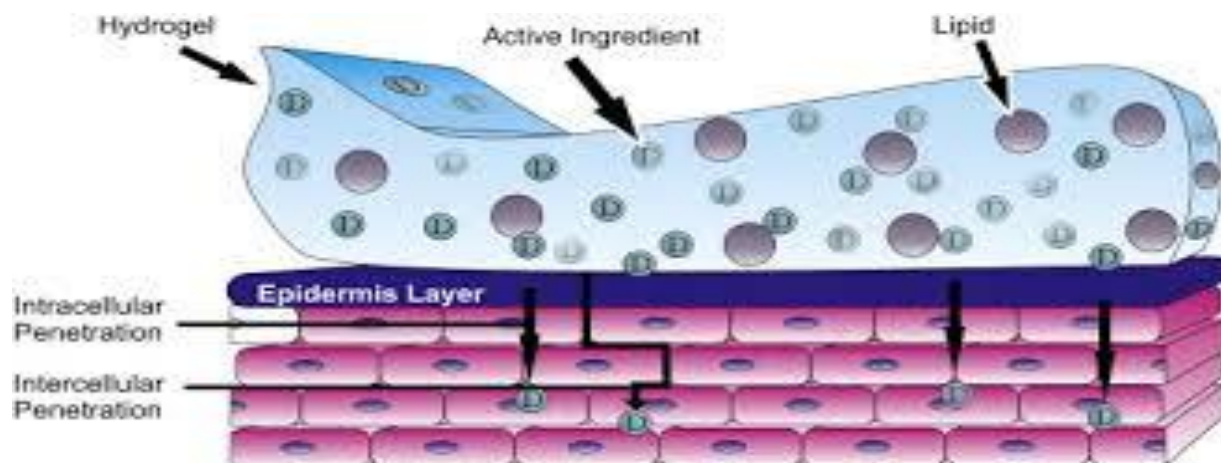


Fig.1 Structure of Emulgel

Emulgel properties

- *Better patient compliance.
- *Good spread ability, and greaseless.
- *Durability and biocompatibility.
- * Easy to removable having a transparent appearance.

Types of Emulgel [8,7,11]

1. Macro emulsion gel

Emulgel in which emulsion drop have a particle size more than 400nm. Despite being optically opaque, the individual drop are fairly visible under microscope. It thermodynamically unstable for macro emulsion.

2. Nanoemulgel

The term of nanoemulgel refer the combination mixture of nano emulsion with gel. The transparent dispersion of oil and water with droplet size of less than 100nm, known as nano emulsion is thermodynamically stable and interfacial coating of molecule of co-surfactant and surfactant both. Nano emulsion formulation have better transdermal distribution capabilities.

3. Microemulgel

Microemulsion whose droplet size about 10 to 100nm, are transparent and thermos stable, water, oil, surfactant, and co-surfactant are combined in precious amount to form microemulsion.

Advantage of Emulgel [12,13]

- ❖ Avoiding hepatic first pass metabolism.
- ❖ Avoiding gastric intolerance.
- ❖ Easy to applied and remove.
- ❖ Hydrophobic drug incorporation.
- ❖ Oil free, greaseless preparation.
- ❖ The ability to Control drug delivery for a during long time.
- ❖ The ability to modify release the properties of the biological barrier to absorption.
- ❖ Production feasibility and low production cost.

Disadvantage of Emulgel [13,14]

- ❖ Large particles of drug are difficult to absorbed and cross through the skin barrier.
- ❖ Many drugs don't pass through epidermal barrier.
- ❖ Bubbles may appear as the emulgel when prepared.

Factor Affecting Topical Drug Absorption [18]

Physiological Factor

Skin density.

Skin pH.

Lipid content.

Blood flow.

Thickness of glands.

Physiochemical Factor

- Partition coefficient.
- Atomic weight
- Effect of Vehicles

Formulation Factor

- Release characteristics.
- pH of vehicles.

- Permeation Enhancer.

PHYSIOLOGY OF SKIN [19]

Almost of the topical preparation are mainly to be applied to the skin. So fundamental knowledge of the skin and its physiology function are important for designing topical. The skin of an average adult body covers a surface area approximately 2m² and received about one third part of the blood circulating through the body. An average human skin surface is known to contain, on average 40-70 hair follicle's and 200-300 sweat duct on every square centimeter of the skin. The pH of the skin varies from 4 to 5.6 sweat and fatty acid secreted from sebum influences the pH of skin surface. The skin can be considered to have four definite layers.

1. Non-viable epidermis
2. Viable epidermis
3. Viable dermis
4. Subcutaneous connective tissue

CONSTITUENTS OF EMULGEL PREPARATION

Active Pharmaceutical Ingredient

Name of API	Uses
1. Gentamicin sulfate	Anti-bacterial
2. Loratadine	Anti-allergic

Table.1 API used in Emulgel

Aqueous Material

To prepare an emulsion, oils are used. The oil phase plays a crucial role in emulsion, micro emulsion, and nano emulsion formulation processes. Olive oil, castor oil, rose hip, balsam oil, are among the oils used in the production of emulgel.

Name of oil	Properties
Rose hip	Anti-inflammatory
Balsam oil	Topical antibiotics
Olive oil	Antioxidant Antimicrobial
Isopropyl myristate	Topical steroids
Light liquid paraffin	Emollients

Table.2 Oils in Emulgel

Emulsifier

Emulsifiers are compounds that stabilize the process. The main ingredients of emulgel are polyethylene sorbitan monooleate (Tween 20), sorbitan monooleate (Span 80), and stearic acid as emulsifying agents.

Chemical name	Formulation
Polyethylene glycol 40 stearate	Emulsion and Emulgel
Sorbitan monooleate (Span 40)	Emulgel and Emulsion
Polyethylene sorbitan monooleate (Tween 80)	Emulgel and Emulsion
Stearic acid	Emulsion
Sodium stearate	Emulsion preparation

Table.3 Emulsifier used in Emulgel

Preservatives

Preservatives are substance use in formulation to prevent the microbial attack, spoiling. The generally used preservatives are methyl paraben, propyl paraben, phenoxyethanol, benzoic acid, benzalkonium chloride, phenoxy ethanol and other.

Preservatives
Benzalkonium chloride
Phenoxy ethanol
Methyl paraben
Propyl paraben

Table.4 Preservatives with concentration

Gelling Agents

Gelling agent are used to create gel base before incorporating emulsion to form emulgel, other uses improve consistency and thickness.

Gelling Agents	Type	Uses
HPMC-2910	Semi-synthetic	Emulgel
HPMC	Semi-synthetic	Gel
Sodium CMC	Semi-synthetic	Gel
Carbopol 934	Synthetic	Emulgel
Carbopol 940	Synthetic	Emulgel
Gaur Gum	Natural	Gel
Xanthan Gum	Natural	Gel

Table.5 Gelling Agents with Type

Penetration Enhancers

These are substance that relate with skin component and change the favorable movement of foreign particle permeability to skin called permeation enhancer.

Penetration Enhancer	Formulation
Oleic acid	Emulgel formulation
Lecithin	Gel formulation
Urea	Gel formulation
Isopropyl myristate	Gel formulation
Linoleic acid	Gel formulation
Clove oil	Emulgel formulation
Menthol	Emulgel formulation

Table.6 Penetration Enhancer

pH Adjuster

These ingredients are used to maintain the pH stability of formulation. E.g. triethanolamine, NaOH, etc.

Humectants

Humectant are included in formulation to stop moisture loss. They reduced the drying of emulgel, which enhance their consistency and ease of application. Example of humectant included propylene glycol, glycerin, etc.

MECHANISM OF PENETRATION ENHANCER [13,14]

Penetration enhancer may act on one or three main mechanisms:

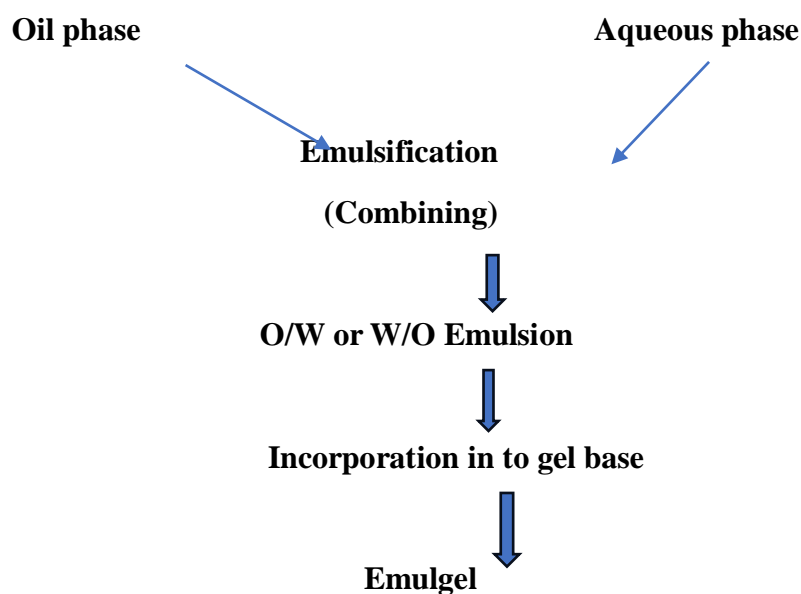
1. Disrupted of the highly ordered structure of stratum corneum's lipid layer
2. Interaction with the intracellular protein structure
3. Improved partition lipid of the drug, so enhance the solvent into the stratum corneum.

The enhancer acts as altering one of three pathways the mostly of altering the polar pathways is to causes protein conformational change or solvent swelling. The fatty acid enhancers increased the fluidity of the lipid protein partition content of the stratum corneum some enhancers act on both polar and non-polar pathway by altering the multiple laminate pathway for penetration. Enhancers can increase the drug diffusivity and possibility through skin protein.

PATHWAY OF TRANSDERMAL PERMIATION

1. Transdermal permeation passes through the stratum corneum.
2. Intercellular permeation, through multiple layer the stratum corneum.
3. Permeation via the hair follicle, sebaceous duct and sweat gland.

METHOD OF PREPRATION OF EMULGEL [21,19]



Gel preparation

- ❖ In a 100-ml beaker, added about 40ml of water and mix at a speed of around 800 rpm.
- ❖ Measured amount of Carbopol 934 was added pinch by pinch to with stirring solution about 10 minutes.

Emulsion preparation

- ❖ 10-ml distilled water was used to dissolve 0.5 %w/w tween 20 create an aqueous phase.
- ❖ Then propylene glycol was combined with methyl paraben and propyl paraben, and mixed with aqueous phase.
- ❖ Span 20 of 1% was mixed with liquid paraffin in an oil phase, and in this oil phase, 0.25% of medication in dissolved with Di-choro methane and 2nd is ethanol.
- ❖ The oil phase and aqueous phase (water phase) were heated both separately water bath 80°C.
- ❖ Then both are phases mixed to create the emulsion by using mechanical stirrer for 20-25 minutes.
- ❖ Then mixture was cooled to room temperature after being stirred.

Emulgel preparation

- ❖ By added gel solution and emulsion solution drop by drop, stirring continuously at moderated speed.
- ❖ Triethanolamine has been added to down the pH 6 to 6.5.
- ❖ Continued stirring for 5-minute emulgel more consistent.

CHARCTERZATION OF EMULGEL [21,22,23,24]

Physical appearance

A visible inspection was conducted to assess the color, homogeneity, and consistency of so the emulgel formulation.

Rheological study

The viscosity of different emulgel formulation is determined at 25°C using cone and plate viscometer with spindle 52 and conduct to a thermostatically controlled circulating water bath.

Measurement pH.

A digital pH meter was applied to measure emulgel pH. Neet Clean the electrode with distilled water and dipped in formulation mixture, process take time 2-3 time.

Spredaability

Spredaability is determined by apparatus suggested by Multimer laboratory and study. Take 2 gram of emulgel and apply bottom side. Side attached to a wooden block and make sandwich by using another glass slide same size that is bound with hook and has 500mg of weight put on it. The pan linked second slide was given additional weight after five minutes. The time taken to cover a distance of 5cm for top slide was noted.

$$\text{Spredaability(s)} = \text{ML/T}$$

Were,

M= Weight tied to upper slide

S= Spredaability

L= length of glass slide

T= time taken to separate the slides complete from each.

Fourier Transforms infrared spectroscopy (FTIR)

The purpose of this spectroscopy was identified stable storage chemical bond surroundings for the drug in solid state and determine compatible excipient for formulation development.

Swelling index

Determine the swelling index of ready topical emulgel, 1 gram sample taken aluminum foil and then placed separately in particular a 50-ml beaker containing 10-ml 0.1 N NaOH. Then sample removed from beaker at different time period put the dry place for some time after then re-weigh and calculated.

Swelling index (SW)%=[wt.-wo)/wo] ×100.

,

Wo= original weight of emulgel at zero time after time t,

Wt.= weight of swollen emulgel.

Drug content Assessment

The drug concentration in the emulgel was determined using spectrophotometer. The amount of drug present in the gellified emulsion was determined by dissolving 2gram of emulgel in a solvent by sonication process. After an appropriate dilution made up, absorbance was measured using UV-visible Spectroscopy(1800CE) from Shimadzu corporation Japan.

Drug content=(concentration ×Dilution factor×Valume taken)×Conversion factor

Stability Screening

The prepared emulgel were packed in aluminum coated tubes (5g) and subjected to stability screening at 5°C,25°C/60%RH, 30°C/65%RH. For a period time of three month. Sample were withdrawn at 15-day time interval and evaluated physical appearance, pH rheological, Drug content, and release study.

Skin Irritation Test

Human volunteers' skin is often tested for skin irritation with there informed consent agreement in writing. The produced medication is applied to the hand skin and any negative effect are monitored.

In-vitro Drug release Study

In -vitro drug release study done with a method Franz diffusion cell in emulgel. Its aids in figuring out the drug release.

Microbiological Assay

Ditch plate technique was used. It is technique for evaluation of bacteriostatic or fungistatic activity of a compound. It is mainly applied for semisolid preparation. The ditch plate technology is embedded in this method. By using the technique, the activity of bacterial and fungi is assessed.

PACKAGING OF EMULGEL

Emulgel is typically packed aluminum coated and aluminum closed tube by molded seal or a membrane sealed with an inner coating of a compound phenoxy-epoxy-based lacquer with propylene screw tight cap.

CONCLUSION

The Topical Drug Delivery of Anti-biotic with Anti-allergic drug combination give more effective for patient and Emulgel based system work as Double strength release of drug to skin.

REFERENCES

1. Ashara KC, Paun JS, Soniwala MM, Chavada JR, Mori NM. Micro-emulsion based emulgel: a novel topical drug delivery system. *Asian pacific journal of topical disease*, 4, S27-32 (2014).
2. Li H, Wang J, Q Xu, S Tian, W Yang. Design and evaluation of glimepiride hydrogel for transdermal delivery. *Drug Development and Industrial Pharmacy*, 48, 8397-405 (2022).
3. Patel S, Aundhia C, Seth A, Shah N, Pandya K. Emulgel: A novel approach for topical drug delivery system. *European Journal of Biomedical and Pharmaceutical Science*, 3(9), 501-506 (2016).
4. Qu F, Geng R, Liu Y, Zhu J. Advance nanocarrier and micro-needle based transdermal drug delivery strategies for skin diseases treatment. *Theranostics*, 12(7), 3372 (2022).
5. Singla V, Saini S, Joshi B, Rana AC, Emulgel: A new platform for topical drug delivery. *International Journal of Pharma and Biomedical Science* 2012; 3(1): 485-98.
6. Pathan IB, Setty CM. Chemical penetration enhancer for transdermal drug delivery system. *Topical Journal of Pharmaceutical Research* 2009; 8(2).
7. Jain A, Deveda P, Vyas N, Chuhan J, Khambete H, Jain S. Development of anti-fungal emulsion-based gel for topical fungal infection (S). *IJPRD*. 2011;2(12);18-22.
8. Kute SB, Saudagar RB. Emulsified gel A Novel approach for delivery of hydrophobic drugs: An overview. *Journal of advance pharmacy Education and Research*. 2013; 3(4); 368-76.
9. Ashara K, Sonowal M, Shah K. Emulgel: A novel drug delivery system. *Journal of Pakistan Association of Dermatologist*. 2016; 26(3): 244-9.
10. Panwar A, Upadhyay N, Bairagi M, Gujar S, Darwhekar G, Jain D. Emulgel: A review. *Asian J Pharma Life Sci*. 2011; 2231:4423.
11. Vishwakarma G, Panwar AS, Emulgel emergent system: at a glance for topical drug delivery. *Asian J Pharma. Clinical Research*. 2022; 15(3):8-14.
12. Rode RJ, Dixit GR, Upadhyay KP, Bakhle SS. A Comprehensive review of Emulgel: A new approach for enhanced topical drug delivery. *IJMPR*. 2021; 5(3): 222-233.

13. Stanos SP, Topical agent for the management of musculoskeletal pain, *Journal of pain and symptom management*. 2007; 33(3): 342-355.
14. Suman D, Beena K. Emulgel for topical drug delivery: A novel approach. *GSC Biological and Pharmaceutical Sciences*. 2020; 11(3): 104-114.
15. Chaudhari P, Ajab A, Malpure P, Kolsure P, Sanap D, Development and in-vitro evaluation of thermo reversible nasal gel formulations of Rizatriptan benzoate, *Indian J. Pharm. Edu. Res.*, 2009; 43: 55-62.
16. Patel RP, Patel G, Baria A. Formulation and evaluation of transdermal patch of aceclofenac, *Int J Drug Del*, 1(3): 41 – 51, (2009).
17. Chaudhari P, Ajab A, Malpure P, Kolsure P, Sanap D, Development and in-vitro evaluation of thermo reversible nasal gel formulations of Rizatriptan benzoate, *Indian J Pharm Edu Res*,43: 55-62, (2009).
18. Laithy HM. and El shaboury KMF. The development of Cutina Lipogels and gel microemulsion for topical administration of fluconazole. *Ame Pharm Sci. PharmSciTech*. 2003; 3:10 25.
19. Puwanti Tutiek, Syamsur Maimuna, Hariyadi Melani Dewi, Erawati Tristina. “Characteristics and release of Gentamicin Sulphate from Sodium Alginate Microsphere Entrapped in Emulgel” *International Journal of Drug Delivery Technology*, 2019; 9(4)705-710.
20. Kumar Vijay, Mahant Shefali, Rao Rekha, Nanda Sanju. “ Emulgel based Topical Drug Delivery System for Loratadine” *ADMET Journal*; 2.4.64; 254-270.
21. Shaaff Setty Chandana, Renukuntla Pranay, Peddapali Himabindu, Jadi Kmar, Rajendra , Kuchukuntla Mounika, Bakshi Vasudha, “Formulation Development and Characterization of Loratadine Emulgel” *Journal of Applied Pharmaceutical Research*, 2024;12(2):.42-52.
22. Sainy J, Atneriya U, MAHESHWARI R. Development of an Aloe vera-based Emulgel for the Topical Delivery of Desoximetasone. *Turkish Journal of Pharmaceutical Sciences*. 2021 Aug; 18(4):465.
23. Ambhore NP, Dandagi PM, Gadad AP, Mandora P. Formulation and characterization of tapentadol loaded emulgel for topical application. *Indian J. Pharm. Educ. Res*. 2017 Oct 1; 51:525-35.
24. Redkar MR, Patil SV, Rukari TG. Emulgel: A modern tool for topical drug delivery. *World Journal of Pharmaceutical Research*. 2019 Jan 29; 8(4):586-97.