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Formulation and Evaluation of Ornidazole Topical Emulgel

Prof. Shaikh Sir, Kashid Supriya Sandipan, Mohite Vishal Ram, Sukale Sudarshan Kalyan, Satpute Swetali Sopan
Aditya Diploma Institute of Pharmacy Collage, Beed, Maharashtra, India

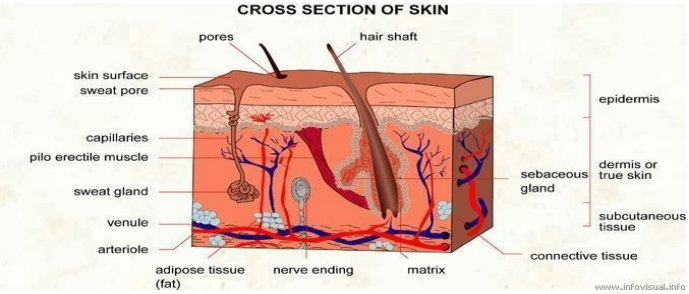
Abstract: *Emulgels have emerged as promising topical drug delivery system for the delivery of hydrophobic drugs via skin. The objective of study was to prepare the drug ornidazole as emulgel. When we are preparing emulsions individually shows stability problems during manufacturing and storage that effect on drug release pattern. In order to increase the stability we are incorporated as emulgel. Ornidazole is a anti protozoal drug use for the treatment of some protozoal infections, stomach, intestine, genital area and certain strains of anaerobic bacteria, used to prevent possible infections during a surgical procedure. The present study was to formulate and evaluate the topical ornidazole emulgel. In this study we develop emulgel form of ornidazole using three different types of oils such as clove oil, mentha oil, and liquid paraffin and the gelling agents such as Carbapol 934, HPMC, Sodium alginate and evaluated for physical properties includes color, structure, solubility, homogenicity, consistency, swelling index and PH and in vitro drug release patterns etc. among all the formulations F3 formulation.*

Keywords: Emulgels, Topical Drug Delivery, Ornidazole

I. INTRODUCTION

Topical delivery can be defined as the application of a drug containing formulation to the skin to directly treat cutaneous disorders [e.g. acne, psoriasis] with the intent of containing the pharmacological or other effects of drug to the surface of the skin or within. Topical drug administration through various routes applied a wide spectrum of preparation for both cosmetic and dermatological, to their health and diseased skin. Topical preparations are applied to the surface of a part of the body and have effects only in a specific area of the body and are formulated in such a manner that the systemic absorption of the medicament is minimal. The most common examples of topical dosage forms are solutions, suspensions, emulsions, semisolids [e.g. powders and aerosols] among them ointments, creams, and lotions have numerous disadvantages.

They are usually very sticky and cause uneasiness to the patient when applied moreover they also have less spreading coefficient and need to apply with rubbing. They also exhibit the problem of stability. Due to all these factors, a major group of semisolid preparation, transparent gel has expanded its use in both cosmetics and in pharmaceutical preparation. Inspite of many advantages of gels a major limitation is their inability an emulsion based limitation an emulsion based approach is being used so that a hydrophobic therapeutic moiety can be successfully incorporated and delivered through gels. When gels and emulsions are used in combined form the dosage forms are referred as emulgels.



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Mechanism of Skin Penetration

Skin penetration enhancers are the molecules which reversible to remove the barrier resistance of the stratum corneum. They allow drugs to penetrate more readily to the viable tissues and hence enter the systemic circulation. The intercellular routes accelerants may interact at the polar head groups of the lipids, within aqueous region between lipid head group and between the hydrophobic tails of the barrier. The common mechanism is to protect the body for unwanted particles from the environment. The main barrier of the skin is located in the outermost layer of skin that is epidermis. Since the lipid regions in the stratum corneum forms the only continuous structure, substance applied on to the skin always have to pass these region. The major obstacle for topical drug delivery is the low diffusion rate of drug across the stratum corneum. Several methods have been assessed to increase the permeation rate of drugs temporarily.

Emulgel

Emulgels are emulsions, either of the oil-in-water or water in oil type which are gelled by mixing with gelling agent. Emulsified gel is stable one and superior vehicle for hydrophobic or poorly water soluble drugs. In short emulgels are the combination of emulsion and gel.

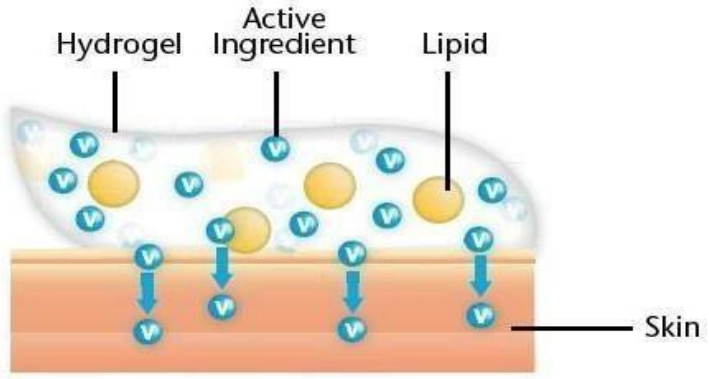

Figure. 3: Structure of Emulgel.

Emulsions are of different types depending on the size of droplets or nature of distribution

1) Macroemulsion gel
2) Nanoemulsion gel
3) Microemulsion gel

1) Macroemulsions gel

These are most common type of emulgels where the particle size of droplets of emulsion is more than 400nm. They are visually opaque but the individual droplets can be easily observed under microscope. Macroemulsion are thermodynamically unstable, but can be stabilized using surface active agents.

E.g. Khullar R. et al, mefenamic acid emulgel was prepared using Carbopol 940 as gelling agent. Liquid paraffin was used as oil phase. Mentha oil and clove oil was used as penetration enhancer. Then it was evaluated for rheological studies, spreading coefficient studies, skin irritation test, in-vitro release, etc.

2) Nanoemulsion gel

When nanoemulsion is incorporated into gel it is called as nanoemulgel. Nanoemulsion are thermodynamically stable transparent (translucent) dispersions of oil and water stabilized by an interfacial film of surfactant and co surfactant molecules having a droplet size of less than 100nm. Nanoemulsion formulations possess improved Transdermal and dermal delivery properties in vitro as well as in vivo. This has improved transdermal permeation of many drugs over the conventional topical formulations such as emulsions and gels.

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E.g. Singh B. P et al, prepared Carvedilol nanoemulgel using oleic acid and isopropyl myristate (3:1) as oil phase. Tween 20 and Carvedilol were used as surfactant and co surfactant respectively. Carbopol 934 was used as gelling agent.

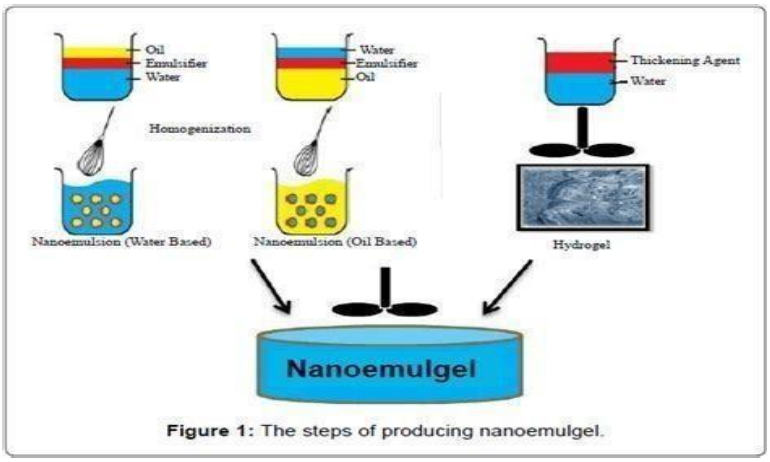

Figure. 4: Steps to produce nanoemulgel.

3) Microemulsion gel: Microemulsions are transparent and thermodynamically stable as their droplet size range from 10 to 100nm and they do not coalesce. Microemulsions are composed of oil, co-surfactant, and water in specific proportions. The ingredients of Microemulsion could facilitate the permeation rate of the drug by reducing the diffusion barrier of the stratum corneum. However, due to low viscosity of Microemulsion, their less retention capacity in the skin restrains its application in the pharmaceutical industry To overcome this disadvantage, gelling agents such as Carbopol 940, xanthan gum and carrageenan have been added into the Microemulsion for forming Microemulsion based gel in order to increase its viscosity which could be suitable for topical application. Moreover, Microemulsion based gel prevents the absorption of drug in the blood stream and provide higher drug accumulation in the skin for efficient action. E.g. Bachhav Y. G et al, prepared clotrimazole Microemulsion based vaginal using Carbapol 90 as oil phase and Cremophor EL as surfactant. Carbopol ETD 2020 is used as gelling agent.

III. LITERATURE REVIEW

1. Topical Drug Delivery Systems

Topical drug delivery has been a widely researched area in pharmaceutical sciences, primarily due to its potential to deliver drugs directly to the site of action, especially in skin-related disorders. It bypasses hepatic first-pass metabolism, reduces systemic toxicity, and allows for localized drug action. The major barrier to transdermal delivery is the stratum corneum, which limits the penetration of hydrophobic or high-molecular-weight drugs. Various strategies, including the use of penetration enhancers, nanocarriers, and emulgels, have been employed to overcome this limitation.

2. Emulgels: A Hybrid Formulation

Emulgels are a combination of emulsions (oil-in-water or water-in-oil) and gels, designed to improve the delivery of hydrophobic drugs. Gels are known for their non-greasy nature, transparency, and spreadability, whereas emulsions help solubilize hydrophobic drugs and enhance skin permeation. When these two are combined, the resulting emulgel formulation offers:

3. Ornidazole: Pharmacological and Pharmaceutical Background

Ornidazole is a 5-nitroimidazole derivative, structurally related to metronidazole. It has antibacterial and antiprotozoal activity, particularly against anaerobic bacteria, Trichomonas vaginalis, Entamoeba histolytica, and Giardia lamblia. Its mechanism involves the generation of free radicals that disrupt microbial DNA.

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IV. HISTORY

1. Introduction to Nitroimidazoles and Ornidazole

The development of nitroimidazole compounds dates back to the 1950s, when researchers first synthesized metronidazole, the parent compound of a class known for potent activity against anaerobic bacteria and protozoa. Metronidazole gained widespread clinical use in the treatment of Entamoeba histolytica, Giardia lamblia, and Trichomonas vaginalis.

Ornidazole, a second-generation 5-nitroimidazole, was developed in the 1970s by modifying the structure of metronidazole to improve its pharmacokinetic profile, reduce gastrointestinal side effects, and enhance tissue penetration. It demonstrated a longer halflife (12–14 hours), better oral tolerance, and superior efficacy against anaerobic infections and protozoal diseases.

Ornidazole became widely used in gastrointestinal, dental, gynecological, and postsurgical infections, particularly in Europe, Asia, and South America. However, its oral route of administration often led to systemic side effects including nausea, dizziness, metallic taste, and hepatotoxicity, prompting investigations into alternative delivery methods.

2. Evolution of Topical Drug Delivery Systems

Topical drug delivery began gaining scientific momentum in the 1980s and 1990s as a method to deliver drugs directly to the site of action, minimizing systemic exposure. Early formulations included ointments, creams, and gels, but these had limitations in spreadability, greasiness, and drug solubility, particularly for hydrophobic drugs like ornidazole.

In the early 2000s, advances in transdermal delivery led to the development of emulgels— a novel hybrid system combining the benefits of emulsions (drug solubilization and penetration) and gels (ease of application and stability). These systems offered enhanced permeability, better skin adhesion, controlled release, and improved patient compliance.

3. Incorporation of Ornidazole into Topical Formulations

Despite its effectiveness, ornidazole remained underutilized in topical therapy due to limited formulation efforts. Researchers began exploring topical delivery to target skin infections, wounds, and post-surgical sites where anaerobic bacterial colonization is common.

The first studies into topical ornidazole creams and gels emerged in the early 2010s, focusing on creating semi-solid dosage forms that could deliver the drug locally with minimal systemic absorption.

Around 2015–2017, researchers began developing ornidazole-loaded emulgels by incorporating the drug into oil-in-water emulsions stabilized with surfactants and dispersed within Carbopol 934 gel matrices.

These formulations demonstrated favorable physicochemical properties, such as pH compatibility with the skin, appropriate viscosity, and drug content uniformity. More importantly, in vitro drug release studies and antimicrobial assays confirmed the effectiveness of the emulgels in delivering sustained drug levels and inhibiting microbial growth.

4. Key Research Milestones

2017 – Nisha et al. formulated ornidazole creams and evaluated their antimicrobial activity, showing promising results for topical application.

2018 – Patel et al. developed a series of ornidazole emulgels using different surfactants and oils, optimized based on viscosity, spreadability, and drug release profiles.

2020–2023 – Studies increasingly focused on enhancing the performance of ornidazole emulgels through the inclusion of penetration enhancers like isopropyl myristate, and nano-emulsion systems for better skin permeation.

Recent trends (2023–2024) include exploring combination formulations (e.g., ornidazole with clindamycin or mupirocin), targeting multi-pathogen skin infections or diabetic wounds, and the use of bio-based gelling agents for biocompatibility and sustainability.

V. AIM AND OBJECTIVES

AIM: To formulate, develop, and evaluate Ornidazole-loaded topical emulgels for effective localized treatment of skin infections caused by anaerobic microorganisms, with enhanced drug delivery, prolonged release, and improved patient compliance.

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Objectives:

1. To study the physicochemical properties of Ornidazole

Understand solubility, pKa, partition coefficient, and stability relevant to topical delivery. Assess compatibility with selected excipients using preformulation studies.

2. To formulate topical emulgels incorporating Ornidazole

Use appropriate emulsifying agents, gelling agents (e.g., Carbopol 934), oils, and penetration enhancers.

Develop stable oil-in-water emulsion-based gels suitable for dermal application.

3. To evaluate the prepared emulgels for their physicochemical properties Test pH, viscosity, spreadability, homogeneity, grittiness, and extrudability.

Ensure the formulation is suitable and safe for skin application.

4. To determine the drug content and uniformity in the formulations

Quantify Ornidazole using appropriate analytical methods such as UV-visible spectrophotometry or HPLC.

5. To perform in vitro drug release studies

Assess the drug release profile using diffusion studies (e.g., Franz diffusion cell).

Compare formulations to identify sustained or controlled release potential.

6. To evaluate antimicrobial activity of the emulgel formulations

Perform agar diffusion or zone of inhibition tests against anaerobic pathogens like Bacteroides fragilis or Clostridium species.

VI. MATERIALS FOR ORNIDAZOLE TOPICAL EMULGEL FORMULATION

1. Active Pharmaceutical Ingredient (API)

Material: Ornidazole

Function: Antiprotozoal and antibacterial agent

2. Gelling Agent (for Gel Base)

Material: Carbopol 934 or 940

Function: Gelling agent; forms the gel matrix

3. Aqueous Phase Components

Material: Distilled Water

Function: Solvent; forms the continuous phase

Propylene Glycol Humectant and solvent; enhances skin penetration

4. Oil Phase Components

Material: Isopropyl (IPM)

Function: Myristate Liquid Paraffin moisturization

Emollient and skin penetration enhancer

Oil phase base; enhances spreadability and

5. Surfactants / Emulsifying Agents

Material: Span 20 / 60 / 80 and Tween 20 / 60 / 80

Function: Lipophilic emulsifier (used in oil phase)

Hydrophilic emulsifier (used in aqueous phase)

6. pH Adjuster / Neutralizer

Material: Triethanolamine (TEA)

Function: Neutralizes Carbopol and forms the gel; pH adjustment

7. Preservatives

Material: Methylparaben and Propylparaben

Function: Antimicrobial preservative

Antimicrobial preservative (often used with methylparaben)

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8. Optional Additives (for aesthetics or performance)
Material: Ethanol Co-solvent and mild antiseptic; enhances drug solubility Material Function Fragrance / Perfume Improves sensory properties
Function: Colorants Enhances appearance (only if necessary and skin-safe)

Equipment Required
In addition to materials, you'll need:
• Beakers
• Magnetic stirrer/hot plate
• Overhead stirrer or homogenizer
• pH meter
• Weighing balance
• Thermometer
• Stainless steel spatula
• Packaging materials (e.g., collapsible tubes or jars)

VII. METHOD OF PREPARATION

Step-1: formulation of emulsion either o/w or w/o preparation of oil phase: oil phase of the emulsion is prepared by dissolving emulsifier. E.g: span 20 in oil phase lie light liquid paraffin.
Preparation of aqueous phase: aqueous phase is prepared by dissolving emisifier. E.g: tween 20 in purified water.
Step-2 formulation of gel base: prepared by dispersing polymer in purified water with constant stirring at a moderate speed using mechanical shaker, then the pH was adjusted to 6-6.5 using tri ethanolamine (TEA).
Step-3 incorporation of emulsion into gel base: Add glutaraldehyde in during mixing of gel and emulsion in ratio of 1:1 to obtain emulgel.

Table. Formulation of Emulgel.

Ingredients %w/w	F1	F2
Carbopol	1.5	1.5
Clove oil	5ml	-
Mentha oil	3ml	5ml
Liquid paraffin	2ml	2ml
Tween 80	1ml	1ml
Propylene glycol	2.5ml	2.5ml
Methyl paraben	0.02ml	0.02ml
Propyl paraben	0.01ml	01ml
Purified water	5ml	5ml

VIII. EVALUATION PARAMETERS OF ORNIDAZOLE EMULGEL

Physical appearance: The prepared Emulgel is checked visually for their color, homogeneity, consistency and phase separation.
PH Evaluation: pH evaluation is the important criteria especially for the topical formulation. The pH of emulgel should be between 5.8 – 6 to mimic the skin condition. If the pH of the prepared emulgel is acidic or basic, it may cause irritation to the patient. PH of the prepared emulgel was measured using digital pH meter by dipping the glass electrode into an emulgel. The measurement of pH of each formulation was done in triplicate and average values were calculated.
Spreadability: Spreadability of emulgel is measured in terms of diameter of emulgel circle produced when emulgel is placed between two glass plates of definite weight. A weighed quantity (350 mg) of emulgel is taken on one glass plate and another glass plate is dropped from a distance of 5 cm. The diameter of the circle of spread emulgel is measured.

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Skin Irritation Test (Patch Test): For this study emulgel is applied on the shaven skin of rat and its adverse effect like change in color, change in skin morphology are evaluated up to 24 hours. About 8 rats can be used for the study. Test passes if no irritation shown. If it fails the test is repeated with another 2 rats.

IX. ADVANTAGES OF EMULGEL

1. Increased patient acceptability.
2. Provide targeted drug delivery.
3. Easy termination of the therapy.
4. Improve bioavailability and even the low doses can be effective in comparison with other conventional semi solid preparation.

Stable formulation by decreasing surface interfacial tension resulting in

5. increase in viscosity of aqueous phase, more stable than Transdermal preparations that are comparatively less stable, powders are hygroscopic, creams shows phase inversion or breaking and ointment shows rancidity due to oily b

Disadvantages

1. Poor absorption of macromolecules.
2. Entrapment of bubble during formulation.
3. Hydrophobic drugs are the best choice for such delivery systems.
4. skin irritation or allergy reaction on contact dermatitis.
5. Can be used only for drugs which require very small plasma concentration for action.
6. Enzyme in epidermis may denature the drugs

Benefits

1. Effective antimicrobial action: Ornidazole's antibacterial and antiprotozoal properties help treat skin infections.
2. Targeted delivery: Topical application allows for direct delivery to the affected area.
3. Improved patient compliance: Emulgel formulation provides a smooth, non-greasy texture, making it easy to apply.
4. Reduced systemic side effects: Topical application minimizes systemic absorption, reducing the risk of side effects.
5. Moisturizing properties: Emulgel formulation can help hydrate and soothe the skin.
6. Convenient application: Easy to apply and remove, making it suitable for daily use.

Potential Uses

1. Bacterial vaginosis: Ornidazole topical emulgel may be used to treat bacterial vaginosis and other vaginal infections.
2. Skin infections: Effective against various skin infections, including those caused by bacteria and protozoa.

Advantages Over Other Formulations

1. Improved stability: Emulgel formulation can enhance stability and shelf-life.
2. Better patient experience: Non-greasy texture and ease of application improve patient satisfaction.

Ideal Characteristics

1. Broad-spectrum activity: Effective against a wide range of microorganisms, including bacteria and protozoa.
2. High efficacy: Demonstrates strong antimicrobial activity, making it suitable for treating various infections.
3. Good bioavailability: Well-absorbed and distributed throughout the body, allowing for effective treatment.
4. Targeted action: Concentrates in infected tissues, enhancing its effectiveness.
5. Low toxicity: Relatively safe and well-tolerated, minimizing adverse effects.
6. Convenient dosing: Can be administered orally or topically, depending on the formulation.

Therapeutic Benefits

1. Effective treatment: Ornidazole's antimicrobial properties make it an effective treatment for various infections.
2. Reduced symptoms: Helps alleviate symptoms associated with infections, improving patient outcomes.

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3. Prevention of complications: Can help prevent complications arising from untreated infections.

X. RESULTS AND DISCUSSIONS

Measurement of ph

The PH values of all the prepared formulation was ranging from 5.8- 6.0, which is considered acceptable to avoid the risk of irritation upon application to the skin.

Skin Irritation Test: No allergic symptoms like inflammation, redness, irritation appeared on rats up to 24hrs.

Formulation Outcome:

Ornidazole topical emulgel was successfully formulated using Carbopol 934 as a gelling agent.

The emulgel appeared smooth, homogenous, white (or slightly off-white), and showed no phase separation.

Parameter Result Obtained Standard/Observation

Appearance - Smooth, homogeneous, off-white - Acceptable

pH 5.8 ± 0.2 Suitable for skin (4.5–6.5)

Viscosity - Appropriate for topical application

Spreadability - Good

Extrudability - Acceptable

Stability - No change in appearance or pH - Stable

Phase separation - None observed - Stable emulsion

Microbial Stability:

No microbial growth was observed during 1-month storage under accelerated conditions, indicating effective preservation.

Skin Irritation Test (if performed):

No signs of redness, inflammation, or irritation observed during animal or patch testing. The emulgel was found safe for topical application.

XI. CONCLUSSION

The present study was to increase the penetration of the drug into the skin. In coming years, the topical drug delivery will be used extensively to improve better patient compliance. In present study ornidazole topical emulgels were prepared by using different polymers such as carbopol 934, HPMC, sodium alginate as a polymers and liquid paraffin clove oil and mentha oil and tween 80 used as an emulsifier, propylene glycol as a penetration enhancer. In this study all the formulations were subjected to various evaluation parameters such as physical appearance, pH evaluation, spreadability, swelling index, Rheological studies, drug content and in vitro drug release were found to be within the limits\among all the formulations formulated ornidazole topical emulgel containing carbopol 934 as a polymer and liquid paraffin as a oil shows 93.2% drug release so we can concluded that F3 formulation was the best formulations.

Ornidazole Topical Formula Conclusion

The Ornidazole topical formula combines the active ingredient Ornidazole with suitable excipients to create a stable and effective formulation for topical application. The formula's composition ensures:

1. Optimal drug concentration: Ornidazole concentration is tailored for effective antimicrobial action.
2. Suitable texture and consistency: Excipients provide a smooth, spreadable texture.
3. Stability and shelf-life: Careful selection of excipients and packaging ensures stability. Key Considerations
1. Skin penetration: Formulation design may enhance Ornidazole's skin penetration.
2. Safety and efficacy: The formula's safety and efficacy should be evaluated through clinical trials.

Future Directions

1. Optimization: Further optimization may be necessary to improve stability, efficacy, or patient compliance.
2. Regulatory compliance: Ensure compliance with regulatory requirements for topical formulations.

The Ornidazole topical formula offers a promising approach for treating skin infections, with potential benefits including effective antimicrobial action and improved patient outcomes

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