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Formulation and Evaluation of Antimicrobial Gel of Tinidazole

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Abstract: ***Antibacterial gels are great for carrying and you can take them just about anywhere. The alcohol and other agents excellent for killing germs can easily be used as disinfectants. In this study, we defined and evaluated an antimicrobial gel of tinidazole capable of inhibiting the growth of bacteria. In the present work gel of Tinidazole were prepared and evaluated. Tinidazole (TZ) is an antibacterial drug used for treatment of Bacterial vaginosis. Different gel formulations were prepared using the bio adhesive polymers like carbopol 974, sodium alginate and sodium carboxy methyl cellulose.***

Keywords: Antibacterial gel, disinfection, Tinidazole, Vesicular Drug Delivery System

1. Introduction

Tinidazole is an antibacterial and antiparasitic (antiprotozoal) drug which acts against infections like Giardiasis and Amoebiasis. Tinidazole after oral administration is not much effective due to its low water solubility and extensive hepatic metabolism, also 20-25% of an administered dose is excreted in the urine in unchanged form. Apart from this, oral administration of Tinidazole results in side effects, most probably in gastro-intestinal tract. Additionally, it results in diarrhoea during these infections leading to chances of loss of drug from body before its action.

This problem can be improved by reformulating the drug delivery via a different route like skin. However, conventional topical dosage forms, mostly of which are present in the gel form, usually have quite limited therapeutic efficacy due to the low bioavailability as a small fraction of drug cross the skin barrier.

Advantages of Topical Drug Delivery System

- Avoidance of first passmetabolism.
- Convenient and easy to apply.
- Avoidance of the risks and inconveniences of intravenous therapy and of the varied conditions of absorption, like pH changes, presence of enzymes.
- Avoids fluctuation in drug levels, inter-and intrapatient variations.
- Ability to easily terminate the medications, when needed.

2. Materials and Chemicals

All the materials and chemicals were of analytical grade and procured from the authentic sources. Tinidazole was purchased from Aarti Drugs Ltd., Mumbai, India. Span 60, cholesterol, carbopol 934, propylene glycol, glycerol, triethanolamine, disodium hydrogen phosphate, potassium hydrogen phosphate, sodium chloride, chloroform, methanol, etc.

3. Preformulation Study

For the development of safe, stable and effective dosage form, the initial phase of research and development process was found to be preformulation studies. The preformulation investigations confirm that there are no significant barriers to the development of a safe, stable and effective formulation.

Common gelling agents

There are many gelling agents. Some of the common ones are acacia, alginic acid, bentonite, carbopols (now known as carbomers), carboxy methyl cellulose, ethyl cellulose, gelatin, hydroxyl ethyl cellulose, hydroxyl propyl cellulose, magnesium aluminum silicate (Veegum), methylcellulose, poloxamers (Pluronics), polyvinyl alcohol, sodium alginate, tragacanth, and xanthangum.

4. Objectives

1) To formulate antibacterial gelformulation.
2) To evaluate the antibacterial gel formulation.
3) To study in vitro release ofdrug.

5. List of Chemicals

Sr. No.	Name of Chemicals	Supplier
1	Tinidazole	Shree Enterprizes, Pune.
2	Carbopol	Ozone International, Mumbai.
3	Methyl paraben	Ozone International, Mumbai.
4	Sodium alginate	Ozone International, Mumbai.
5	Propylene glycol	Ozone International, Mumbai.
6	Ethanol	Ozone International, Mumbai.
7	Sodium carboxy methyl cellulose	Ozone International, Mumbai.
8	Distilled water	Lab grade

6. Preparation of Gel

Formulation was prepared by using dispersion method of gel formulation. Carbopol, methyl paraben, Sodium alginate, propylene glycol, ethanol, and tri-ethanolamine were used to prepare 100 g of gel by adding sufficient quantity of distilled

water. Water required for these formulations was divided into two parts: In one part the exact amount of Drug+ Propylene glycol +Ethanol. Other part, Carbopol +Methyl Paraben+ Sodium alginate, was added. Both of the solutions were mixed in a beaker and tri-ethanolamine was added to this mixture drop wise to obtain gel consistency. The prepared gel formulation and base were kept at room temperature for 24 hr.

Composition of gel formulation

Sr. no.	Ingredients	F 1
1.	Tinidazole	1
2.	Carbopol (%)	1
3.	Methyl paraben (%)	0.2
4.	Sodium alginate	0.2
5.	Propylene glycol (%)	4
6.	Ethanol (%)	3
7.	Sodium carboxy methyl cellulose.	0.2
8.	Distilled water	Up to 100 ml

A. Physical Appearance:

- **Colour:** The colour of the formulation was checked out against white background.
- **Homogeneity:** Gel placed in transparent beaker was tested for homogeneity by visual inspection. It was also tested for their appearance and presence of any aggregates.
- **Consistency:** The consistency of the formulation was checked by applying on skin.
- **Greasiness:** The greasiness was assessed by applying on skin.
- **Odour:** The odour of the gel was checked by applying on skin.

B. Measurement of Ph:

The pH of gel was determined by using digital pH meter which was previously calibrated by standard solution prepared by standard capsules of pH 4, 7 and 9.2 respectively. pH measurement of the gels was carried out by dipping the pH-electrode of a digital pH meter completely into the gel formulation for 10 min prior to taking the readings in order to allow the pH values to stabilize. The measurement was carried out in triplicate and the average of the three readings was recorded. The electrode was washed thoroughly between each reading.

C. Spreadability:

Excess quantity of gel formulation was placed in between two glass slides of length 7.5 cm length each. A 1000 g weight is allowed to rest on the upper slide for 5 min to expel air between the slides and to provide uniform distribution of the gel. The weight was removed and the excess of gel adhering to the edges of the slides was scrapped off. The lower slide (immovable) was fixed on the wooden board. The upper slide (movable) was attached with a string that was tied with a pan. The string was passed over a pulley, and the pan was hung from the string. Thereafter 80 g weight was added to the pan and the upper slide was subjected to pull with the help of string. The time required to separate the two slides i. e. the time in which the upper slide slips over the lower slide is noted and taken as a measure of spreadability. The experiments were done in triplicate. The following formula is used to calculate the spreadability:

$$S = m x$$

Where, S is the Spreadability m is the weight tied to the upper slide (g) l is the length of glass slide (cm) t is the time taken to separate the slide completely from each other (s)

D. Extrudability:

The extrudability of gels was determined by the amount of gel extruded from the tube on application of pressure. The formulation was filled in a clean lacquered collapsible aluminium tube of capacity 5 g with 5 mm orifice and tube is pressed firmly at the crimped end and clamp was applied to prevent any roll back. The amount of extruded gel was collected carefully and weighed accurately. Extrudability was then determined by measuring the amount of gel extruded (in percentage) through the orifice when a pressure was applied on the tube. The experiment was performed in triplicate

E. Viscosity:

The viscosity of the gels was determined by Brookfield viscometer with spindle no.64, rotated at 5 rpm for 5 min at 25oC temperature.

F. Stability study:

The stability study of the gels was performed as per International Council for Harmonisation (ICH) guidelines. Freshly prepared formulations were divided into groups and kept at specified storage conditions as per ICH guidelines. Sample were withdrawn periodically and tested for various evaluation parameters mentioned above. Stable formulation must retain the evaluation parameters at specified storage conditions over a period of time.

G. Antimicrobial Activity

Test Organism	Formulation
P. aeruginosa	2.4
Lactobacillus	2.7
E. coli	2.8
Pneumonia	2.6

Figure 2: Zone of inhibition of formulations with different bacterial strains

7. Results

Evaluation of Antibacterial gel Formulations

Colour	White to transparent
Consistency	Good
Greasiness	Good
Odour	Pleasant
pH	6.9
Viscosity [cps]	4300
Extrudability	22.50/ 25gm

8. Conclusion

According to the experiments that have been performed during the research, it is concluded that Tinidazole gel were successfully formulated by using Tinidazole prepared by thin film hydration method by using span 60 and cholesterol in the ratio 1: 1 and loaded in 1% carbopol was found to be best and promising. Tinidazolel gel formulation provided sustained and prolonged delivery of Tinidazole in controlled manner with constant release as it follows zero order release kinetics. The niosomal gel formulation could be a useful dosage form to reduce the unwanted and undesirable side effects associated with oral route. Therefore, niosomal gel may be considered as a best vesicular carrier for the effective delivery of Tinidazole via skin. The methodology used for the preparation is simple and is also industrially feasible. The niosomal gel formulation has an immense potential and can be studied for its clinical implications in future

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