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Formulation *In-vitro* evaluation of Sulfanilamide 15% vaginal cream

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Abstract
Sulfanilamide is a sulfonamide antibiotic that has been used to treat various bacterial infections, especially in the genitourinary tract. However, its oral administration is associated with adverse effects such as nausea, vomiting, hypersensitivity, and hemolytic anaemia. Therefore, the aim of this study was to formulate and evaluate a sulphanilamide 15% vaginal cream as an alternative dosage form. The cream was prepared by using a fusion method with Lanoline as a base. The cream was then evaluated for its physicochemical properties, such as pH, viscosity, spreadability, homogeneity, and stability. The cream was also tested for its *in-vitro* antimicrobial activity against Escherichia coli, Staphylococcus aureus, and Candida albicans using agar diffusion method. The results showed that the cream with mixed base had the most favorable characteristics, such as pH of 4.8, viscosity of 25789 mpa.s, spreadability of 10 cm, and homogeneity of 98.5%. The cream also exhibited good stability under accelerated and normal conditions for three months. The cream showed significant antimicrobial activity against all the tested microorganisms, with inhibition zones ranging from 15 to 25 mm. The cream was found to be non-irritant and safe for vaginal application.

Keywords: Sulfanilamide, virginal cream, anti-microbial activity, skin treatment

Introduction
In the last decade there has been a rapid increase in skin diseases due to change in lifestyle and fashion. Sulfanilamide is not given orally due to the Elixir Sulfanilamide tragedy in 1937 caused over 100 fatalities due to acute kidney failure from the medicines. This event led to the implementation of new US regulations for drug testing. The topical drug delivery systems designed to have systemic effects appears to be beneficial for a number of drugs on account of several advantages over conventional dosage forms routes of drug administration. The drug Sulfanilamide is bacteriostatic antibiotic with broad sprectrum against the gram positive and gram-negative microbes. Which can be used topically to cure the disease of skin like bacterial infection, prevention infectious burns, etc. Creams have advantages over conventional drug delivery system as follow; avoidance of first pass metabolism, convenient and easy to apply, avoid risk, Inconveniences of intravenous therapy and of the varied conditions of absorption like pH changes presence of enzymes gastric emptying time. The sulphonamide antibiotic, Sulfanilamide functions by competitively inhibiting (that is, by acting as a substrate analogue) enzymatic reactions involving para-amino benzoic acid (PABA). Specifically, it competitively inhibits enzyme. Dihydrofolate syntheses PABA is needed in enzymatic reactions that produce folic acid which acts as a Coenzyme in the synthesis of Purine and pyrimidine. Mammals do not synthesize their own folic acid so are unaffected by PABA inhibitors, which selectively kill bacteria. However, this effect can be reversed by adding the end products of one-carbon transfer reactions, such as thymidine, purines, methionine, and serine. PABA can also reverse the effects of sulfonamides.

Material and Methods
The Sulfanilamide were given by SYGMOS Fine Chem., Lanoline, Cetyl alcohol, Methyl paraben, propyl paraben, SLS, propylene glycol this excipients from Labline Stocks, Mumbai.

Methodology

Dissolved in distilled water and added to the above mixture and stir continuously until formation of cream. The preservatives propylparaben and methylparaben were added after cooling to room temperature.

Oil Phase (A): Lanoline, Ceteyl alcohol, Propylene glycol
Aqueous Phase (B): Methylparaben, Propylparaben, SLS& Sulphanilamide & Purified water.

Table 1: Formulation Table for Cream

Sr. No.	Ingredient	Role of Ingredient	F1	F2	F3
1	Sulphanilamide	Active pharmaceutical ingredient	7.5gm	7.5gm	7.5gm
2	Methyl paraben	Preservative	0.125gm	0.125gm	0.125gm
3	Propylparaben	Preservative	0.05gm	0.05gm	0.05gm
4	SLS	Surfactant	1gm	1gm	1gm
5	Propylene glycol	Moisturizing agent	12 ml	1 ml	10 ml
6	Ceteyl alcohol	Emollient	9 gm	8.5 gm	8gm
7	Lanoline	Base	5 gm	7.5 gm	10 gm
8	Purified water	Solvent	q. s	q. s	q. s

Evaluation Tests

Colour

Color for the formulations was determined based on the texture they provided after the final product was developed.

Odour

Choosing the Fragrance for the Formulation the scent of the formulation was chosen based on its aroma after being smelled. Alternatively, the formulation's fragrance was determined by sniffing it.

Homogeneity

To determine the cream's appearance and identify any aggregates, visual inspection was utilized.

pH Determination

The pH of formulated cream is determined by dipping the glass electrode into the cream with a digital pH meter. Each batch pH was measured three times, and the average result were determined.

Spreadibility

To measure the spreadability of the cream formulation, two glass slides (14*5 cm) were used, each of equal length. One gram of cream was applied to one slide while weights (125 g) were added to the other. The time it took for the second slide to separate from the first was calculated. Smaller intervals indicate better spreadability. The following formula was used to calculate the spreadibility.

$S = M^* L/T$

Where:
S denotes spreadibility.
M is the weight attached to the higher slide.
L denotes the length of the glass slides.
T denotes the time necessary to completely separate the slides

Viscosity

The viscosity of cream was determined by using a Brookfield viscometer with a L-Bar spindle in combination with a helipath stand Spindle L4 was used for the measurement of viscosity of all the Cream. The viscosity was measured using 50 gm of cream filled in a 100ml beaker.

Stability

Physical stability were monitored for 3 months of all 3 batches at room temperature.

Anti-Microbial

The Mueller-Hinton (MH) agar medium was prepared and autoclaved. After autoclaving, the agar medium was cooled to 40-45 ℃ in a water bath then solution was poured into petri dish. The agar was allowed to cool to room temperature and stored in refrigerator. E. coli was used to evaluated antimicrobial activity of cream. To inoculate the MH agar plate, a sterile cotton swab was dipped into the E. coli culture and streaked over the surface of the agar media. Then the dried inoculated MH agar plate prepared above were used to perform the agar well diffusion assay.

Result and Discussion

Colour

The colour appearance of the formulated cream was tested, and it was discovered that formulations containing varying amounts of Lanoline had distinct colours and appearances.

Odour

The odour of all Formulated cream was recorded, and it was labelled as moderate+, good++, best+++.

Homogeneity

The homogeneity of the Formulated cream was examined, and it was found that all formulation have good homogeneity except F3

pH Analysis

The PH values of all the formulated creams ranged from 4.8 to 5.5, which is considered optimal to prevent skin irritation when applied to the skin.

Spreadibility

The spreadibility results reveal that the formulated cream is easily spreadable with a little amount of shear. The F1 spreadability was 10 cm/s, showing that the cream was effective.

Viscosity

The L-bar spindle was used for determining the viscosity of the cream. The average of three reading taken in one minute was noted as the viscosity of cream. The viscosity of F1 was 25789 mpa.s.

Stability

The physical stability of formulation was found compliance there was no complications.

Anti-Microbial

For determination of anti-microbial activity, we have used two different concentrations 40 µg/ml and 20 µg/ml inhibition range of 15-25 mm.

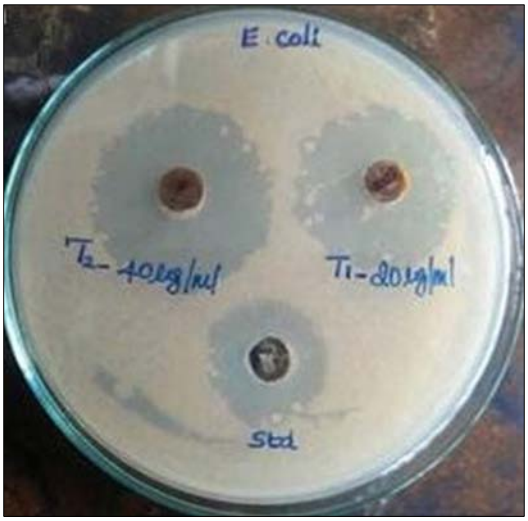

Table 2: Evaluation Parameters of Formulated Cream

Sr. No	Parameters	F1	F2	F3
1	Colour	Light Yellow	Pale Yellow	Dark Yellow
2	Odour	+++	++	++
3	Homogeneity	98.5%	96%	95%
4	pH	4.8	5.1	5.5
5	spreadibility	10	8	7
6	Viscosity	25789 mpa.s	30254 mpa.s	38331 mpa.s
7	Anti-Microbial	15-25 mm	15-25 mm	15-23 mm
8	Stability	+++	++	++

Conclusion

The aim of this study was to formulate and evaluate sulfanilamide 15% vaginal cream as a potential treatment for vulvovaginal candidiasis and bacterial vaginosis. Sulfanilamide is a sulfonamide antifungal that inhibits the synthesis of folic acid in microorganisms, thereby arresting their growth. The cream was prepared by using a fusion method and was characterized for its physical appearance, pH, viscosity, spreadability, and stability. The cream was also tested for its antimicrobial activity against E. coli by using agar well diffusion method. The results showed that the cream had a smooth and homogenous texture, a pH of 4.8, a viscosity of 25789 mpa.s, a spreadability of 10 g.cm/s, and stability of 3 months at room temperature. The cream exhibited significant antimicrobial activity, with zones of inhibition ranging from 18 to 24 mm. The cream was found to be non-irritant and safe for vaginal use, as confirmed by the histopathological examination of the thinnest part of skin behind the ear. The study concluded that sulfanilamide 15% vaginal cream is a promising formulation for the treatment of microbial infections, as it has a dual mode of action, a favorable physicochemical profile, and a potent antimicrobial activity. The cream could be a valuable alternative to the existing therapies for these common vaginal infections.

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