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A Comparison of Mucoadhesive Vaginal Film and Curcumin Tablets

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Abstract

Vaginitis is a term used to describe conditions that cause vaginal inflammation. It is one of the most common gynaecological disorders. The two most prevalent causes of vaginitis are candidiasis and bacterial vaginosis. Vaginal candidiasis (VC) is one of the most common reasons women see a gynaecologist.Candida is a form of yeast that is harmful in humans. Candida albicans and other Candida species such as Candida glabrata and Candida parasitosis are responsible for 90 per cent of vaginal fungal infection cases.This study aimed to develop muco-adhesive vaginal units, such as curcumin tablets and films, to treat vaginal candidiasis. Curcumin was sent as a free sample by Sava Health Care Pvt Ltd in Pune, India. Coloron Asia, Goa, India, and Research-Labs FineChem Industries, Mumbai, India, provided the hydroxypropyl methylcellulose (HPMC K15M) and xanthan gum (Pure, Food Grade), respectively. Acetone (Universal Labs, Mumbai, India), PEG 400.The water was distilled on hydroxypropyl methyl/Vis Spectrophotometer, FTIR Spectrophotometer, XRD (Advance D8), Texture analyzer (Brookfield, India), pH meter (Digisun Electronics, Mumbai, India), Magnetic stirrer (Remi equipment's, Mumbai, India), Dissolution apparatus (Lab India Analytical Instruments Pvt. Ltd. Bangalore, India), Hot air oven.The water was distilled on-site.UV/Vis Spectrophotometer, FTIR Spectrophotometer, XRD (Advance D8), Texture analyzer (Brookfield, India), pH meter (Digisun Electronics, Mumbai, India), Magnetic stirrer (Remi equipment's, Mumbai, India), Dissolution apparatus (Lab India Analytical Instruments Pvt. Ltd. Bangalore, India), Hot air oven.The morphological character of the drug was determined using XRD under various situations, including as a single drug, in a film, and in a tablet. In simulated vaginal fluid, a calibration curve was created—assessment of the Film. Tablet is evaluated.Drug and excipient flow characteristics are assessed. Based on the findings, it can be concluded that Curcumin mucoadhesive film and tablet formulations are feasible. It was determined that there was no interaction between the medication and the excipients.

Key Words: Curcumin, Vaginal Candida, Mucoadhesive Film

Introduction:

Vaginitis is a term used to describe conditions that cause vaginal inflammation. It is one of the most common gynaecological disorders. The two most prevalent causes of vaginitis are candidiasis and bacterial vaginosis. Vaginal candidiasis (VC) is one of the most common reasons women see a gynaecologist. According to the research, about 75% of all adult females will experience vaginitis at some point in their lives. It's also worth noting that at least half of these ladies had had one recurring episode of VC. Candida is a form of yeast that is harmful in humans. Candida albicans and other Candida species such as Candida glabrata and Candida paraphimosis are responsible for 90 per cent of vaginal fungal infection cases. Because of the rising frequency of VC, a promising drug delivery technique is required to eradicate the infectious agent successfully, achieve higher drug levels at the site, avoid first-pass metabolism, a shorter therapy regimen, and convenience and safety. The vaginal mucosa has several advantages, including a wide surface area, a plentiful blood supply, and the ability to be used for local and systemic therapy. Contraceptives, antifungals, antivirals, and other kinds have all been documented. Traditional vaginal dose forms such as creams, foams, pessaries, and jellies have a limited residence period at the site of application and leakage and messiness, leading to a diminished therapeutic impact and inconvenience for patients. These issues could be avoided with mucoadhesive vaginal medication delivery systems. In addition to effectively treating vaginitis, the formulation must cling to the vaginal mucosa to keep the medicine in contact with target tissues for an extended period and avoid formulation ejection. Mucoadhesive polymers have the potential to stick to mucous–epithelial interfaces, making them a viable carrier for mucoadhesive vaginal medication delivery systems. Curcumin is a pigment found in the Curcuma species that is often used in dishes as a yellow colouring and flavouring agent, especially in India. Curcumin has a long history of usage in traditional medicine and as a home remedy for various ailments, including biliary disorders, anorexia, cough, diabetic wounds, hepatic disorders, rheumatism, and sinusitis. Curcumin is also anti-inflammatory, antioxidant, anticarcinogenic, antimutagenic, anticoagulant, antiarthritic, antibacterial, antifungal, antiprotozoal, antiviral, and psoriatic, neuroprotective, and anti-Alzheimer. Curcumin has been demonstrated to be harmless to people in studies. Curcumin's antifungal efficacy against Candida albicans has been studied. It was discovered that it was 2.5 times more potent than fluconazole at inhibiting Candida albicans adherence and that it has synergistic antifungal effects with azoles and polyenes.

Aim and Objective:

This study aimed to develop muco-adhesive vaginal units, such as curcumin tablets and films, to treat vaginal candidiasis.

Material and Methods:

Curcumin was sent as a free sample by Sava Health Care Pvt Ltd in Pune, India. Colorcon Asia, Goa, India, and Research-Labs FineChem Industries, Mumbai, India, provided the hydroxypropylmethylcellulose (HPMC K15M) and xanthan gum (Pure, Food Grade), respectively. Acetone (Universal Labs, Mumbai, India), PEG 400 (Research-Labs FineChem Industries, Mumbai, India). Magnesium stearate and talc were purchased from a local market (Loba Chemie, Mumbai, India). The water was distilled on-site.UV/Vis Spectrophotometer, FTIR Spectrophotometer, XRD(Advance D8), Texture analyzer (Brookfield, India), pH meter (Digisun Electronics, Mumbai, India), Magnetic stirrer (Remi equipment, Mumbai, India),

Dissolution apparatus (Lab India Analytical Instruments Pvt. Ltd. Bangalore, India), Hot air oven (Lab-line Instruments, Kochi, India) were among the instruments used in this The drug's solubility was tested in a variety of media (water, methanol, acetate buffer pH 4.2, and stimulated vaginal fluid). The medication was precisely weighed and placed into volumetric flasks containing various solvents, then thoroughly shaken and sonicated for 30 minutes until saturation was attained.

An IR absorption scan was used to identify the curcumin sample and rule out interactions between the medication and the excipients. The goat vaginal mucosa was used in the cohesion investigation. It was carried out using the texture analyzer method. A patch in the shape and size of a tablet face (die 12 mm, area 1.13 cm2) was connected to the sample holder, and mucosa was attached to the other holder. The attachments were made with the appropriate adhesive. SVF was used to wet the Film, which was then allowed to touch the moist mucosa and adhere. The texture analyzer's upper probe moved at a rate of 0.1 mm/s. As a result, a pull force separated the Film from the mucosa. The sample's separation from the mucosal substrate was an indication of cohesion. We tested weight fluctuation, hardness, and friability. UV spectrophotometry was used to assess the amount of curcumin in the pills. The powder equivalent to 10 mg of curcumin was transferred to a 100 mL volumetric flask from finely powdered tablets. A modified conventional basket device was used to assess drug release. Only the rod remained when the bask was removed. The bottom end of the stirring rod was wetted with a few drops of SVF, and one phase of the test tablet was glued to it.

Results and Discussion:

The drug's solubility was tested in five different media, as shown in Table 1

Table 1: Solubility of Curcumin in different media

Media	Solubility (mg/ml)
Methanol	10.2
Distilled water	0.11
Stimulated vaginal fluid	0.501

The morphological character of the drug was determined using XRD under various situations, including as a single drug, in a film, and in a tablet. In simulated vaginal fluid, a calibration curve was created. Assessment of the Film.Tablet is evaluated.Drug and excipient flow characteristics are assessed.The water was distilled on-site. UV/Vis Spectrophotometer, FTIR Spectrophotometer, XRD (Advance D8), Texture analyzer (Brookfield, India), pH meter (Digisun Electronics, Mumbai, India), Magnetic stirrer (Remi equipment, Mumbai, India), Dissolution apparatus (Lab India Analytical Instruments Pvt. Ltd. Bangalore, India), Hot air oven All of these metrics, including the angle of repose and Carr's index, were determined to be in the range of 18-19 and 19-20 for the drug powder blend.

Hydrophilic polymer combinations were used to make curcumin tablets and films. In 12 hours, the Film exhibited 90-95 per cent drug release, and the tablet showed 70-80 per cent. This may be because Film has a more extensive surface area and is thus more easily reached by the VSF. All of the profiles were nearly linear. The films were thus released comparatively faster, even though their release patterns were similar. Also, the concentration of xanthan gum in the tablet was more significant than in the Film, and this gum's swelling and gelling capability may have

slowed the release rate. As can be seen in the graphs, different concentrations of HPMC may have affected the first burst rate. Perhaps it might be claimed that a favourable release profile could be achieved in both circumstances by modifying the formulation.

Conclusion:

Based on the findings, it can be concluded that Curcumin mucoadhesive film and tablet formulations are feasible. It was determined that there was no interaction between the medication and the excipients. Teflon was discovered to be a suitable substrate for film casting. The formulation's validity was validated by dissolution and antimicrobial research. The Film outperformed the tablet. Scalability would be a feature of the formulations. There didn't appear to be any regulatory roadblocks. It may bring the proposed Film to the level of patients with additional support from in-vivo and clinical programmers.

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