

(54) Title of the invention : TERBINAFINE LOADED CONTROL RELEASE TRANSDERMAL PATCH AND METHOD OF PREPARATION THEREOF

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(57) Abstract :

Transdermal patches represent a non-invasive and controlled drug delivery system designed to deliver therapeutic agents across the skin into the systemic circulation. They offer several advantages over traditional oral and injectable routes, including sustained drug release, avoidance of first-pass metabolism, improved patient compliance, and reduced dosing frequency. The development of an effective transdermal patch requires careful selection of polymers, permeation enhancers, and plasticizers to ensure optimal adhesion, flexibility, and drug permeability. Characterization parameters such as thickness, tensile strength, drug content uniformity, moisture absorption, and in vitro release profiles are critical for assessing the patch's performance. The present research work was undertaken to develop and evaluate transdermal patches of Terbinafine hydrochloride for effective and sustained treatment of onychomycosis and other fungal infections. The primary aim was to overcome the limitations of oral therapy such as poor bioavailability, gastrointestinal side effects, and the hepatic first-pass effect. A total of nine formulations (F1–F9) were prepared using various concentrations of polymers like HPMC K15M and PEG 400, with plasticizers and penetration enhancers to optimize patch performance. The prepared patches were evaluated for physicochemical properties including thickness, weight variation, drug content, folding endurance, moisture content, pH, and surface characteristics- all of which were within acceptable limits, confirming good formulation quality. The in vitro drug release studies revealed a sustained release pattern for all formulations. Among them, formulation F9 showed the highest cumulative drug release (~75% in 8 hours). The drug release data were fitted into various kinetic models, and it was found that all formulations predominantly followed first-order kinetics, with high R² values (0.998). Further, the Higuchi and Korsmeyer–Peppas models indicated that the mechanism of drug release was primarily diffusion-controlled, with some formulations exhibiting anomalous transport behaviour, confirming the role of both diffusion and polymer relaxation in drug release. Recent advancements have expanded the applications of transdermal systems for both local and systemic treatments, making them a promising platform for future drug delivery technologies. Ongoing research aims to address challenges like limited permeability for certain drugs and skin irritation, thereby enhancing the clinical utility of transdermal patches.

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