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Enhancing bioavailability of generics through product design

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Generic Drug development represents an increased field of interest from national and multinational pharmaceutical companies. Since original patents expiry left an open window for these companies. Most active pharmaceutical ingredients are hydrophobic moieties and thus, dissolution stage represents a difficult problem to solve. From many years scientists have attempted to enhance dissolution by different chemical or physical means, examples of these technologies include: physical reduction of particle size, solubilization by micellar inclusion, liposome encapsulation, and niosome technologies. Nanotechnology has opened a new window either for dissolution enhancement, drug absorption and final drug availability at the site of action. Drug absorption from different physiological barriers represents a second hurdle to overcome. Particle engineering by supercritical fluid crystallization, spherical crystallization and surface treatment by polymers represents an alternative either for inhalation delivery, oral and injectable delivery routes. New polymer associations increased functionalities and more strict regulations for excipients allows for the obtention of reproducible and reliable results on a long term basis. Amorphicity achieved on surfaces either from polymers, bulk excipients and active pharmaceutical ingredients can be used as a strategy for drug dissolution and included into new formulation design. It is interesting to note that R&D pharmacist must evaluate these technologies at the design stage not only to enhance bioavailability but to optimize drug delivery systems and either patenting them.

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In-vitro and *in-vivo* assessment of topical delivery of anti-fungal vidang extract formulation

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The present research work aimed at development as well as *in-vitro* and *in-vivo* assessment of Herbal Topical Gel Formulation (HTGF) for local delivery of antifungal vidang extract. Embelin is the major constituent of the vidang which is used to prevent fungal skin infections and is not absorbed at all in entire upper portions of GI tract and remain as such in colon. Hence, vidang was chosen as a drug to formulate HTGF. Because of the prolonged contact of drug with infected part and poor solubility of embelin, suitable semi-solid bases and appropriate co-solvent system are required to develop stable and safe HTGF. Each formulation was characterized in terms of viscosity, spreadability, pH measurements, drug content, and in vitro diffusion study. A 32 full factorial design was employed to investigate the influence of formulation variables (effect of amount of Carbopol 934 and amount of propylene glycol (PG)) on the viscosity, time required for 50% release of drug (T50%) and drug release at 1 hr (DR1). On the basis of percentage similarity with maximum desirability, formulation containing 1.6% carbopol 934 with 12% PG was selected as an optimized formulation. The optimized formulation was evaluated for ex vivo permeation study, in vitro antifungal study and its effect on *Candida albicans* on skin infection in guinea pigs. Optimized formulation significantly ($p<0.005$) *inhibited Candida albicans, Trychophyton rubrum and Microsporum canis in vitro* as well as significantly ($p<0.005$) eradicated *Candida albicans* from infected skin in guinea pigs. The results revealed that optimized formulation exhibited superior physical characteristics and promising performance for local topical delivery.

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