

ABSTRACT

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Title of Thesis:

Evaluation of rheological properties of terbinafine hydrochloride creams

The aim of the rigorous work was to evaluate the rheological properties of creams with terbinafine hydrochloride at different stages of the formulation of a generic preparation using a suitable methodology and their comparison with the commercial preparation Lamisil 10 mg/g crm. (GlaxoSmithKline), which was specified as a standard. The theoretical part deals with the characterization of generic drugs, pharmaceutical and therapeutic equivalence. Tests suitable for measuring the flow properties of semi-solid preparations and evaluation methods are presented. The properties of terbinafine hydrochloride and the process of developing generic semi-solid formulations are summarized. Testing was performed at 25 °C on a Kinexus Pro+ rotational rheometer using cone-plate geometry. The flow properties of the creams were evaluated by nonequilibrium flow and viscosity curves, which were analysed by the power law model and Herschel-Bulkely model. The coefficient of consistency, the index of flow behaviour and the yield point were expressed. The thixotropic behaviour was described by the area of the hysteresis loop and the rate of structure recovery of the cream structure in a three-steps thixotropic test. Based on a comprehensive evaluation of the results of the tests performed and their statistical evaluation, it can be stated that out of the five generic creams tested, the F5 formulation shows compliance with the standard.

Keywords: generic formulations; terbinafine hydrochloride; creams; flow curve; thixotropy.