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Characterization of Antifungal Nail Lacquer Formulations Containing Fluconazole

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Onychomycoses, fungal nail infections, are responsible for 50% of all nail disorders affecting up to 18% of general population in some countries [1]. Nail lacquers (also transungual therapeutic systems) represent new drug forms specifically designed to enable longer release and sustained action of active principle into the infected nail plate [2]. We developed six formulations of nail lacquer containing 0.9% (w/v) fluconazole, Eudragit RS 100 and acetone. The formulations contain di-butyl phthalate, polyethylene glycol 400 or propylene glycol as plasticizers in two different concentrations. We characterized the developed formulations with regard to the drying time, fineness of formed film, fluconazole assay and viscosity.

The drying time for the formulations with lower plasticizer content was 25 s, and for those with higher plasticizer content was 30 s. All developed formulations gave homogenous, smooth, glossy and transparent films.

We developed simple derivative spectrophotometric method for fluconazole assay in all six formulations and the obtained results were in range of 97.5–103.9% of the declared content.

Viscosity was measured using rotating viscometer in accordance to Ph.Eur.6.0 [3]. The viscosity values were in range of 0.0055–0.0079 Pa×s, which are 50 times lower viscosity values in comparison to the cosmetic nail lacquers. Lower viscosities are preferred since they ensure better coverage and intimate contact with the nail plate leading to better therapeutic response.

The obtained results comply with the standards for this type of preparations with regard to the drying time, film appearance, as well as good flow characteristics. The content of fluconazole is within usually prescribed limits of 100±5%. The results indicate good compatibility of the used ingredients in all six developed formulations.