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(57) Abstract :
The present invention relates to an amorolfine nanoemulsion formulation with improved nail permeation and enhanced antifungal efficacy for treating onychomycosis. The nanoemulsion comprises amorolfine hydrochloride incorporated into oil-in-water nanoemulsion droplets with mean particle size of 50 to 150 nanometers. The formulation includes an oil phase of undecylenic acid, surfactant system of polysorbate 80 and transcutol P, optional penetration enhancers including thioglycolic acid and urea, and an aqueous phase. The nanoemulsion demonstrates 2.48-fold enhanced transungual permeation compared to conventional nail lacquer formulations. The optimized formulation exhibits thermodynamic stability, narrow droplet size distribution with polydispersity index below 0.3, and superior antifungal activity against Trichophyton rubrum with minimum inhibitory concentration of 0.125 micrograms per milliliter. The invention provides reduced treatment duration and improved therapeutic outcomes for patients suffering from fungal nail infections through enhanced drug penetration to the nail bed.

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