Abstract:

This study focused on the incorporation into orodispersible films (ODFs) of the dried extracts of five selected Indonesian medicinal plants: Lagerstroemia speciosa (L.) Pers. (LS), Phyllanthus niruri L. (PN), Cinnamomum burmanii Blume (CB), Zingiber officinale Roscoe (ZO) and Phaleria macrocarpa (Scheff.) Boerl (PM). Suitable formulae for solvent casting were developed to produce extract containing films with either a combination of hypromellose (HPMC) with carbomer 974P or only hydroxypropyl cellulose (HPC) as film forming agent. Each extract and dose in a formulation rendered different ODF characteristics. Extracts of ZO and CB and a low dose of PM extract (5 mg) could be formulated into an ODF containing HPMC with carbomer 974P. For extracts of LS, PN and high doses of PM extract HPC were the most suitable film forming agents. For each extract a different maximum load in a film was found, up to maximum 30 mg for extracts of LS and PN. Good products were obtained with 5 mg and 10 mg of each extract. The quality of the produced ODFs was tested organoleptically, and characterized by determination of uniformity of weight, thickness, disintegration time, surface pH, crystallinity, mechanical properties, water content, residual ethanol, dynamic vapour sorption, physical stability and control of the qualitative profiling of extract composition in the film. Thin layer chromatography indicated that all five extracts remained chemically unaffected during ODF production. In conclusion, ODFs are a suitable novel dosage form for herbal extracts, provided that tailor-made formulations are developed for each extract and each dose.

**Keywords:** Orodispersible film; dried herbal extracts; product development; extract load; product quality

**Introduction**

Orodispersible films (ODFs) are a novel advanced pharmaceutical dosage form targeted especially for geriatric and pediatric patients (Slavkova and Breitkreutz, 2015). Various studies have been published on ODFs containing active pharmaceutical ingredients, but literature on the incorporation of dried herbal extracts in ODFs is scarce. Up to now ODFs containing herbal extracts are used limitedly, as over the counter medicine used for the