

FLORITE® R AS A MODEL FOR INCORPORATION OF ESSENTIAL OILS AS ACTIVE SUBSTANCES INTO A SOLID DOSAGE PHARMACEUTICAL FORM

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Application of essential oils in modern medicine has a limited use due to its specific physico-chemical properties which can make them extremely unsuitable for the formulation of stable pharmaceutical forms. The aim of this study was to develop robust hard capsules formulation with natural essential oil mixture (HerbELICO®) which has confirmed anti-*Helicobacter pylori* activity. Unique Calcium Silicate (Florite® R, Tomita Pharmaceutical Co., Ltd.) with its high liquid adsorption ability was used for preparing Unique HerbELICO® powder where HerbELICO® mixture of essential oils was loaded on Florite® R by mixing in the range from 70 to 80 % (w/w). The factorial design of experiments was applied to systematically optimise the physical characteristics of capsules containing Unique HerbELICO® Powder and filler in different ratio. The prepared Unique HerbELICO® Powders were evaluated for their flowability, bulk and tapped density and angle of response, and based on these parameters the optimum formulation was selected. HerbELICO® solid capsules were evaluated for their weight variation. The experimental results have shown that the content of up to 30% (w/w) of Unique HerbELICO® Powder per capsule still provided physico-chemical properties in the acceptable limits. The present study promotes HerbELICO® solid capsules formulation as a model of the successful incorporation of essential oils into a solid dosage form. The advantage of the developed capsules is possibility to use essential oils in robust pharmaceutical form suitable for massive production, and convenient for oral use.

FLORITE® KAO MODEL ZA INKORPORIRANJE ETARSKIH ULJA KAO AKTIVNIH SUPSTANCI U ČVRSTE FARMACEUTSKE OBLIKE

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Primena etarskih ulja u modernoj medicini je ograničena zbog njihovih specifičnih fizičko-hemijskih osobina koje ih mogu učiniti izuzetno nepogodnim za formulisanje stabilnih farmaceutskih oblika. Cilj ove studije je bio da se razvije čvrst farmaceutski oblik, tvrda želatinska kapsula, sa prirodnom mešavinom etarskih ulja (HerbELICO®), sa prethodno potvrđenom anti-*Helicobacter pylori* aktivnošću. Jedinstveni kalcijum silikat (Florite® R, Tomita Pharmaceutical Co., Ltd.) sa svojom visokom sposobnošću da adsorbuje tečnosti, korišćen je za pripremu jedinstvenog HerbELICO® praška, pri čemu je mešavina etarskih ulja HerbELICO® nanošena na Florite® R mešanjem u odnosu od 70-80% (w/w). Faktorijalni dizajn eksperimenata je primenjen za sistemsku optimizaciju kapsula koje sadrže HerbELICO® prašak i sredstvo za dopunjavanje u različitim odnosima. Pripremljeni jedinstveni HerbELICO® praškovi su procenjeni na osnovu njihove protočnosti, nasipne i sabijne gustine, nasipnog ugla i na osnovu tih parametara kao i na osnovu variranja mase HerbELICO® kapsula, odabrana je optimalna formulacija. Eksperimentalni rezultati su pokazali da su fizičko-hemijski parametri kapsula koje sadrže do 30% (w/w) jedinstvenog HerbELICO® praška po kapsuli, u prihvatljivim granicama. Ova studija promovira HerbELICO® formulaciju u obliku tvrdih želatinskih kapsula kao model za uspešno inkorporiranje etarskih ulja u čvrst farmaceutski oblik. Prednost razvijenih kapsula je mogućnost upotrebe etarskih ulja u robusnom farmaceutskom obliku koji je pogodan za serijsku proizvodnju i koji je prihvatljiv za oralnu upotrebu.