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Original Article

Validated high performance liquid chromatography for simultaneous determination of stability of madecassoside and asiaticoside in film forming polymeric dispersions

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ABSTRACT

The objective of the work was to validate the high performance liquid chromatography for simultaneous determination of stability of madecassoside and asiaticoside in Centella asiatica (L.) Urb., Apiaceae, extract-loaded film forming polymeric dispersions. High performance liquid chromatography method was validated in five topics: linearity and range, limit of detection and limit of quantitation, specificity, precision, and accuracy. Results showed the method had a good linearity ($R^2 > 0.9990$) in the range of 5–150 µg/ml and specific. The limit of detection and limit of quantitation of madecassoside were 81 and 245 ng/ml and asiaticoside were 21 and 64 ng/ml, respectively. The percent relative standard deviation of intraday and interday precision were less than 1 and 3%, respectively. The accuracy presented as percent recovery was 101.54-103.29% for madecassoside and 100.39-102.58% for asiaticoside. This validated high performance liquid chromatography method was used to determine the stability of the formulation containing Centella asiatica extract. Centella asiatica extract-loaded film forming polymeric dispersions used Eudragit[®] RS 30D and Eudragit[®] RL 30D as film former, glycerin as plasticizer, and absolute ethanol as solvent and penetration enhancer. Three formulations with different ratio of Eudragit[®] RS 30D and Eudragit[®] RL 30D were prepared and stored for 90 days at 4 °C, 25 °C, and 40 °C. Stability results showed that almost all of the formulations were unstable at 25 °C and 40 °C. Except, two of three formulations were stable at 4 °C. However, the formulation was further developed to improve the stability of madecassoside and asiaticoside in the formulation.

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23 Introduction

Centella asiatica (L.) Urb. is a well-known herbal medici-24 nal plant in the family of Apiaceae. In Thailand, it is listed 25 in National Essential Drug List; topical cream containing 70% 26 ethanol extract of dried C. asiatica in a concentration of 7%w/w 27 is used for wound healing purpose. Currently, C. asiatica is 28 29 commonly used for the treatment of dermatological diseases including bacterial infection, psoriasis, scleroderma, and wound. 30 Furthermore, antioxidant activity is reported as well (Bylka et al., 31

2014). Other biological and pharmacological effects are also reported. It is used as an adaptogen, antibiotic, blood-purifier, central nervous system relaxant, detoxifier, diuretic, emmenagogue, laxative, peripheral vasodilator, and sedative (Khare, 2007). It contains various chemical compounds including pentacyclic triterpenoids called centelloids such as madecassic acid, asiatic acid, and its glycosides; madecassoside and asiaticoside is a main chemical compound that exhibits wound healing property. The chemical structures of madecassoside (1) and asiaticoside (2). *Centella asiatica* also contains other compounds *e.g.*, asiaticoside C, asiaticoside D, asiaticoside E, asiaticoside F, centellasaponin B, centellasaponin C, isothankunic acid and oleanane-type saponins (*e.g.* terminolic acid and centellasaponin D) (Bylka et al., 2014).

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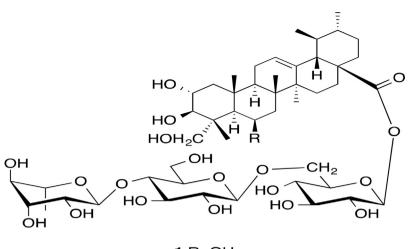
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1 R=OH 2 R=H

The film forming polymeric dispersions (FFPD) is a new drug delivery systems. It is composed of active ingredient and inactive pharmaceutical additives including film former, plasticizer and other additives. When applying FFPD on the skin, a drug in the liquid form can permeate into the skin immediately. Subsequently, the solvent evaporates and the film is in situ formed on the skin and controls the drug permeation (Zurdo Schroeder et al., 2007). There are several publications which reported that FFPD can deliver some drugs such as betamethasone-17-valerate (Frederiksen et al., 2015; Garvie-Cook et al., 2015), ethinylestradiol (Zurdo Schroeder et al., 2007), and nicotine (Pichayakorn et al., 2013; Pichayakorn et al., 2015).

Stability study of herbal products is an important step 58 in the drug approval process to assess the quality of the 59 product at various time under the effect of environmental 60 issues. So, the objective of the work was to validate the high 61 performance liquid chromatography (HPLC) for simultaneous 62 63 determination of stability of madecassoside and asiaticoside in C. asiatica extract-loaded film forming polymeric dispersions. HPLC method was validated in five topics including linearity 65 and range, limit of detection (LOD) and limit of quantitation 66 (LOQ), specificity, precision, and accuracy. The 90-day stability 67 of the formulations stored at different temperatures was also investigated.

70 Materials and methods

Chemicals and reagents

Madecassoside (purity 95.0%, HPLC) was purchased from 72 Sigma-Aldrich Inc., Missouri, USA. Asiaticoside (purity 99.81%, 73 HPLC) was purchased from Chengdu Biopurify Phytochemicals 74 Ltd., Sichuan, China. Eudragit[®] RS 30D and Eudragit[®] RL 30D 75 (Evonik Nutrition & Care GmbH, Darmstadt, Germany) were 76 gifted from Jebsen & Jessen Ingredients, Bangkok, Thailand. 77 Commercial, standardized C. asiatica extract (Centella asiatica 78 Cosmélène[®] containing madecassoside and asiaticoside (1%) in 79 butylene glycol) was purchased from Greentech Biotechnologies, 80 Saint Beauzire, France. Glycerin was purchased from Namsiang 81 Co., Ltd., Bangkok, Thailand. Absolute ethanol was purchased 82 from QRëC, New Zealand, Methanol and acetonitrile (HPLC grade) 83 were purchased from Honeywell-Burdick & Jackson, Michigan, 84 USA. Orthophosphoric acid (85%) was purchased from Carlo 85 Erba, Val de Reuil, France. Reverse-osmosis water and ultra-86 pure water were produced by water purifier (Mirae ST Co., Ltd., 87 Gyeonggido, Korea). 88

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Preparation of Centella asiatica extract-loaded FFPD solution

Three formulations of *C. asiatica* extract-loaded FFPD were prepared. Eudragit[®] RS 30D and Eudragit[®] RL 30D were used as film forming agent. Glycerin was used as plasticizer. Absolute ethanol was used as solvent and penetration enhancer. *C. asiatica* extract was used as an active ingredient. The 50 g of Eudragit[®] was used; F1, F2, and F3 composed of Eudragit[®] RS 30D and Eudragit[®] RL 30D in a ratio of 35:15 g, 25:25 g, and 15:35 g, respectively. Glycerin (20 g) was added and mixed using magnetic stirrer (CMAG HS7, Ika, North Carolina, USA). Absolute ethanol (20 g) was then added. Finally, *C. asiatica* extract (10 g) was added and mixed.

Stability test of Centella asiatica extract-loaded FFPD

Three formulations of *C. asiatica* extract-loaded FFPD were stored at 4°C, 25°C, and 40°C. The formulations were sampled every 30 days for 90 days to analyze madecassoside and asiaticoside remaining in the formulations. The remaining madecassoside and asiaticoside were compared to an initial time. The formulation was diluted in water, sonicated, and adjusted to 100 mg/ml before analysis.

HPLC condition

Madecassoside (1) and asiaticoside (2) analysis was performed by reversed-phase HPLC (Agilent 1260 infinity, Agilent, California, USA). It was equipped with autosampler and photodiode array detector. The ACE 5 C18-PFP column (250×4.6 mm internal diameter, 5 µm) was used as stationary phase. It was controlled at 25 °C. Mobile phase was composed of acetonitrile (A) and 0.01% orthophosphoric acid (B) was used. The gradient elution system holding 80% B for 2.5 min, decreased to 50% B in 4 min and holding for 2.5 min. Then, increased to 80% B in 1 min and holding for 2 min to equilibrate before the next injection. The flow rate of mobile phase was 1 ml/min. The injection volume was 10 µl. The detection wavelength was 210 nm.

Method validation

Linearity and range

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The 1 mg/ml of stock solution of madecassoside and asiaticoside was prepared using methanol as solvent. The seven concentrations of the mixed standard were prepared: 5, 10, 25, 50, 75, 100, and $150 \,\mu$ g/ml. The standard solutions were filtered through 0.45 μ mpore size nylon syringe filter. They were then analyzed by the HPLC

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