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Silymarin content in *Silybum marianum* extracts as a biomarker for the quality of commercial tinctures

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Abstract

Silybum marianum (L.) Gaertner (Milk thistle) extracts have been widely used for the treatment of liver pathologies and as a hepatoprotectant against alcohol-induced liver diseases and other harmful drug metabolites or toxins. Silymarin, the active fraction of *Silybum marianum* tinctures, accounts for 70-80% of the plants hydro-alcoholic extract and consists of a mixture of flavonolignans and a flavonoid. *Silybum marianum* tinctures are commonly prescribed by herbal practitioners for the treatment of liver diseases. However, previous studies have showed inconsistency in the therapeutic efficacy of *Silybum marianum* tinctures, which is believed to have arisen from the content variability of silymarin, resulting from lack of standardized and regulated manufacturing processes. This work was conducted to quantify the silymarin content in commercial *Silybum marianum* tinctures in order to evaluate their quality. In this study, we report the determination of the total silymarin content in eleven different commercial tinctures produced in the U.K. using a convenient and accurate HPLC-UV method. The tinctures analyzed differed in the ratio between herb and liquid as well as percentage of ethanol used during the extraction process. Our results showed a direct correlation between the silymarin content in tinctures and the alcohol strength. Following our protocol, silymarin could not be detected in tinctures extracted with 25% ethanol. Effective therapeutic doses were found only in tinctures with a concentration ratio herb to liquid 1:1 (kg/L) and an alcoholic content of 70%. To guarantee quality and safety of herbal medicinal products, legal requirements to produce plant-based products under regulatory frameworks are needed.