Standardization of Polyherbal Formulation for use in the Management of Menopausal Symptoms

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Abstract

Menopause is an experience that is unique to each woman. Ovarian failure and the accompanying decline in estrogen production are responsible for the changes of menopause. Natural therapies using phytoestrogens are receiving increased attention as dietary components are beneficial in countering the manifestations of menopausal state. β-sitosterol is a phytoestrogen occurring widely in plants with many pharmacological activities and exhibits an estrogen-like effect and accentuates the effect of estradiol on Glucose 6 phosphate dehydrogenase, Phosphohexose isomerase and total lactate dehydrogenase activities. In the present work nine medicinally important plants are screened on the basis of β-sitosterol using HPTLC technique and selected for preparation of polyherbal combination. The developed method was subjected to method validation to determine its suitability for the intended use. The parameters that were validated include Linear Dynamic Range, accuracy and precision, System suitability. Out of the nine plants *Vitex negundo*, *Linum usitatissimum* and *Asteracantha longifolia* showed maximum amount of β-sitosterol. Further β-sitosterol enriched residue of three shortlisted plants was prepared in a polyherbal combination and evaluated for its safety. Estrogenic activity of the polyherbal combination was evaluated using the ovariectomized rat model. Parameters such as uterine weight, uterine histoarchitecture, estrogen and progesterone levels were evaluated. Palatable forms of polyherbal formulation like *vati* and *avaleha* were prepared and were subjected to stability studies using HPTLC technique.

Keywords: β - sitosterol, HPTLC, Polyherbal combination, Safety, Estrogenic