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Formulation and validation of analytical methods of ursolic acid in gel dosage form

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INTRODUCTION

Plantago major has been empirically used for wound healing. One of its chemical compounds, ursolic acid, exhibited wound healing activity on hyperglycemic rats.

OBJECTIVES

The aims of this study were to formulate ursolic acid (UA) isolated from *Plantago major* into gel dosage form and validate its analytical methods using TLC-densitometric method.

MATERIALS AND METHODS

Ursolic acid was isolated from methanol extract of *P. major* using vacuum and open column chromatography. The physical data, IR, ESI-MS, ^{1}H NMR, and ^{13}C NMR data of the isolated compound were then analyzed. Gel of UA was prepared using carbomer as gelling agent. Methods validation was carried out using TLC-densitometric methods on Silica Gel GF_{254} as stationary phase under influence of toluene-ethyl aetate:formic acid (8:2:0.1) as stationary phase.

RESULTS

The results showed that UA could be formulated into gel using carbomer. The preparation was able to maintain its pH and physical properties (visual appearance, specific gravity, viscosity, and flow properties) under accelerated stability test (40°C±2°C; 75%±5% RH) and room temperature (27±2°C/73±5% RH) during 45 days. Methods validation indicated that the method complied the validation parameters, i.e.: linearity (r=0.999), LOD and LOQ (4.55 and 15.17 ng/spot, respectively), recovery (92.86-118.01%), intraday as well as interday precision (CV=1.24-1.96% and 6.29%, respectively).

CONCLUSION

It can be concluded that UA in the gel preparation was stable under accelerated and room temperature stability test during 45 days and TLC-densitometric method can be applied to determine its chemical content in that dosage form.