

Design and development of a stable polyherbal formulation based on the results of compatibility studies

Shrinivas G. Bhope, Dheeraj H. Nagore, Vinod V. Kuber, Pankaj K. Gupta, Manohar J. Patil
Department of Research and Development, Tulip Lab Pvt. Ltd., Ranjangaon, Pune.

ABSTRACT

Introduction Ayurvedic and herbal medicinal products contain a combination of botanicals; each of these contains a number of chemical compounds that may give the anticipated activity in combination. Therefore, it is very important to analyze and evaluate the compatibility of various active constituents and markers from different medicinal plants for their possible chemical interactions with various excipients at different storage conditions during the development of a stable polyherbal formulation. **Objective** To study chemical stability of kalmegh (*Andrographis paniculata*) and kutki (*Picrorhiza kurroa*) extract for their active markers andrographolide, kutkoside and picroside-I and to develop stable polyherbal formulation based on the incompatibility studies. **Materials and Methods** The compatibility study was carried out on individual ethanolic extracts of these two plants along with the commonly used excipients in the ratio of 1:1 at 40 $\pm$ 2 degC and 75 $\pm$ 5% relative humidity and at a refrigeration temperature of 5 $\pm$ 1 degC for initial, 7-, 15- and 30-day intervals. The analysis was carried out using the validated reverse phase-high- performance liquid chromatography methods. A stable tablet dosage form was developed based on the results of these studies. **Result** The study suggested that the active markers of kutki (kutkoside and picroside-I) were found to be degraded in the presence of the kalmegh extract. However, the active marker of the kalmegh extract (andrographolide) was found to be stable. Both the extracts showed excellent compatibility with all the excipients used in making this formulation. No significant decrease in the kutkoside and picroside-I content from the formulation was observed. **Conclusion** By separate granulation process the exposure of both the extracts can be minimized thus avoiding the degradation of active markers.

KEYWORDS

Compatibility . andrographolide . kutkoside . picroside-I

REFERENCES