Abstract

Background

Present study is aimed to design, develop and evaluate polyherbal formulations for treatment of liver diseases, using some indigenous plants. The study includes preliminary investigation of plant extracts and screening for hepatoprotective activity, further formulation were prepared using extracts showing promising activity then evaluated.

Method

Three indigenous plants were selected i.e. Coccinia indica, Sida cordata and Scoparia dulcis. After authentication, plant parts were subjected for standardization according to WHO guideline followed by pharmacological screening of all the extracts to assess their potential in control of hepatotoxicity. CCl₄ induced liver toxicity model is used for hepatoprotective activity. Various biochemical parameter analysis and histopathological observations were conducted. Three tablet formulations were prepared by direct compression method using plant extracts, which have shown significant activity. Prepared Tablet formulations were subjected to physical, chemical and Pharmacological evaluation according to Pharmacopieal and WHO guideline. Finally prepared tablets were evaluated for stability testing to assess its shelf-life.

Results and Discussion

Result obtained from hepatoprotective activity screening indicate that Ethanol extract of Coccinia indica (CIEE); Aqueous extract of Sida cordata (SCAE) and Ethanol extract of Scoparia dulcis (SDEE); Petroleum ether extract of Coccinia indica (CIPE); Ethanol extract of Sida cordata (SCEE); Aqueous extract of Scoparia dulcis (SDAE) and Chloroform extract of Scoparia dulcis (SDCE) shown significant hepatoprotective activity. The extracts which were showing promising activity for hepatoprotective activity were selected for polyherbal tablet formulations. Polyherbal formulations are made to improve the efficacy of the extracts. The mixtures of extracts were assessed for their physical and chemical compatibility with each other and with excipients by HPTLC studies. Three polyherbal tablet formulation were developed. Formulation HF₁ was prepared by using the extracts showing maximum hepatoprotective activity. Formulation HF₂ was a combination of extracts showing moderate hepatoprotective activity. Formulation HF₃ was a combination of extracts of HF₁ & HF₂ both.

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Polyherbal tablets were prepared by direct compression method with specialized additives as per the requirements and physical nature of extracts in order to achieve acceptable tablets. Formulated tablets were evaluated for Pre-Compression Parameters like angle of repose, bulk density and compressibility index and post-compression parameters like color and shape of tablets, thickness and diameter, weight variation test, friability test, hardness test, disintegration time test, heavy metal analysis and microbial load tests.

Chemical evaluations of polyherbal tablet formulations (HF₁, HF₂ and HF₃) were carried out by using HPTLC Technique. The drug content study was carried by the estimation of β-sitosterol in the tablet formulation by HPTLC. Each extract has already been standardized to specific marker (β-sitosterol) by its estimation using HPTLC.

All the three formulation showed significant hepatoprotective activity and was significantly comparable with Liv-52. However the maximum hepatoprotective activity was found with formulation HF₃. The hepatoprotective activity was in the order of HF₃ > HF₁ > HF₂.

The polyherbal formulations also pass the stability testing. The formulation had pleasant appearance and acceptable odour, indicating that the formulation is stable at accelerated conditions. There was no significant change observed in the HPTLC finger print graph and drug content (β-sitosterol) of formulation (initial) and after accelerated stability studies. This showed that the phytoconstituents present in formulations (HF₁, HF₂ and HF₃) are stable in nature.

Conclusion

All three tablet formulations (HF₁, HF₂ and HF₃) comply with the standard of Indian Pharmacopeia and WHO guidelines. Formulations were found to be stable when subjected to accelerated stability studies at at 25°C/ 60% RH and 40°C/ 75% RH for a period of 30 days. There was no significant change in the physicochemical properties and their pharmacological activity.

The antioxidant potential of the formulation was responsible for its activity; as well as the formulations has enhanced antioxidant enzymes present in the liver tissue. Still more extensive studies can be envisaged to find the exact mechanism of action and phytochemical(s) responsible for its hepatoprotective effects.

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