CHAPTER 10

AYURVEDIC
RASASHASTRA & BHAISHAJYA KALPANA

Doctoral Theses

01. BHATTACHARJYA (Dr. Niladri)
Pharmaceutical Revalidation of Shwasakuthara Rasa and its Preclinical Safety and Phase I-II Dose Determination (Safety &Efficacy) Study.
Supervisor: Dr. Divya Kajaria
Th 28534

Abstract

Shwaskuthar Rasa (SKR), an ancient formulation of the herbomineral class, is clinically prescribed in different long-term doses. As quality and safety are major concerns, this study evaluates its preclinical safety and the safest and most effective dose for managing bronchial asthma (BA). Material & methods: SKR prepared as per AFI. HPTLC, Raman spectroscopy, FTIR, SEM-EDS, XRD, and ICP-AES were employed to ensure the quality. For preclinical safety, healthy Wistar rats were divided into six groups and treated with saline water (VC), SKR (TED, 5TED, 10 TED), HgCl2(NC-Hg), and Na2AsO2(NC=As) for 90 days with a recovery of 30. Open-level dose escalation with pre-post comparison in healthy volunteers was employed to determine maximum tolerable dose and dose-limiting toxicity. In phase II, diagnosed patients of BA were treated with four different doses (250mg (A), 375mg (B), 500mg (C), and 750mg/day(D)) of SKR for 6 weeks and the most suitable dose was determined. Result: The drug consists of irregular and flake-shaped particles (0.5–10 mm), a cocktail of inorganic (crystalline β-HgS, β-As4S4, and amorphous S) and organic substances (3.35 μg/mg, 6.72 μg/mg of piperine, and β-caryophyllene). In preclinical study, no trace of toxicity was found up to the 5TED. However, changes in biochemicals and anti-oxidants in 10 TED were recorded after 90 days which tend to reverse in recovery phase. In phase I, flatulence, heartburn, and constipation were self-reported in 1g/day dose, from the 10th -14th day of intervention. The phase II study recorded a significant improvement in PEF value, BODE index and ACQ in group B, C & D, indicating dose-dependent efficacy. Conclusion: SKR, a mixture of inorganic and organic phytochemicals, is safe for up to 10 TED in long-term use. Clinically, it is tolerable up to 1g/day, and increased frequency (TDS) in treatment can be a better control for BA.

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02. KAUSHIK (Dr. Shreshtha)

Safety and Biological Activities of Sanjivani Vati prepared with two different species of Vatsanabha.

Supervisor: Dr. Pramod Yadav

Th 28542

Abstract

Sanjivani Vati (SV) is a widely used Ayurvedic medicine, recommended for addressing various conditions like fever, indigestion, dysentery, etc. It comprises ten herbal ingredients including two Schedule E-1 drugs: Vatsanabha (Aconitum ferox Wall. Ex Ser.) and Bhallataka (Semecarpus anacardium Linn.) along with Cow's urine for Bhavana (impregnation). Vatsanabha, though highly toxic, has long been a potent therapeutic agent in Ayurveda after Shodhana (processing). Its identification is very challenging and it is subjected to extensive adulteration with less active species. Previous studies have documented significant qualitative and quantitative variations in total alkaloid content among Vatsanabha species. However, the effects of using different species on the quality and efficacy of formulations remain unexplored. Thus, the present study was planned to evaluate differences in safety and biological activities of SV prepared with two different species of Vatsanabha. So, SV was prepared with two different species of Vatsanabha viz. Aconitum nepellus L. (SVN: naturally sourced drug) and Aconitum balfourii Holmes ex Stapf. (SVB: market specimen). Variations have been observed in different activities (Antipyretic, Antioxidant, Antimicrobial) of SV from both the groups. Furthermore, no indications of toxicity were detected in the initial limit test, OECD 236 for both groups of SV. However, the LC50 value of SVB was found less than SVN. The concentration of aconitine was found as: 440.32ug & 16.90ug/ 100mg of Aconitum nepellus and Aconitum balfourii respectively in HPTLC. But, no aconitine was detected in any of the SV group, These findings suggest that both the tested species of aconite can be utilized for drug preparation if properly processed according to classical guidelines, though dosage caution is necessary. Naturally sourced drug should be generally preferred for their quality and potency, but this may not always hold true for different activities due to variations in the nature and quantity of constituent responsible for that desired activity. Further, validation across diverse models is recommended.

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