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In vitro and *in vivo* antitumor activity of bulbus *Fritillariae cirrhosae* and preliminary investigation of its mechanism

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Bulbus *Fritillariae cirrhosae* (BFC) is widely used in China both for food and folk medicine due to its powerful biological activities. Firstly, this study was designed to examine the anti-proliferative activities of the different fractions from BFC *in vitro* by MTT assay. The results showed that Chloroform Extracts (CE) and the purified Total Alkaloids of BFC (TAF) exhibited stronger anti-proliferative activity than the other fractions. We further determined the total alkaloids and three main alkaloids monomers content of CE and TAF by UV and HPLC-ELSD methods, respectively. Moreover, we assessed the antitumor activity of TAF *in vivo* and made preliminary investigation of its anti-tumor mechanism by histological and immuno-histochemical staining technique. These results demonstrate that TAF showed significant antitumor activity and low toxicity *in vivo*. Meanwhile, TAF significantly inhibited tumor angiogenesis and induced apoptosis by improvement of expression level of caspase-3. These results suggest that alkaloids of BFC could hold a good potential for use as an antitumor drug.

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Challenges & issues of quality assurance of botanicals for developing standardized herbal drugs for global positioning

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There has been an increasing realization that the green medicine is safer and this has led to the spurt in the use of plant based medicines across the world and in India too. The global herbal market is about US \$90 billion which is growing at the rate of 10-15% annually and is expected to cross US \$5 trillion by 2030. The traditional medicine in India functions through two streams, i.e., the folk stream and the classical organized stream that includes the Ayurveda, Unani, Siddha, etc. Thus, the use of medicinal plants amounts to around 8000 wild plants in these medicines. Although the global market of herbal drug is growing at a fast pace, the Indian share is only 2%. The major reason for this is the lack of proper quality, safety and efficacy of herbal drugs despite having in-depth knowledge in Ayurvedic medicinal system. There are opportunities in 21st century for developing countries like India with traditional knowledge base to develop globally acceptable newer Ayurvedic drugs/nutraceuticals and convert their rich bio-resources & associated traditional knowledge systems & for economic wealth & thereby bring prosperity to the nation. Indian herbal drug industries generally face the problem of adulteration & substitution. It is observed that in herbal markets of the country, sometimes not only the various species of particular genus but entirely different taxa are being sold under the same vernacular name. For example, in the name of 'Talispatra' an important Ayurvedic drug, different leaves of *Taxus wallichiana*, *Abies spectabilis* and *Rhododendran anthopogan* are being sold in Dehradun, Kolkatta & Amritsar markets, respectively. The lack of confidence in the quality of drug in traditional medicine is hindering us from capitalizing these systems at global level. It is well documented that the quantity and nature of secondary metabolites in medicinal plants is influenced by growth, season, edaphic and environmental factors. Therefore, there is a need to develop quality parameters of raw drugs, proper collection and processing along with HPTLC/HPLC finger printing to get desirable quality of raw material. Indian government has taken a number of initiatives including the preparation of the Ayurvedic Pharmacopoeia of India (AYUSH) and also preparation of monographs of individual plants in Quality Standards of Indian Medicinal Plants (ICMR). Such initiatives are mainly aimed at providing the quality parameters for standardization of herbal drugs. Further, under GTP, AYUSH, CSIR, ICMR are working together for validation of number of Ayurvedic formulations for global market. In the whole process, development of herbal drug/product based on traditional knowledge needs proper taxonomically identified safe raw material and scientific validation of the products. Further, get constant supply of right raw material whether procured from wild or cultivated and their storage one has to follow. Good Agriculture Practices (GAP), Good Collection Practices (GCP), Good Ethical Practices (GEP), Good Procurement Practices (GPP), Good Safety Practices (GSP) (Pesticide, heavy metal, microbial load as per WHO guidelines) and Good Storage Practices (GSP).

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