OMICS International
Pharmaceuticalconferences.com

Pharm Anal Acta 2015, 6:1
http://dx.doi.org/10.4172/2153-2435.S1.025

5th International Conference and Exhibition on

Pharmaceutics & Novel Drug Delivery Systems

March 16-18, 2015 Crowne Plaza, Dubai, UAE

Considerations in pre-formulation stage of solid and semi-solid dosage forms

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Solid and semi-solid dosage forms are the most widely marketed and administered drugs nowadays. Almost 70% of the administered drugs are in solid states. It is preferred by the pharmaceutical companies due to its high safety, low cost and marketing issues.

Pre-formulation is a stage of development during which the physicochemical properties of drug substance are characterized. Before the formulation of a drug substance into a dosage form, it is essential that to be chemically and physically characterized. Pre- formulation begins with calculation/prediction 'in silico' of many of the important physicochemical characteristics of the API. Literature search of similar type of compounds is the second step of pre-formulation process.

Pre-formulation influences on selection of the drug candidate itself, selection of formulation components, API & drug product manufacturing processes, determination of the most appropriate container closure system, development of analytical methods, assignment of API retest periods, the synthetic route of the API and toxicological strategy.

The most important function of pre-formulation stage is solid state characterization which determines the next step in the formulation work of the studied API. Physical properties of the studied API influence on its physical and chemical stability. It influences on the rout of administration, delivery system and the drug activity. Moreover, Chemical stability of the drug is affected by the physical properties. Crystal morphology, polymorphism, amorphous forms and hygroscopicity are usually studied. In addition, solubility, salt form, melting point, dissolution of the API are also studied.

Certain properties are studied in pre-formulation stage of the solid dosage forms. These properties relate mainly to the ability of the powder to flow in the compressing machine and subsequently its compressibility. They influence on the dissolution rate of the API, stability, bioavlaibility, degradation rate and purity. The studied properties include particle size, its distribution, its surface area and porosity. It includes also true density, flowability, API color, electrostaticity, caking and polymorphism.

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In vitro cytotoxicity and free radical scavenging activity of ethanolic and alkaloidic extracts of *Delphinium Staphisagria*

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In this study, the *in vitro* cytotoxicity and antioxidant properties of the ethanolic and alkaloidic extract of *Delphinium staphisagria* seeds were assessed. The antioxidant activity of the plant extracts and the standard was assessed on the basis of the radical scavenging effect of the stable 1, 1-diphenyl-2-picrylhydrazyl (DPPH)-free radical activity. The *in vitro* cytotoxicity was carried out by using the 3-(4,5-dimethylthiazol- 2-yl)-2,5-diphenyl tetrazolium bromide (MTT) assay, against two animals cancer cell lines; Vero cell line, initiated from the kidney of a normal, adult African green Monkey and Neuro-2a (N2a) from a spontaneous tumor of a strain A albino mouse. The DPPH scavenging activity of both extracts was concentration-dependent (increasing from 15.62 µg/ml to 500 µg/ml), exhibited considerably ($P<0.05$) DPPH radical-scavenging activity and was able to inhibit the formation of DPPH radicals with a percentage inhibition of 62.19 and 94 % respectively at the highest concentration. The results showed that the alkaloidic extract (1000-31.25 µg/ml) of *Delphinium Staphisagria* possesses significant IC50 compared to the drug positive control on all cancer cell lines used.The lower IC50 represent the highest potency of a compound to inhibit the growth of cells and cause toxicity and death of cells. The result obtained in this work demonstrated a high activity at low alkaloids extracts doses (500µg/ml).In conclusion, the results of the present study suggest that *Delphinium staphisagria* seeds plant have various secondary metabolites and has good quantity of alkaloidic compounds (diterpenoid alkaloids). Plant has potent free radical scavenging activity. Detailed studies on chemical composition, isolation of active constituents and pharmacological evaluation are essential to characterize them as biological antioxidants. The present findings of this study support the view that *Delphinium staphisagria* seeds are a promising source of potential antioxidant which can be used in treatment of various ailments.

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