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To determine better drug delivery approaches: Pre-formulation and formulation studies of natural products analogues

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Nowadays, natural products based analogues are valuable and shows potent pharmacological activity but does not give expected drug delivery. The objective of this abstract is to perform some of the important pre-formulation and formulation studies of New Chemical Entities (NCEs) to achieve the routes of enhancement. Prior to this, any screened NCEs will take part in clinical trial. It is mandatory to pass from physiochemical characterization and *in-vivo / in-vitro* stability profile of NCEs further to enter into drug delivery phase during intense preclinical studies. These are basic evaluation for physiochemical characterization such as aqueous stability, biorelevant media/solvent/pH solubility, degradation profile, partition coefficient, ionization constant, LogP/D, pKa, solid state characterization, polymorphism, thermal transformation, drug-excipient compatibility studies. In the next stage, development of analytical / bioanalytical methods, selection of compatible internal reference standard with NCEs at similar wavelength, formulation of dose for animal studies, bioavailability / toxicity/ metabolic studies and also comparison with authentic *in-silico* softwares are carried out which give some clues to get promising NCEs which may improve drug delivery approaches. It will help to provide regulatory relief and implementation in the drug delivery development and improve public safety standards.

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Pharmaceutical scale up for solid dosage forms

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Scale-up is defined as the process of increasing batch size. Scale-up of a process is viewed as a procedure for applying the same process to different output volumes. There is a subtle difference between these two definitions: batch size enlargement does not always translate into a size increase of the processing volume. In mixing applications, scale-up is indeed concerned with increasing the linear dimensions from the laboratory to the plant size. On the other hand, processes exist (e.g., tableting) where the term 'scale-up' simply means enlarging the output by increasing the speed. To complete the picture, one should point out special procedures where an increase of the scale is counter-productive and 'scale-down' is required to improve the quality of the product. In moving from Research & Development (R&D) to production scale, it is sometimes essential to have an intermediate batch scale. This is achieved at the so-called pilot scale, which is defined as the manufacturing of drug product by a procedure fully representative of and simulating that used for full manufacturing scale. This scale also makes it possible to produce enough products for clinical testing and to manufacture samples for marketing. However, inserting an intermediate step between R&D and production scales does not, in itself, guarantee a smooth transition. A well-defined process may generate a perfect product both in the laboratory and the pilot plant and then fail quality assurance tests in production.

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