17. PARTICULARITIES OF VALIDATION HPLC METHOD DOSING

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Introduction: Chromatographic methods are commonly used for the quantitative and qualitative analysis of raw materials, drug substances, drug products and compounds in biological fluids.Validation of a method is the process by which a method is tested by the developer or user for reliability, accuracy and preciseness of its intended purpose.

Materials and methods: Advanced bibliographic study.

Results: Though many types of HPLC techniques are available; the most commonly submitted method, the reversed-phase HPLC with UV detection, is selected to illustrate the parameters for validation.A. Accuracy is the measure of how close the experimental value is to the true value. Accuracy studies for drug substance and drug product are recommended to be performed at 80-100 and 120% levels of label claim as stated in the Guideline for Submitting Samples and Analytical Data for Methods Validation. B. Limit of Detection and Limit of Quantitation specifications are submitted with the regulatory impurities method relating to release and stability of both drug substance and drug product. C. Linearity range of detectability that obeys Beer's Law is dependent on the compound analyzed and detector used. D. Precision is the measure, that expresses the closeness of data values between a series of measurements obtained under unchanged analytical conditions. E. Range is the interval between the upper and lower levels of analyte studied. F. Recovery is defined as the observed result obtained from an amount of the analyts compared to the expected result obtained from theoretical amount and expressed as a percentage. G. Robustness is defined by ICH as a measure of the method's capability to remain unaffected by small, but deliberate variations in method parameters. H. Sample Solution Stability of the drug substance or drug product after preparation according to the test method should be evaluated according to the test method.I. Specificity/selectivity: the analyte should have no interference from other extraneous components and be well resolved from them. J. System Suitability Specifications and Tests are parameters that provide assistance in achieving this purpose.

These parameters will be used to validate the method of assay of cinnamic acid from Tolu Balm in tablets.

Conclusions: The variations due to the drug product manufacturing process, the laboratory sample preparation procedure and the performance instrument contribute to the accuracy of the data obtained from the analysis. Only with good reliable validated methods, data, generated for release, stability, and pharmacokinetics, can be trust-worthy.

Keywords: HPLC, accuracy, detection limit, linearity, precision,range, recovery, robustness, stability, specificity

18. EVALUATION OF ACUTE TOXICITY OF POLYPHENOLS AND POLYSACCHARIDES EXTRACTS FROM *CENTAUREA CYANUS* L.

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Introduction: *Centaurea cyanus L.* is one of the species of *Asteraceae* family. It is an annual plant, growing as a weed in the fields. It is also used as ornamental plant due to its intense blue flowers. Cornflower has a long history of herbal use. The officinal vegetal product is *Cyani flores.* Externally it is used as anti-inflammatory and astringent for eye ailments and skin cleansing.The dried flowers have antipruritic, antitussive, weakly diuretic, emmenagogue, ophtalmic, very mildy