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## Determination of doxycycline in human plasma by liquid chromatography tandem mass spectrometry

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A simple, rapid, specific and sensitive liquid chromatography tandem mass spectrometric method has been developed and validated for the estimation of Doxycycline from  $150\mu$ L of human plasma. Doxycycline is extracted from human plasma by Solid Phase Extraction. Demiclocycline was used as an internal standard. Detection was performed using TSQ Quantum Discovery max mass spectrometer. Chromatographic separation of analytes and internal standard were carried out using a reverse phase C18, column at  $500\mu$ L flow. The assay of Doxycycline is linear over the range of  $0.055\mu$ g/mL to  $7.612\mu$ g/mL with a precision <14.83% and the limit of quantification in plasma for Doxycycline was  $0.055\mu$ g/mL. Mean extraction recovery obtained was 95.55%. Samples are stable at room temperature for 6 hrs, processed samples were stable at least for 30.20 hrs and also stable at three freeze–thaw cycles. The method has been used to perform pharmacokinetic and bioequivalence studies in humans.

## Enhancement of bioavailability of fenofibrate with alpha tocopherol and phospholipids: An approach to optimize formulations with taguchi design

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The purpose of this study was to investigate the effect of different solubilizers namely alpha tocopherol, soy phosphatidylcholine 70, Phospholipon 80H, and Phospholipon 90H on the bioavailability of sustained release fenofibrate pellets using fluid bed coating by applying Taguchi design. Runs with alpha tocopherol 1% and Phospholipon 90H 2% showed significant differences in in vitro dissolution and partition behavior of drug. The pharmacokinetics of reference and test was evaluated in healthy male Wistar rats and found that t1/2 was reduced significantly while  $AUC_{0-t_i}C_{max}$  were improved markedly compared to the pure drug. The extent of the mean plasma exposure of fenofibrate was 2.7 and 3.1 fold higher in animals treated with test. The ANOVA results revealed that type and concentration of solubilizer are crucial for enhancement of in vitro dissolution profile. Hence use of solubilizers may be the promising way to improve the oral bioavailability of fenofibrate.

## **Bio-analytical method validation requirements – regulatory prospective**

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A nalytical methods employed for the quantitative determination of drugs and their metabolites in biological samples must generate reproducible and reliable data in order to permit valid interpretation of the studies they support. The quality of studies is directly related to the quality of the underlying bioanalytical data. It is therefore important establishment of validation of these analytical methods. Validation of bioanalytical methods include all of the procedures that demonstrate that a particular method used for measurement of analyte is selective, sensitive, reliable and reproducible for the intended use. A strategy is discussed in this manuscript for the validation of bioanalytical methods that are developed for the quantification of drugs in biological matrix. It also include all the applicable regulatory specified validation parameters. The information described in this manuscript applicable to all types of analytical methods. This article provides complete, relevant updated information in the field of analytical method validation.