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Common Stability Indicating Chromatographic Methods in Shelf Life Prediction of Pharmaceutical Preparations

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Shelf life determination of different dosage forms of a drug substance should be performed prior to manufacturing as well as the final preparation to ensure the producer and also the consumer about the quality and the stability of the medicinal product before reaching the expiration date.

According to ICH guidelines (ICH Topic Q1E) the shelf life determination needs real time data and no extrapolation is permitted. For example a drug product that is labeled to be stored at room temperature should be preserved at 25 ± 2 °C and 60 ± 5% RH (Long term studies) and the mean percentage of the remaining drug at predetermined time intervals (every 3 months for first year) should be reported in initial drug product submission and will be completed and sent over the specified expiration date to regulation authorities. The rule indicates that the time at which the line for the 95% lower one sided confidence interval of the mean intersects the lower acceptance criteria of a special drug product according to pharmacopeial monograph is to be determined as the shelf life [1]. Accordingly Arrhenius method is no longer accepted in ICH because an extrapolation to room temperature is needed to report the shelf life.

There is another ICH approach based on the quantification of the degradation product of a certain drug substance within a drug product [1]. The main prerequisite for this is the complete qualification of the degradation product and the presence or introduction of a stability indicating analytic method to distinguish between the drug compound and its degradation product [2]. In order to establish a stability indicating method, liquid and solid samples of drug substance is exposed to stress conditions such as high temperature and high humidity and or extremes of pH as well as mechanical stresses [3-6]. The proposed analytical method should be able to present the pure drug response as well as some degradation products.

Among different analytical methods special attention is given to chromatographic methods due to their ease of application and high accuracy and precision [7-18].

Different chromatographic methods can be applied in order to evaluate the stability of a drug substance within a drug product. If a drug has different dosage forms such as tablet, oral solution and or transdermal delivery systems, the stability of the drug product in each dosage form should be established individually. Usually a same analytical method linked to special extraction techniques can be applied to different drug dosage forms [19,20]. High pressure Liquid Chromatography is a beneficent analytical tool in this area.

Thin Layer Chromatography (TLC) is a simple and high output technique to follow the drug molecule and its known degradation products [21-23]. Unfortunately the only way to gain quantitative data through common TLC is to scratch the absorbent layer on the plate and subsequent analysis which is not accurate and precise and is also applied to reach preparative goals [24-27]. High pressure Thin Layer Chromatography (HPTLC) is a modern technique based on common TLC and provides reliable quantitative data [28,29]. The unique performance of HPTLC is related to its specific solvent running system as well as efficient detectors such as Photo Diode Array (PDA) and Florescent with full scanning option [29,30]. In shelf life prediction of a new drug product, stability indicating chromatographic methods such as HPTLC and HPLC can be applied successfully.

The most time consuming step in HPLC is the method set up procedure especially in stability indicating ones. It should be noted that HPTLC is a low cost and more convenient method compared to HPLC and can be utilized in order to provide as useful data as HPLC [29,31]. The reason is based on the low solvent volume and almost cheap stationary phases compared to HPLC. Any spot in HPTLC can be detected via PDA or florescent detector qualitatively and quantitatively. If the stationary and mobile phases in HPTLC are being selected as similar as to HPLC the successful HPTLC method can be considered as a fundamental method to initialize HPLC method as well.

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