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Analytical characterization of cyclodextrins: history, official methods and recommended new techniques

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Abstract

The main goal of this review is to provide a comprehensive overview on the methods used for analysis of cyclodextrins (CDs) and CD-derivatives. The paper intends to act as a guide for the readers in looking around the classical and modern instrumental analytical methods suitable for identification, characterization and determination of CDs themselves, CDs in finished products or even in biological samples.

At present, in the European and United States Pharmacopoeias, the three parent CDs and two synthetic derivatives, namely the (2-hydroxypropyl)-beta-CD and sulfobutylether-beta-CD Na salt are official. Besides these modified CDs, two other derivatives are approved as excipients in human pharmaceutical products: the (2-hydroxypropyl)-gamma-CD and the randomly methylated-beta-CD.

Although most of the official analysis methods in the pharmacopoeias have been well used for decades, new aspects of the functional excipient CD characterization suggest a need to revisit compendial methods.

Comparison of strengths and weaknesses of current official methods with new improved techniques intends to help analysts to decide on changing traditional analytical methods with improved new ones. This review also deals with the analytical aspects of the first single isomer CD derivative approved as a drug active (Sugammadex/Bridion®) as well as analytical considerations of using CDs themselves as active pharmaceutical ingredients.

Stability-indicating instrumental methods suitable to adequately follow chemical- and enzymatic degradation of CDs will also be discussed. Challenges in the determination of CDs in different biological matrices will be illustrated on real pharmaco- and toxicokinetic studies of CD-enabled drug formulations.

Keywords

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