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Influence of Dissolution Media Composition on Cefaclor Release from Capsules

A. SPASIĆ, I. HOMŠEK

R&D Institute, Galenika a.d., Batajnički drum b.b., 11080 Belgrade, Serbia
E-mail: sandraspasic80@yahoo.com (A. Spasic)


In vitro dissolution testing serves as an important tool for drug manufacturing process control and quality assurance. In certain cases it can serve also as an indicator of how the formulation will perform in vivo [1].

Cefaclor, cephalosporin antibacterial drug, was chosen as a model drug, classified in BCS class II (high soluble and low permeable) [2]. It is effective against many different bacterial organisms such as Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, E. coli, and many others [3].

The aim of this study was to investigate the impact of experimental conditions on drug release from capsules having the same composition, but containing 250 mg (product A) and 500 mg (product B) of cefaclor. Solubility, the drug intrinsic dissolution rate and in vitro drug release tests were performed in water as well as in three EP buffer media: pH 1.2, pH 4.5 and pH 6.8.

It has been shown that the solubility of cefaclor was two times lower comparing to that observed in other tested media. The drug intrinsic dissolution decreased in the following order: pH 1.2>pH 6.8>water>pH 4.5. The dissolution media composition strongly, and to variable extent, influence cefaclor release from the investigated drug products. At pH 1.2 the drug dissolution was very fast with more than 85% of cefaclor dissolved within 15 and 30 minutes for product A and B, respectively. In the case of EP pH 4.5 buffer medium, the drug dissolution was notably slower and, consequently, more than 75% of the drug dissolution was accomplished after 60 minutes. The employment of EP pH 6.8 buffer medium resulted in slow and incomplete drug release. The differences between the release profiles obtained for the investigated drug products A and B in each tested dissolution medium were found to be statistically insignificant. In addition to the drug characteristics, it is evident that the formulation factors strongly affected cefaclor dissolution rate and must be taken into account in selecting a test method that will be sensitive enough to reflect its bioavailability.

