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STUDY OF PH-DEPENDENT DRUGS SOLUBILITY IN WATER*

Abstract

The solubilities of five sparingly soluble drug-compounds in water were measured at constant temperatures (298.2 and 310.2 K) by the classical saturation shake-flask method. All substances presented in this work are derivatives of anthranilic acid: flufenamic acid (FLU), mefenamic acid (MEF) niflumic acid (NIF), diclofenac sodium (DIC) and meclofenamic sodium (MEC). All of them have anti-inflammatory action. Since the aqueous solubility of the ionized drug is significantly higher than the unionized, the experimental conditions that affect equilibrium solubility values such as composition of aqueous buffer were examined. The Henderson-Hasselbalch (HH) relationship was used to predict the pH-dependent solubility profiles of chosen drugs at two temperatures. For this purpose the pK_a values of the investigated drugs were determined using the Bates-Schwarzenbach spectrophotometric method at a temperature of 310.2 K. At temperature of 298.2 K these values were reported previously. Similar values of pK_a were obtained from the solubility measurements.

Keywords: derivatives of anthranilic acid, pH-solubility profile, pKa; shake flask method, Henderson-Hasselbalch approach.

The solubility of a drug is defined as the maximum quantity of a drug dissolved in a given volume of a solvent at chosen temperature, pressure and pH. For ionizable drugs, the solubility can be affected by the pH of the solution, and the intrinsic solubility (S_0) is defined as the concentration of a saturated solution of the neutral form of the drug, in equilibrium with its solid at constant temperature and pressure.

Nowadays, drug design approaches based on a combination of chemistry and quantitative structure--activity relationship led to new active substances that are less water soluble and more lipophilic. Not very lipophilic drugs reveal lower solubility in water and have trouble crossing membranes. The acidic group of a drug molecule becomes negatively charged by losing a hydrogen ion at pH < 7. Research in pharmaceutical chemistry has devoted little attention to the physicochemical properties of the chemical leads and has focused mainly on optimization of the *in vitro* activity [1-3]. The rate at which a drug goes into the solution when it is dissolved in an acidic or a basic medium is proportional to the solubility of the drug. Many drugs have different solubilities at different pHs. These pH-dependent solubility differences lead to pH--dependent dissolution profiles. The solubility-pH profile of drugs or amines has already been reported by many authors [4–13].

The Henderson-Hasselbalch (HH) equation [14] has been used many times for the mathematical description of the solubility-pH profile of drugs or amines existing in the solution as a monomer [4,6,7].

Aqueous solubility has an essential role in the bioavailability of oral drug formulations. There is an established classification, namely, the biopharmaceutical classification system (BCS), which divides drugs into four classes in terms of their solubility and permeability [15]. The BCS classification correlates the *in vitro* solubility and permeability to the *in vivo* bioavailability.

In recent years, the problem of drug solubility in water has become more acute and more common as pharmaceutical companies have improved drugs for certain therapeutic areas [16]. The accuracy of many

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