CYCLODEXTRIN NEWS

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Piroxicam/Cyclodextrin: 25 years on the market

A recent review of C. Scarpignato with 201 references gives an overview on this nonsteroidal anti-inflammatory drug (NSAID) covering the details on the development, pharmacokinetic properties and efficacy of the cyclodextrin formulation [1].

One of the possible ways to develop NSAIDs with better gastrointestinal (GI) tolerability is to complex these molecules with cyclodextrins (CDs). Complexation of NSAIDs, such as Piroxicam, with βCD potentially leads to a more rapid onset of action after oral administration and improved GI tolerability because of minimization of the drug gastric effects.

Piroxicam/βCD has been used for 25 years. During this period plenty of knowledge has been collected on the properties and application. In the Cyclodextrin News Database there are approx. 250 entries on Piroxicam complexation including about 20 patents.

In the early studies the 2:1 stoichiometry has been proved by X-ray diffractometry and molecular dynamics calculations (Fig. 1) [2]. Based on these results the molar ratio of 2.5:1 has been applied in the commercial products [3]. A technology using supercritical carbon dioxide has also been developed to avoid the use of organic solvents [4]. To improve the patients compliance and reduce the GI irritation, effervescent tablets and sachet formulations were worked out and marketed under various trade names such as Brexin®, Cycladol®, and Flamexin®. A recent paper reported on the development of taste masked orally disintegrating tablet of Piroxicam formulated with βCD [5].

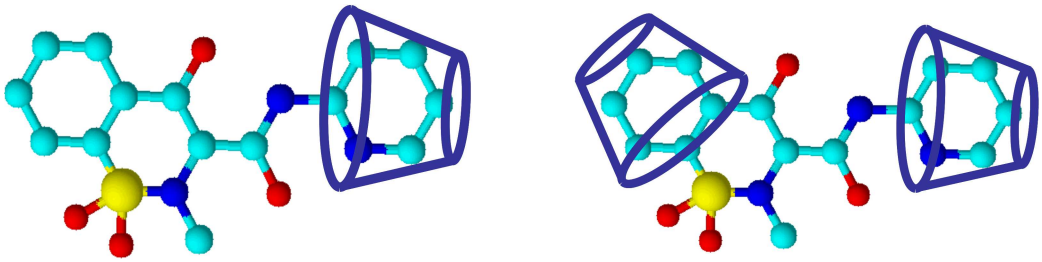

Fig. 1 Scheme of Piroxicam/βCD complexes (1:1 and 1:2 guest:host ratio)

The analgesic and anti-inflammatory efficiency of the complex was at least as high as that of the pure drug in rats [6]. Pronounced and marked gastric ulceration with complete loss of the mucosa, extensive deposition of fibrin and dense neutrophilic infiltrate were observed in rats treated with Piroxicam alone while no damaged tissues were found in rats treated with the complex [7].

Randomized crossover single- and multiple-dose studies of Piroxicam/βCD in healthy volunteers have confirmed the expected more rapid absorption of this formulation, compared with uncomplexed Piroxicam without significantly changing the other pharmacokinetic parameters [8].

When Piroxicam/βCD was administered after food a slower unset of action was observed as usual in case of oxicams: the mean t_{max} occurred between 4.3 to 4.6 h, compared to 1.4 h in the fasting state [9]. Plasma levels of Piroxicam, however, were higher than those measured after postprandial administration of the free drug.

The bioavailability depends on the age as well: the mean plasma concentration of free Piroxicam at the steady-state was significantly higher in elderly subjects (9.30±0.69 μg/ml) than in younger adults (6.24±0.58 μg/ml), a behavior similar to that of the uncomplexed drug [10]. Both steady state plasma levels and areas under concentration-time curve (AUC) correlated significantly with age, suggesting dose reduction in the elderly [1].

The fast onset and enhanced duration of action were proved in patients with dysmenorrhea [11], postoperative [12] and dental pain [13], headache [14], back pain [15], degenerative or inflammatory knee diseases [16], etc. The efficiency in pain relief was usually similar to that of the free Piroxicam but better tolerated in the upper GI tract.

A detailed analysis of nearly 100 published and unpublished studies of Piroxicam/βCD documenting the incidence of minor and major GI adverse events in a total of 29,190 patients showed that the incidence of minor GI events was lower for the complex (0.07-1.37%) than for Piroxicam alone (0-6.4%) or placebo (0.11-3.21%) or the other reference agents (0.1-3.45%), while hardly any major events were recorded during chronic treatment with the complex [1].

Scarpignato concludes that "after 25 years of use in Europe and South America, also Piroxicam/βCD - like Piroxicam - has stood the test of time and, on the grounds of its efficacy and safety, should be considered as a useful addition to our therapeutic armamentarium" [1].

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CRYSMEB, meloxicam, aceclofenac

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HPBCD, perfusion, intraperitoneal injection, cell surface binding, neurodegeneration

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elicitation, trans-resveratrol

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