DEVELOPMENT OF CAPSULE DOSAGE FORMS WITH LOW DRUG CONCENTRATION FOR HOSPITAL USE

*Tombolato F., Cazzoli G., Realdon N. and Dal Zotto M.
University of Padua, Dept. Pharmaceutical and Pharmacological sciences, Via Marzolo 5 - 35131 Padova (Italy)
* federico.tombolato@gmail.com

Purpose:
Capsules and suspensions are widely used dosage forms to obtain extemporaneous preparations in hospital pharmacy.
Their stability is not risk free and the pharmacist is responsible for their quality assurance. The aim of the present study is to evaluate different manufacturing methods to develop extemporaneous preparations containing low dosages of active ingredients of interest for pediatric therapy, focusing the interest on captopril, metoprolol tartrate, ketoconazole and metoxalene.
Methods:
The capsules were manufactured by three different methods commonly used in the hospital pharmacy, named in the study *"volume method"*, *"weight method"* and *"double method"*.
The formulations were developed from industrial dosage forms for captopril and metoprolol tartrate and from API for ketoconazole and metoxalene.
All the batches were tested according to Ph. Eur 8th ed./FUI XII ed.
The content uniformity was evaluated by HPLC analytical methods.
Results:
Regardless the preparative methods, all the capsules batches passed Ph. Eur 8th ed./FUI XII ed. tests, and the *"weight method"* showed lower relative standard deviations, although metoxalene produced technological problems due to its physical characteristics.
Conclusions:
It has been demonstrated that all the three experimented manufacturing methods can be used to obtain extemporaneous dosage forms, assuring both content and mass uniformity.