

STABILITY OF AMIODARONE IN CAPSULES FOR PAEDIATRIC PATIENTS USING A HPLC METHOD



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AIM OF THE STUDY

Evaluation of the stability of amiodarone at different dosages (10, 60 and 100 mg) in capsules for paediatric use stored in three primary packaging at ambient temperature and under dark conditions as per International Conference of Harmonization (ICH) guidelines.

MATERIALS AND METHODS

➤ Three dosages : 10, 60 and 100 mg

➤ Excipient : mannitol

➤ Three primary packaging : plastic cup, blister and pillbox

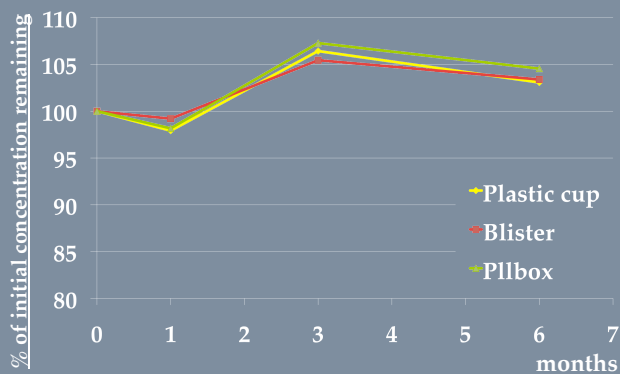
➤ For each dosage and for each primary packaging, three samples were analysed by HPLC on day 0 and at months 1, 3, 6 according to ICH recommendations.

➤ HPLC method adapted from an analytical method of Martin-Algarra *et al.*^[1] was validated according ICH guidelines before use. European pharmacopoeia High-Performance Liquid Chromatography (HPLC) method was not performed because of worldwide shortage of acetonitrile at the beginning of the study.

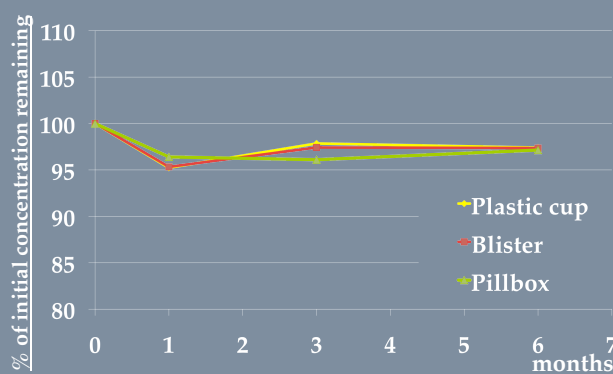
➤ The physical stability of amiodarone chlorhydrate capsules was assessed by visual inspection (capsule and powder) at each analysis time.

RESULTS

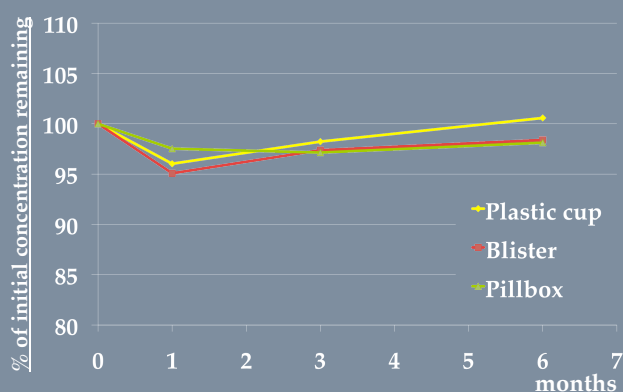
Stability of amiodarone chlorhydrate 10 mg capsules



Stability of amiodarone chlorhydrate 60 mg capsules



Stability of amiodarone chlorhydrate 100 mg capsules



⇒ The initial concentration of the drug was designated as 100%.

⇒ All subsequent concentrations were expressed as percentage of initial concentration.

⇒ Stability was defined by concentrations > 95% of initial ones.

⇒ No detectable degradation product was observed at any time.

DISCUSSION-CONCLUSION

The 10, 60 and 100 mg amiodarone paediatric capsules were stable for six months when stored in the three packages at ambient temperature and under dark conditions. There was no influence of primary packaging. This stability study will be extended during two years.

BIBLIOGRAPHIC REFERENCE

[1] Martin-Algarra RV, Pascual-Costa RM, Merino M, Casabo VG. Intestinal absorption kinetics of amiodarone in rat small intestine. *Biopharmaceutics and drug disposition*. 1997;18(6):523-32