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THE PHYSICAL STABILITY OF INJECTABLE DRUGS MUST BE PROVED TO ENSURE PATIENT'S SAFETY

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Background

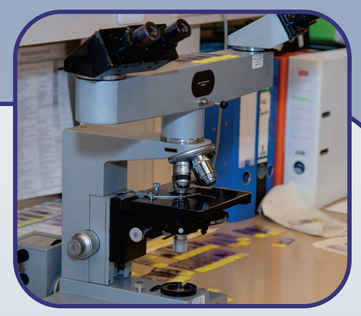
The physical stability of injectable drugs must be proved to ensure patient's safety.

Objectives

To investigate the physical stability of amiodarone hydrochloride 600 mg in 24 ml of 5% glucose solution stored at room temperature

Material and methods

- Five polypropylene syringes of 600 mg of amiodarone hydrochloridee were prepared under aseptic conditions and stored at room temperature during 48 hours.
- Immediately after the preparation (hour 0) and after hours 1, 4, 8, 24 and 48 of storage, 2 ml of solution were withdrawn from each synringe and placed in glass tubes.
- Then, each solution was visually inspected in front of a black and of a white background and a centrifuged aliquot was examined microscopically.
- The PH of each solution was measured with glass electrode PH-meter (Inolab level 1, WTW Weilhem, Germany with biotrode electrode, Hamilton, Bonaduz, Switzerland) and spectrophotometric measurements (Genesys 10 series, New-York, USA) were performed at three wavelenghts : 350, 410 and 550 nm.



Results

- There was no color change, no turbidity or opacity and no precipitation observed in the solutions during the storage at room temperature for 48 hours.
- No microaggregate was observed microscopically or revealed by a change of absorbance. There was no significant change in pH during storage.

Conclusion

- According to this study, amiodarone hydrochloride in 5% glucose polypropylene syringes is physically stable at room temperature for 48 hours.
- These results allow us to consider a study of chemical stability by high-performance liquid chromatography (HPLC).

Possible conflict of interest : nothing to disclose.

Reference
Maqueda-Palau M & al. Physical compatibility of amiodarone in continuous infusion. Enferm Clin. 2011 ; 21(1) : 25-29