High Performance Liquid Chromatography assay of amiodarone capsules

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BACKGROUND

Since amiodarone is used in paediatric patients, it has been widely dispensed as capsules prepared in the pharmacy department. A stability study of these capsules was performed to determine their expiry date. But, European pharmacopoeia High Performance Liquid Chromatography (HPLC) method was not performed because of worldwide shortage of acetonitrile at the beginning of our stability study.

PURPOSE

The objective was to develop a HPLC assay of amiodarone capsules without using acetonitrile.

MATERIAL AND METHOD

1. Chromatographic conditions

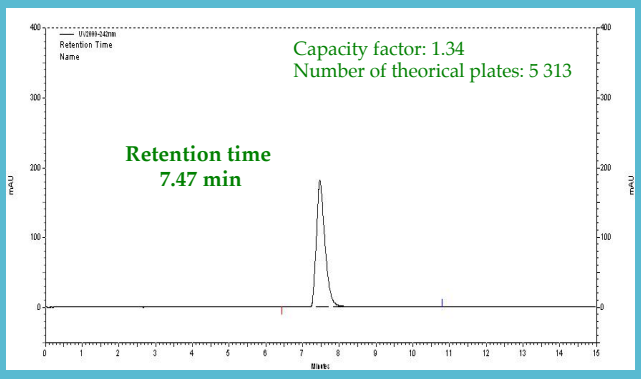
- Chromatographic system:
  Spectra-Physics Analytical HPLC chain
- Column: C18 (120Ä, 250 mm x 4.6 mm, 5 µm)
- Mobile phase:
  0.01 M phosphate buffer pH 2.30 (17%) + methanol (83%)
- Flow rate: 1 mL/minute
- Sample injection volume: 20 µL
- Analysis time: 15 minutes

2. Validation study according to ICH

- Chromatographic parameters measures
- Specificity
  Interference from mannitol (excipient)
- Linearity
- Precision
  Repeatability and intermediate precision
- Accuracy

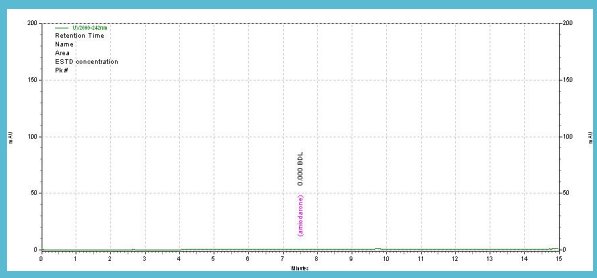
RESULTS

1. Chromatographic parameters



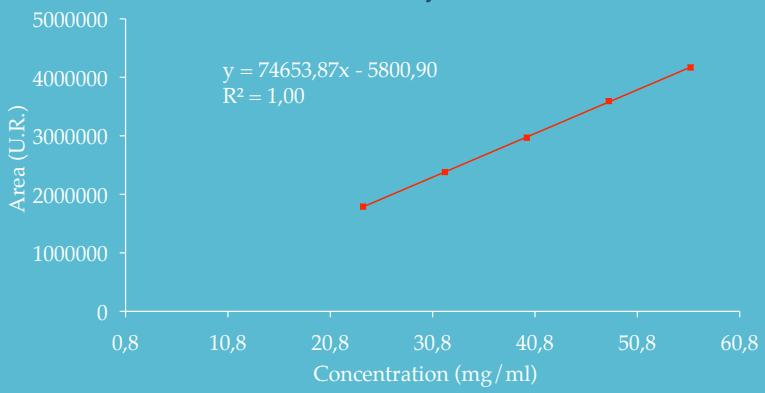
The tailing factor didn't exceed 1.5.

2. Specificity



No interference from mannitol could be observed at 242 nm.

3. Linearity



4. Precision

	Relative Standard Deviation
Repeatability	<2%
Intermediate precision	<2%

5. Accuracy

100% value was in the confidence limits.

DISCUSSION – CONCLUSION

The method developed in this study has the advantage of being simple, precise, accurate and convenient. This method is applicable for qualitative and quantitative amiodarone capsules. The results are accurate and precise and confirmed by statistical parameters.

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