



LIQUID CHROMATOGRAPY MASS SPECTROMETRY ANALYSIS OF DOXORUBICIN AND EPIRUBICIN AFTER FREEZING

V. Garau¹, M. Crobeddu², G.A. Carrucciu¹, P. Serra¹, P. Caboni²

A. Businco Oncology Hospital, Hospital Pharmacy, Cagliari, Italy¹, University of Cagliari, Italy².

L01- ANTINEOPLASTIC AGENTS

BACKGROUND

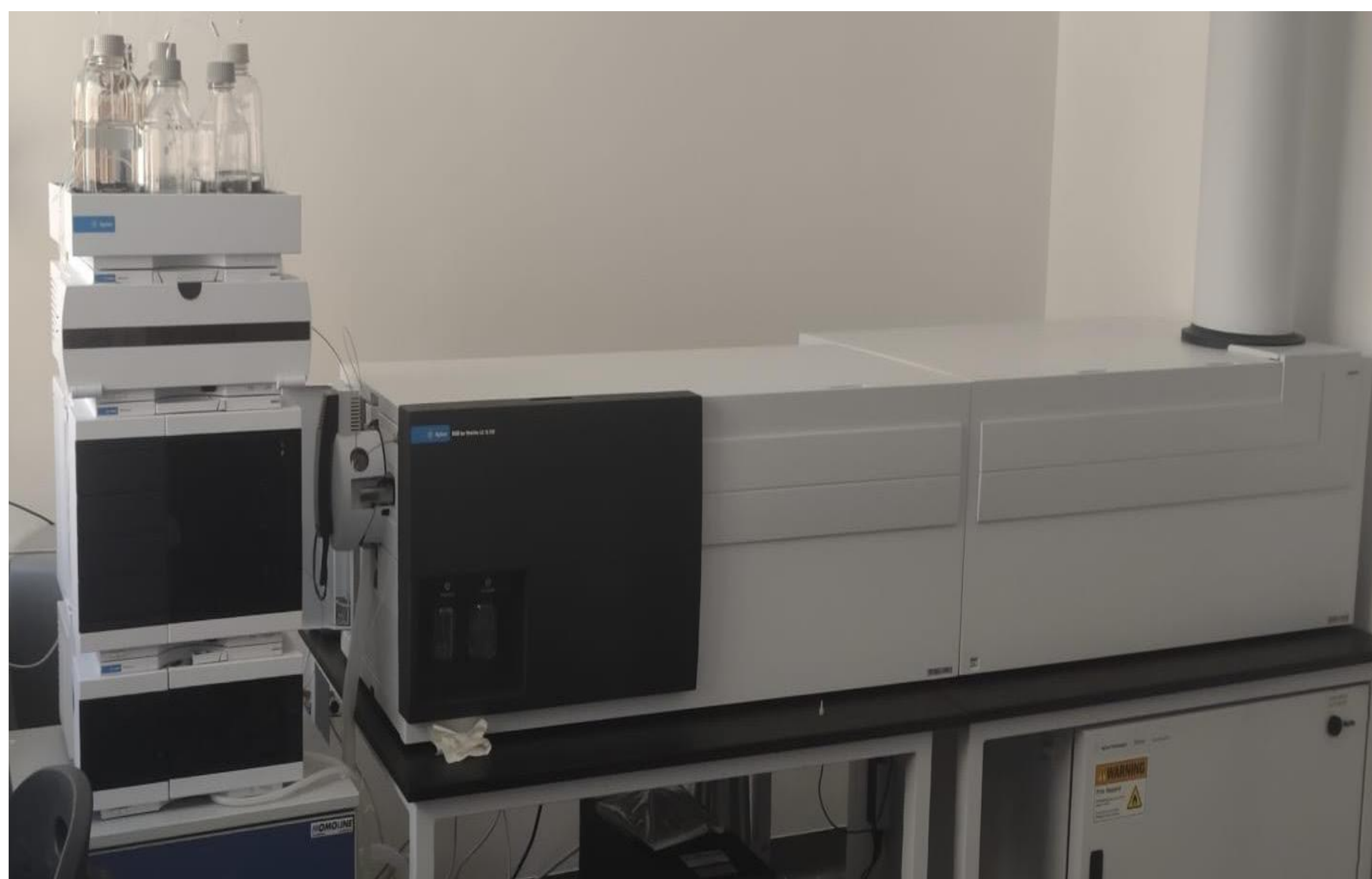
The chemical-physical stability, reported among the technical characteristics of the drugs, indicates the parameters to be respected for the safety use of the preparations but often the conditions of storage of the drugs can undergo significant variations. The stability data reported by the manufacturers are often limited while in clinical practice it is necessary to extend the conditions of use and the validity times of the preparations. In reality, it may happen that drugs are transported, stored and used at temperature conditions other than those indicated by the manufacturer without, however, having sufficient data on safety and stability for use outside the certified conditions.

AIM AND OBJECTIVES

The objective of the analysis performed is to evaluate the chemical and physical stability of doxorubicin and epirubicin after being stored in the freezer.

MATERIALS AND METHODS

The formulations of doxorubicin and epirubicin stored in the freezer for a period exceeding 48 h were analyzed. The drug solutions were thawed at room temperature and stored in the refrigerator until the time of the chemical-physical analysis. For analysis 10 microliters were subsequently diluted from each vial and injected into by using an ultra-high performance liquid chromatograph coupled to a triple quadrupole mass spectrometer UHPLC-MS/MS LC QTOF MS (n=4).



SAMPLES	U.M.	EXPERIMENTAL DATA
DOXORUBICIN	mg/ml	1.996
DOXORUBICIN OVER-RANGE	mg/ml	1.995
EPIRUBICIN	mg/ml	2.009
EPIRUBICIN OVER-RANGE	mg/ml	2.005

RESULTS

Data obtained from the analysis carried out with a mass chromatographic technique highlighted the chemical and physical stability of the drugs analyzed. The measured concentration of doxorubicin for the over-range sample was 1.995 ± 0.005 mg/ml while for the external doxorubicin standard was 1.996 ± 0.008 mg/ml. Same trend was observed for epirubicin, 2.009 ± 0.007 mg/ml versus 2.005 ± 0.005 mg/ml for the overrange sample.

CONCLUSION

The analysis showed the chemical-physical stability of the compounds studied allowing their use even outside the storage conditions indicated in the technical data sheet. The results showed that there were no statistically significant differences in the concentration of overrange doxorubicin and epirubicin samples even after accidental freezing. This consists in a reduction of drug waste in real conditions. An easy access to mass spectrometry analytical platform may allow the evaluation of drug stability, redefining the chemical-physical stability with certified data.