TCH035

17th Congress of 21-23 March 2012, Milan, Italy

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STABILITY OF DOCETAXEL INFUSIONS

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BACKGROUND

According to the manufacture, docetaxel infusions should be used within four hours at room temperature (<25°C).

PURPOSE

To determine the stability of intravenous mixtures (IVM) at a concentration of 0.7 mg/mL in 0.9% sodium chloride prepared from three different specialties generic docetaxel at room temperature and refrigerated

MATERIAL & METHODS

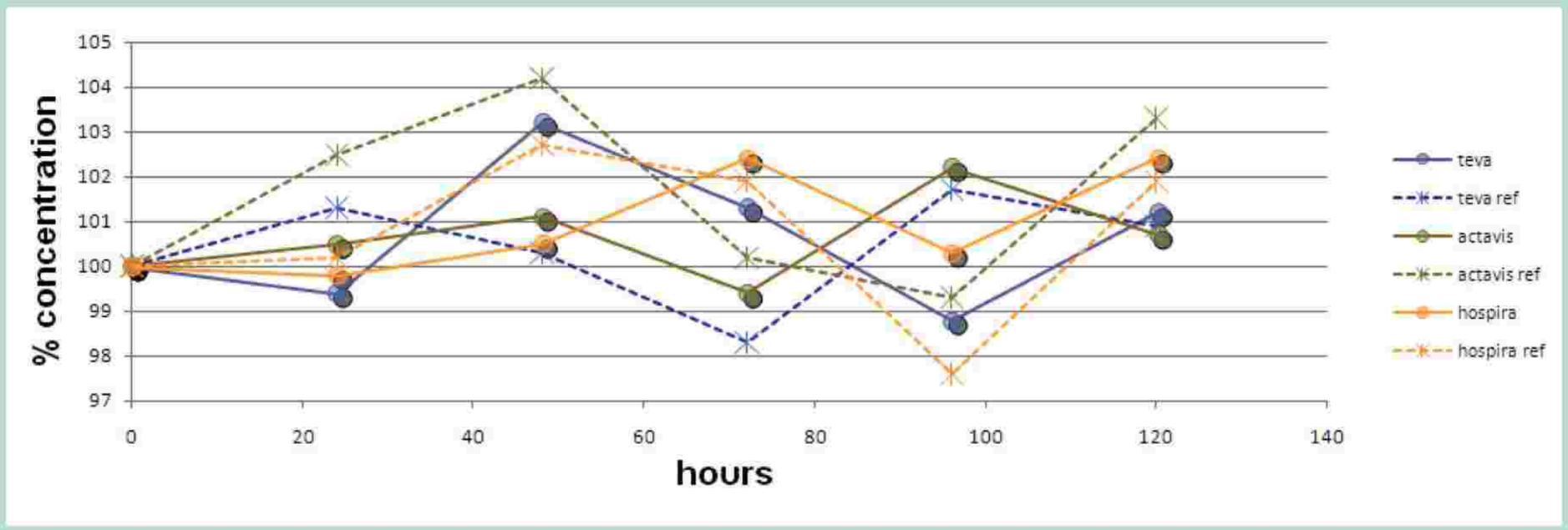
In vertical laminar flow hood two IVM were prepared for each specialty (docetaxel Teva® 80mg/2mL, docetaxel Actavis® 20 mg/mL and docetaxel Hospira® 10 mg/mL), diluted in 0.9% sodium chloride 100 mL (Grifols Physiological saline Fleboflex®) at a final concentration of 0.7mg/mL, one of which is kept at ambient temperature and the other kept refrigerated (2-8°C).

In each of the IVM, was taken an aliquot of 0.5 mL at 0, 24, 48, 72, 96 and 120 hours for the determination of docetaxel. The concentrations are expressed as a percentage of the remaining concentration with respect to the initial concentration obtained immediately after preparation of each of the IVM.

The determination of the concentrations of docetaxel was performed using high performance liquid chromatography (HPLC). We used a Merck-Hitachi® HPLC System, consisting of a pump, an autoinjector system, a UV detector and an integrator in the form of software. We used the following chromatographic conditions: stationary phase C18 column (5µm 150mm x 4mm), mobile phase: water and acetonitrile (48:52) both of HPLC grade. The flow was set at 1 ml/min. The retention time is 5.5 min. The wavelength used by the UV detector is 233nm.

RESULTS

None of the IVM analyzed, turbidity or precipitation was observed. The percentages of the remaining concentrations of docetaxel in the IVM compared to the initial concentration were: 99.4-102.5, 100.3-104.2, 98.3-102.4, 97.6-102.2, 100.7-103.3% at 24, 48, 72, 96 and 120 hours respectively in both IVM stored at room temperature and under refrigeration. Additional peaks were not seen in any chromatogram from test samples.



CONCLUSIONS

The physicochemical stability of docetaxel at the conditions used both room temperature and refrigerated, is at least 120 hours, allowing us to reuse the vials for intravenous administration through centralized preparation in intravenous therapy unit in the Pharmacy Service.