STABILITY STUDY OF GANCICLOVIR IN 0.9% SODIUM CHLORIDE IN DIFFERENT TYPES OF CONTAINERS: OPTIMIZATION OF RESOURCES

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OBJECTIVES

- to verify and demonstrate the stability of ganciclovir in 0.9% sodium chloride in two different types of containers up to 21 days;
- to organize the work of the hospital pharmacist and technical personnel in accordance with the criteria for optimization of resources;
- to reduce the wastage caused by bags of ganciclovir thrown by the department if not immediately used.

STUDY DESIGN

Twelve admixtures, six for every concentration (4.55 e 0.8 mg/mL), of ganciclovir sodium in 0.9% sodium chloride, stored at room temperature, at 4°C and -20°C (in darkness) in two type of containers, polyethylene and polyolefin, were prepared.

The run has been performed in isocratic condition followed by a wash step and a reconditioning step (Tab.1).

RESULTS

In Figure 3 has been shown the 0.8 mg/mL concentration of ganciclovir sodium in 0.9% sodium chloride, stored at room temperature, at 4°C and -20°C (in darkness) in two type of containers, polyethylene and polyolefin, were prepared.

The admixtures were evaluated up to 21 days at the three temperature conditions. For this aim, a simple UPLC-UV method was developed.

In UPLC-PDA method, retention time of ganciclovir has been 3.4 minutes (Fig.1).

Fig.1: Chromatogram of ganciclovir showed a retention time of 3.4 minutes.

Ganciclovir sodium 4.55 mg/mL and 0.8 mg/mL in 0.9% sodium chloride in two different kind of containers (Viaflo® and Ecolac® 100 mL) was visually compatible and chemically stable for at least three weeks when stored at room temperature, 4°C and -20°C (Fig.2,3).

Fig.2: Stability in containers [A] and [B] of ganciclovir at 4°C in the range of time considered (4.55 mg/mL)

Fig.3: Stability of ganciclovir at 4°C and at room temperature, without significant Stability differences between temperatures considered.

In Figure 3 has been shown the 0.8 mg/mL concentration at 4°C and at room temperature, without significant Stability differences between temperatures considered.

DATA WERE EXPRESSED IN PERCENT (%)
AS RATIO BETWEEN THE CONCENTRATIONS MEASURED AT DIFFERENT TIME OF ANALYSIS AND THE CONCENTRATION AT TIME ZERO.

DISCUSSION

Many drugs used in modern medicine have very limited stability data which are often insufficient to meet certain requirements. As a consequence, there is a need of other data to support the quality of these practices. The relatively long stability allows to prepare this drug every 21 days instead of every day (except for patients to whom the dosage is changed). Furthermore, containers returned by hospital wades (stored at 4°C) are reused until the expiration of 21 days. This allows the minimization of waste and a reduction of the direct and indirect costs.

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