



Stability of midazolam and noradrenaline stored in cyclic olefin copolymer AT-Closed Vials[®] and polypropylene syringes during 365 days

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Introduction

Midazolam (MDZ) and noradrenaline (NA) are drugs commonly used in intensive care units to control sedation and hemodynamic status of patients. They required a dilution step by the nurse several times a day. To decrease preparation risks, they could be compounded by the pharmacy, provided that stability is sufficient.

Methods

50mL cyclic olefin copolymer AT-Closed Vials[®] (Aseptic Technologies) and polypropylene syringes (Plastipak[®], Becton Dickinson) were filled with MDZ or NA (Mylan) diluted in saline at respectively 1mg/mL and 0.2mg/mL. Study was performed according to the SFPC/GERPAC guidelines during 365 days at 2 temperature conditions: -20°C, 5°C. Concentrations were determined by an HPLC/UV stability indicating method, expressed as mean±standard deviation and considered stable if the concentration stayed over 90% of the initial concentration value. Particulate contamination, pH evolution and sterility were followed.

Results

Solutions were stable during 365 days in AT-Closed Vial[®] at -20°C (MDZ 99.01±0.90%, NA 98.91±0.54%) and 5°C (MDZ 97.98±0.96%, NA 99.52±0.36%) and in syringes at -20°C (MDZ 99.29±0.85%, NA 98.92±0.98%) and 5°C (MDZ 97.89±0.51%, NA 99.42±0.51%). There was no modification of pH. Sterility and particle tests were in accordance with European Pharmacopeia after 365 days whatever the storage conditions.

Discussion/Conclusion

MDZ and NA are stable during 365 days at 5°C and -20°C. Storage at 5°C should be preferred to exclude freezing-thawing issues. AT-Closed Vial[®] could be chosen for their automated aseptic filling process and for logistic considerations particularly taking into account the space gains.

Source: <http://www.gerpac.eu/stability-of-midazolam-and-noradrenaline-stored-in-cyclic-olefin-copolymer-at-closed-vials-r-and-polypropylene-syringes-during-365-days>