



# Stability of Reconstituted and Diluted Mitomycin C Solutions in Polypropylene Syringes and Glass Vials

## Abstract

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Mots-clés	HPLC UV [6], ICH [7], Mitomycin C [8], Stability [9], stability indicating method [10]
Résumé en anglais	<p><b>Purpose:</b> Mitomycin C (MMC) is widely used in treatment of non-muscle invasive bladder cancer at a 1 mg/mL concentration, by intravesical instillation. MMC is also used as an ophthalmic procedure in glaucoma care mostly with 0.2 mg/mL concentration. To accelerate syringes provision, it could be interesting to demonstrate the stability of the drug, in order to be able to prepare the chemotherapeutic drug several hours before the chemotherapy administration.</p> <p><b>Methods:</b> A stability indicating HPLC-UV method was developed and validated according to the ICH guidelines. Concentrations of the MMC stored at 25 °C and 60 % of relative humidity and protected from light in polypropylene syringes (1 mg/mL and 0.2 mg/mL) or glass vials (1 mg/mL) were evaluated for 96 h and compared to the initial observed concentrations.</p> <p><b>Results:</b> MMC stability was demonstrated in syringes and glass vials at 1 mg/mL only for 8 h in water for injections and for 10 h at 0.2 mg/mL in 0.9 % sodium chloride solutions, because relative concentrations (95 % confidence interval of the mean of 3 samples) were systematically over 90 % of the initial concentrations. After 96 h the relative concentrations were found below 80 % as compared to initial concentrations, thus indicating instability of these solutions. Degradation products were observed and remained below 3 %.</p> <p><b>Conclusion:</b> This study confirms that MMC solutions for ophthalmic application at 0.2 mg/mL or vesical instillation at 1 mg/mL have to be formulated extemporaneously to maintain the desired concentration.</p>

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