

**SUGGESTED FORMULA****Mitomycin 1mg/mL Sterile Bladder Instillation**

Version number: 1.0

Volume: 40 mL

Mitomycin, USP		0.04 gm
Mannitol, USP		0.08gm
Sterile Water for Injection	QS	40 mL

Note: This is a suggested formula for extemporaneously compounded Mitomycin Bladder Instillation. Alternatively, when the commercial injection is available it may be diluted with sterile water to prepare the same formula as a low-risk CSP.

SUGGESTED COMPOUNDING PROCEDURES

1. Weigh powdered ingredients and add to calibrated, depyrogenated beaker with $\frac{3}{4}$ final volume of sterile water.
2. Dissolve the powders in solution with spin bar – bring solution to QS and spin until uniform. This may take 30-60 minutes.
3. Transfer solution to BSC or CACI.
4. Filter solution through 0.2 micron filter into final container – syringe or vial – use closed-system transfer devices whenever possible.
5. Package, seal and label.
6. Suggested Quality Assessments – follow pharmacy SOPs:
 - a. Bubble point integrity test
 - b. Particulate
 - c. Sterility
 - d. Antineoplastic caution label(s)

Store in air tight amber plastic containers

Store at Room Temperature – Refrigeration may cause precipitation at this concentration.

No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, and intended duration of therapy, formulation from commercially available

products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date. It is recommended that you follow USP <795> recommendations for potency testing.

Beyond-Use Date for batches of injections that have passed sterility testing is estimated to be 7 Days at Room Temperature – per University of Maryland Baltimore Washington Medical Center.

<http://www.mybwmc.org/library/41/088000>

Precautions

Hazardous drugs should be handled according to USP and NIOSH standards and pharmacy SOPs. This preparation should be compounded in a vertical airflow hood, in a biological safety cabinet or barrier isolation technology. Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. Wear appropriate personal protective equipment.

Although much attention has been paid to ensure the accuracy of the formulation contained here, Spectrum Pharmacy Products accepts no liability for the loss or damage arising from reliance on the information. Compounding pharmacists using this formula take full responsibility for the formulations and hold Spectrum Pharmacy Products and Spectrum Chemical Mfg Corp. and its officers, directors and employees harmless for any claim arising from use of or reliance on information contained therein.

09/15 RD