Mitosol®

Reduce Variables

Compounded MMC makes it difficult to achieve a consistent dose.

MMC degrades rapidly[1] and its potency depends on a variety of variables:

- Where it is stored.
- Shipping conditions.
- Elapsed time since compounding.
- Variability in compounding each dose to the next.

Take Control

Mitosol® ensures identical potency for every patient.

Mitosol® is shelf-ready and ALWAYS at time zero. It is reconstituted on the sterile field at the time of use, reassigning control of drug potency to those actually administering it.

Deliver Consistency

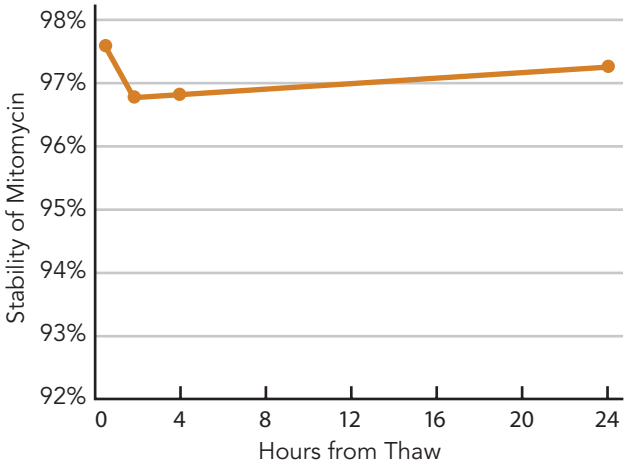
0.1%
Percentage of compounded MMC degradation per hour

25%
Percentage of compounded MMC potency that can be lost

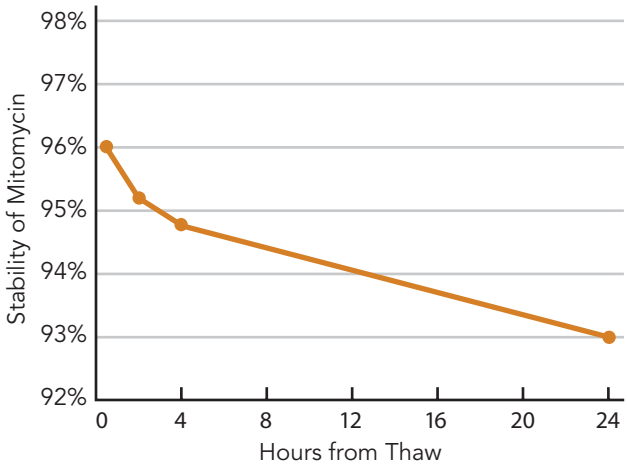
ZERO
Number of times you will worry about Mitosol® consistency & potency

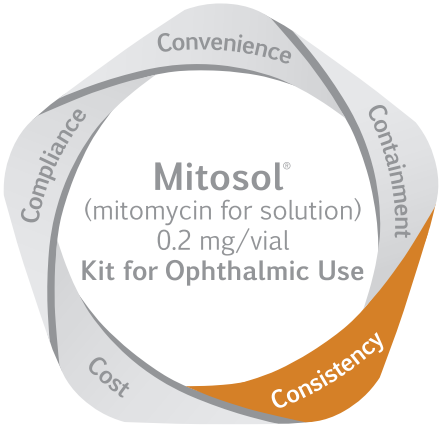
[1] Degradation of Mitomycin Under Various Storage Conditions; Kinast RM, Mansberger SL; Poster 83-111; AGS 2014

Stability of Dry Powder (Mitosol®) at Room Temperature after Storage



Stability of Compounded Mitomycin at Room Temperature after Storage





Mitosol® Facts

FDA-Approved for Ophthalmology	☑
Assured Sterility, Potency, Dosing	☑
AORN Compliant Sterile Transfer	☑
Closed Fluid Transfer	☑
Room Temp Storage	☑
cGMP Manufacturing Controls	☑
Detailed Instructions for Use	☑
NIOSH Compliant Disposal	☑
No "Black Box Warning"	☑
Shelf Life up to 24 months	☑

INDICATION
Mitosol® (mitomycin for solution) 0.2 mg/vial Kit for Ophthalmic Use is an antimetabolite indicated as an adjunct to ab externo glaucoma surgery.

Dosage & Administration
Mitosol® is intended for topical application to the surgical site of glaucoma filtration surgery and must be reconstituted prior to application. Sponges provided within the Mitosol® kit should be fully saturated with the entire reconstituted contents in a manner prescribed in the Instructions For Use. The sponge(s) should be applied to the treatment area for two minutes.
Reconstituted Mitosol® should be used within one hour of reconstitution.

IMPORTANT SAFETY INFORMATION
Contraindications
Mitosol® is contraindicated in patients that have demonstrated a hypersensitivity to mitomycin and in women who are or may become pregnant during therapy.

Warnings & Precautions
Cell Death, mitomycin is cytotoxic. Use of mitomycin in concentrations higher than 0.2mg/mL or use for longer than 2 minutes may lead to unintended corneal and/or sclera damage including thinning or perforation. Direct contact with the corneal endothelium will result in cell death.
Hypotony. The use of mitomycin has been associated with an increased instance of post-operative hypotony.
Cataract Development. Use in phakic patients has been correlated to higher instance of lenticular change and cataract formation.

Adverse Events & Reactions
The most frequent adverse reactions to Mitosol® occur locally and include hypotony, hypotony maculopathy, blebitis, endophthalmitis, vascular reactions, corneal reactions, and cataract.