



BVI

Enhancing Capsular Bag Visualization

Ultra-Pure Trypan Blue

MONOBLUE SafR (Safe for Rhexis)



MONOBLUE SafR Introduction

MONOBLUE SafR is a ultra-purified Trypan blue solution indicated for temporary staining of the capsule.

DESCRIPTION

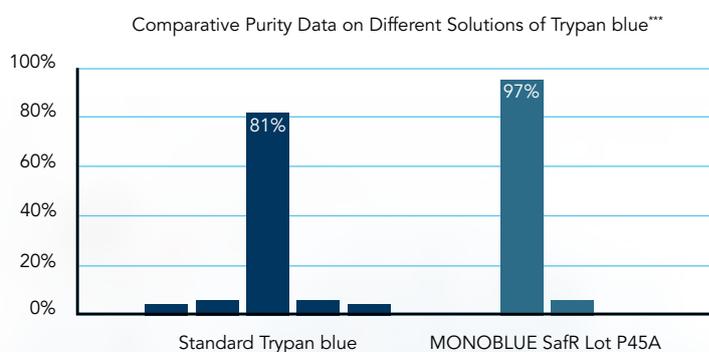
MONOBLUE SafR is a purified Trypan blue isotonic sterile solution presented in single dose syringe containing 0.75 ml of a 0.055% solution. The syringe is packaged in a pouch. It is externally sterile to allow its use in the operating theatre. Each box contains 5 syringes.

MONOBLUE SafR Advantages

AN ULTRA-PURE STAINING AGENT

Enhanced safety and tolerability

- O-tolidine*: not detectable**
- Preservative free
- Latex free
- Endotoxin: ≤ 0.2 UE/ml



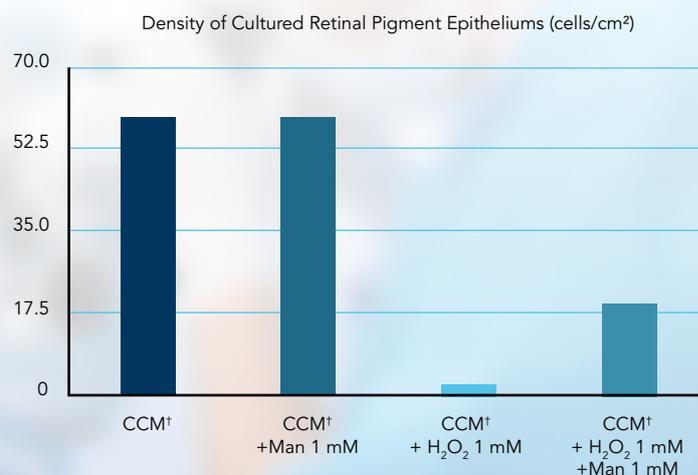
PROTECTIVE EFFECT OF MANNITOL

Mannitol is a free radical scavenger with anti-oxidant effect

Mannitol is a key component of MONOBLUE SafR, it protects retinal pigment epithelium cells from the oxidative effect of H₂O₂^{1,2}.

Density of retinal pigment epithelium cells in:

- CCM[†] + H₂O₂ 1 mM: 3 cells/cm²
- CCM[†] + H₂O₂ 1 mM + Mannitol 1 mM: 18 cells/cm²
- CCM[†] + Mannitol 1 mM: 59 cells/cm²



1 Liu JH and a. Therapeutic effects and mechanisms of action of Mannitol during H₂O₂-induced oxidative stress in human retinal pigment epithelium cells. J Ocul Pharmacol Ther. 2010 Jun;26(3): 249-57.

2 Gupta LY, Marmor MF. Mannitol, dextromethorphan, and catalase minimize ischemic damage to retinal pigment epithelium and retina. Arch Ophthalmol. 1993 Mar;111(3):384-8.

*Toxicity concern may arise with high concentration of Trypan blue and impurities like O-tolidine and byproducts.

**Detection limit: less than 0.11 ppm.

***Data In House for Gas Chromatography.

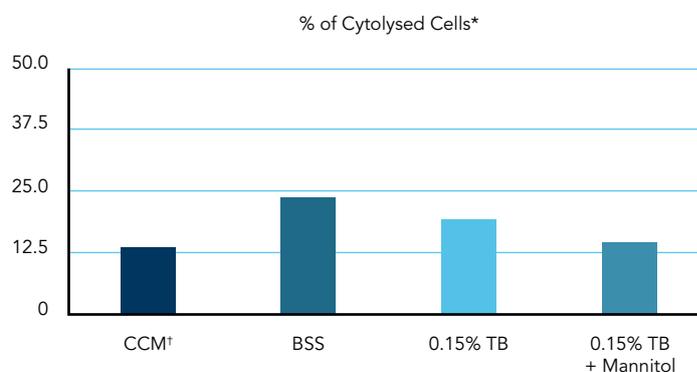
† Cells Culture Medium.

ENHANCED TOLERABILITY

Improved protection of human retinal cells

The presence of Mannitol in MONOBLUE SafR formulation improves significantly its tolerance. Number of cytolysed cells in contact with Trypan blue plus Mannitol is lower than with Trypan blue alone.

- Trypan blue without Mannitol: $22,73 \pm 6,6\%$.
- Trypan blue with Mannitol: $13,73 \pm 6,2\%$.



THE INJECTION SYSTEM GUARANTEES A CONTROLLED ADMINISTRATION

Sterile Single-Use

- Pre-filled 0,75mL syringe individually pouched ready to use
- Long barrel to monitor the injected volume
- Soft sliding plunger to smoothen the injection



MONOBLUE SafR Safety Facts

- ISO 13485: 2016 certified company
- Unique advantage with the addition of Mannitol
- No case of cytotoxicity over 15 years of production³
- More than 1.000.000 syringes of Trypan Blue solutions placed on the market
- Unique purification process
- European legal manufacturer

Instructions For Use

- Open the pouch over the sterile operating field or inside the sterile area to remove the syringe
- Mount an appropriate cannula
- Mobilize the plunger
- Fill the anterior chamber with a viscoelastic or air bubble
- Slowly push the plunger to lay the dye directly onto the tissue to be stained
- Thoroughly rinse the excess dye with a saline solution

³ ARCAD_PMS-PMCF_05_Report_V0 No case of cytotoxicity reported.

*Study of human retinal ARPE-19 cells tolerance to various Trypan Blue solutions. (Datas Arcadophtha).

Trypan Blue, An Effective Staining For Capsulorhexis And Various Applications For An Anterior Segment Use (See Clinical Applications References Below)

TO STAIN THE ANTERIOR CAPSULE OF THE LENS

- 1 Nodarian M, Feys J, Sultan G, Salvanet-Bouccara A. [Capsulorhexis staining by trypan bleu in mature cataract surgery]. J Fr Ophthalmol. 2001 Mar;24(3):274-6
- 2 Saini JS, Jain AK, Sukhija J, Gupta P, Saroha V. Anterior and posterior capsulorhexis in pediatric cataract surgery with or without Trypan blue dye: randomized prospective clinical study. J Cataract Refract Surg. 2003 Sep;29(9):1733-7

CATARACT / VISUALIZATION OF CRYSTALLINE EPITHELIAL CELLS

- 1 Werner L, Pandey SK, Escobar-Gomez M, Hoddinott DS, Apple DJ. Dye-enhanced cataract surgery Part 2: learning critical steps of phacoemulsification. J.Cataract Refract Surg. 2000 Jul;26(7):1060-5
- 2 Sharma N, Gupta V, Vajpayee RB. Trypan-blue-assisted posterior capsule plaque removal. J Cataract Refract Surg. 2002 Jun;28(6):916-7
- 3 Kiel AW, Butler T, Gregson R. A novel use for trypan blue to minimize epithelial cell proliferation in pediatric cataract surgery. J Pediatr Ophthalmol Strabismus. 2003 Mar-Apr;40(2):96-7

Safety First For Our Product Line



ARCIOLANE

Fractionated and Purified
Silicone Oil



ARCALINE - ARCOTANE

Heavy Liquids for
Ophthalmic Surgery



OP'COVER

Corneal Protection



ARCEOLE

Ready-to-Use Set
of Ophthalmic Gas

FOR COMPLETE PRODUCT INSTRUCTIONS, PLEASE REFER TO THE IFU SUPPLIED WITH THE PRODUCT