FORMULATION RECORD

Name: Papaverine and Phentolamine Injection
Strength: 30 mg/ml papaverine, 1 mg/ml phentolamine
Dosage Form: Solution
Route of Administration: Injection

Date of Last Review or Revision: Today
Person Completing Last Review or Revision: RPS

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Papaverine hydrochloride	300 mg	white crystalline	1 g/40 ml water;soluble in alcohol	vasodilator
NaCl	15 mg	white granules	1 g/2.8 ml water; very slightly soluble in alcohol	topical antiinflammatory; osmotic agent
EDTA 0.1%	0.5 ml	clear, non-viscous solution	soluble in water	chelating agent
Phentolamine mesylate	10 mg	white crystals	1 g/50 ml water	active ingredient
Sodium metabisulfite	10 mg	white granules	freely soluble in water	antioxidant
Mannitol	50 mg	white granules	1 g/5.5 ml water; 1 g/83 ml alcohol	osmotic agent
Purified Water	qs 10 ml	clear, non-visous liquid	NA	solvent

Calculations:

Ingredient	Quantity	Quantity for 18 ml
Papaverine hydrochloride	300 mg	540 mg
NaCl	15 mg	27 mg
EDTA 0.1%	0.5 ml	0.9 ml
Phentolamine mesylate	10 mg	18 mg
Sodium metabisulfite	10 mg	18 mg
Mannitol	50 mg	90 mg
Purified Water	qs 10 ml	qs 18 ml

Equipment Required:

- Class A balance
- Small beaker and small stir bar
- 10 ml syringe with appropriate needles
- A sterilizing filter
- A sterile parenteral vial
- Venting needle
- A scintillation vial

Method of Preparation:

1. Calibrate a beaker **with the stir bar in it**.
2. Accuracy weigh the papaverine and add to the beaker. Rinse the weigh boat with about 5 ml of purified water.
3. Add the NaCl via an aqueous stock solution. Add the EDTA solution. Begin stirring the beaker's contents.
4. Add **very low** heat (i.e., not more than 40°C)
5. Add approximately 5 ml of purified water.
6. Accuracy weigh the phentolamine trituration and add to the beaker. Rinse the weigh boat with 1 – 2 ml of purified water.
7. Turn off the heat. Bring the solution to volume.
8. Using a needle attached to a 10 ml syringe, draw up the solution from the beaker.
9. Remove the needle, attach a sterilizing filter, and attach a new needle.
10. Dispense 10 ml into a vented parenteral vial.
11. Store the remaining solution in a scintillation vial.

Description of Finished Product:

Clear to slightly yellow non-viscous solution. No visible particles.

Quality Control Procedures:

Analysis of both the filtered and unfilter solutions

Packaging Container:

A sterile parenteral vial
A scintillation vial

Storage Requirements:

Beyond-Use Date Assignment:

USP Guidelines:
Aqueous solutions:
When prepared from ingredients in solid form, the beyond-use date should be not later than 14 days when stored at cold temperature.
Assign 14 days. Storage in cold temperature is not required.

Label Information:

Source of Recipe:

Literature Information:

Benson, GS, Seifert Jr, WE: Is phentolamine stable in solution with papaverine. Journal of Urology 140:970-971, 1988

Thon, WF, Seidl, E, Kramer AE, Jonas, U: Andropen – preset self-injection pen for intracavernous auto-injection therapy in erectile impotence. World Journal of Urology 8:87-89, 1990