QUANTITY TO PREPARE: 25 vials  Last update: 08/09/2011

ACTIVE INGREDIENTS AND EXCIPIENTS

A.- Phenylephrine CLH powder*  750 mg
B.- B.S.S  c.s.p.  50 mL

CHARACTERISTICS

1.- ORGANOLEPTIC
   • COLOUR: Colourless
   • SMELL: not appreciated
   • FOREING BODIES: Limpid (do not contain)

2.- PHYSICAL
   Vol= 2 mL± 0,1 mL

3.- CHEMICAL

MATERIALS Y COMPONENTS
Sterile amber glasses vials type I, sterile elastomers, sterile metal capsules, 50ml sterile flask, 100ml sterile beaker, 0,22 micron milipore filter.
Precision balance, horizontal laminar flow cabinet, nitrogen bullet,sterile system for gasification.
MODUS OPERANDI

1.- Weigh A
2.- Add 1 to the sterile flask and dissolve with B. Mix homegeneously.
3.- Empty the content of 2 in the sterile beaker.
4.- Fill in 3 with an 20 mL sterile syringe.
5.- Include to 4 a 0,22 micron sterile filters, 5LLG02SSS reference.
6.- Include 5 to the vials, previously gasify with liquid nitrogen using a 0,22 micron sterile filter and using a sterile adaptor for the gasification system.
7.- At the end gasify with liquid nitrogen each vial before encapsulate.

BOTTLING

At the horizontal laminar flow cabinet (CFLH), in cleaning rooms.
# Checks

<table>
<thead>
<tr>
<th>Osmolarity: 410 mOsm/Kg</th>
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</thead>
<tbody>
<tr>
<td>pH: 6.5</td>
</tr>
<tr>
<td>Particles: Exempt</td>
</tr>
<tr>
<td>Volum: 2 ± 0.1 mL</td>
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<tr>
<td>Microbiological: Negative</td>
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<tr>
<td>Assay: 100% (It contains not less than 90.0 percent and not more than 115.0 percent) U.S.P.</td>
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</tbody>
</table>

## Observations

## Expiry Date

| 2 months |

## Therapeutics

**Indications:** (At operating room):

- It is an adrenergic vasopressive phenylephrine with sympathomimetic activity. With exclusive use at ophthalmology operating room. It is used by administering directly 0.6 mL of phenylephrine 1.5%. Each vial is apt for three administrations, shuck off the vial used within the 24 hours after opening. It is used in patients on tamsulosin.

## Preservation

- Ambient temperature. Protected from light. Dry conditions.

### Redacted by:  
Juan Varela  

### Revised by:  
Juan Varela  

### Approved by:  
Juan Varela  

*Phenylephrine powder*  
Hydrochloride phenylephrine Ref P6126  
Sigma Chemical Company