

# ELABORACIÓN DE AMPOLLAS Y VIALES A PARTIR DE MATERIALES Y MATERIAS PRIMAS NO ESTERILES



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## PREPARACIÓN Y LAVADO



VIALES

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## Fin de Lavado



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## PREPARACIÓN Y LAVADO



TAPONES Y CÁPSULAS  
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## Escurreido y Colocación



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## Secado y Despirogenado



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## Preparación de la disolución



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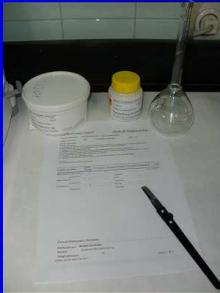
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## HOJA ELABORACIÓN



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## Registro en Hoja Elaboración

Entorno:  
En cámara de flujo laminar horizontal.

| Nombre M. prima               | Orden Pesada | Nº Control | Cantidad | Unidad | Peso Real | Unidad Real | CSP            |
|-------------------------------|--------------|------------|----------|--------|-----------|-------------|----------------|
| Agua apirogna para preparacio | 0            | 300772     |          |        |           |             | c.s.p., 250 ml |
| Localización:                 |              |            |          |        |           |             |                |
| Sodio cloruro de              | 0            | 1051       | 2.25     | g      | 2.25      |             |                |
| Localización:                 |              |            |          |        |           |             |                |
| fentilefina cih               | 0            | 1272       | 300      | mg     | 300       | mg          |                |
| Localización:                 |              |            |          |        |           |             |                |

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## Fenilefrina 1 mg/ml Amp.

- Composicion:
- Fenilefrina Hcl ..... 0,3 g
- Sodio Cloruro de ..... 2,25 g
- Agua apirógena c.s.p. .... 250 ml

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## Pesada P. Activo



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## Pantalla Balanza



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## Pesada del Isotonizante



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## Dilución para Análisis

3,5 ml en 50 ml



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## Datos Bibliográficos

**Phenylephrine Hydrochloride**  
*Synonyms:* Mesatomum; Metaxedrin; Chloridum.  
*Proprietary Names:* Fenox; Isophrin; Mylfrin; Nazex; Neophryn; Optocrymal; Pretrin Liaguilm; Sief; Soothe; Visadros. It is an ingredient of Buomydrin, Bronchilator, Colrex Compound, Demazin, Deyless, Dimotane (expectorant), Dimotap, Dristan (tablet), Eryphen, Hayphryn, Isopto Frin, Naldecon, Neotep, Nethaprin Dospan, Tussis, Uniflu, and Zinctrin.  
 $C_{12}H_{17}NO_2 \cdot HCl = 203,7$   
*CAS—61-76-7*  
 A white crystalline powder. M.p. 140° to 145°. A solution in water is levorotatory.  
*Soluble* 1 in 2 of water and 1 in 4 of ethanol.  
**Dissociation Constant.** pK<sub>a</sub> 8,9 (-OH), 10,1 (-NH-), (20°).  
**Colour Tests.** Mandelin's Test—brown; Marquis Test—red.  
**Thin-layer Chromatography.** System TA—Rf 33; system TB—Rf 01; system TC—Rf 01. (Acidified potassium permanganate solution, positive.)  
**Gas Chromatography.** System GC—R1 1934.  
**High Pressure Liquid Chromatography.** System HA—K' 1,3; system HC—k' 1,64.  
**Ultraviolet Spectrum.** Aqueous acid—273 nm ( $A_1^1 = 110 a$ ); aqueous alkali—238 nm ( $A_1^1 = 534 a$ ), 291 nm ( $A_1^1 = 182 a$ ). (See below)  
**Infra-red Spectrum.** Principal peaks at wavenumbers 1594, 1273, 784, 696, 1304, 900 (phenylephrine hydrochloride, KBr disk). (See below)

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### Ley de Lambert.Beer

$A = A1 \cdot B \cdot C$   
Epsilon =  $A1 \cdot 0,1 \cdot M$   
C= Concentración g/100 ml  
A= Absorbancia  
A1=Absortividad  
M= Peso molecular

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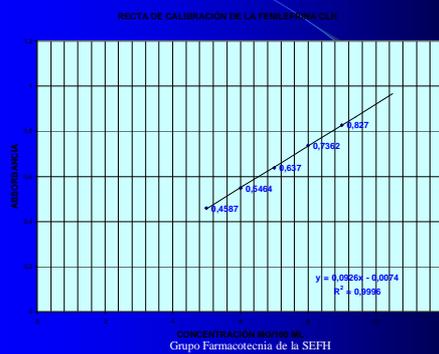
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### Recta Calibración Fenilefrina



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### Osmometría



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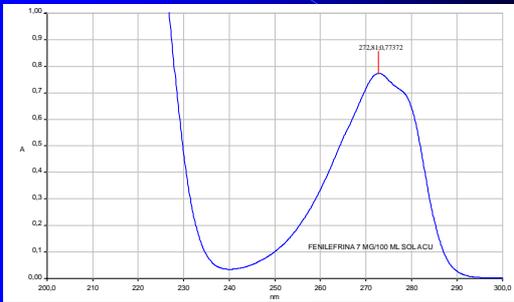
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### Barrido de 300 a 230 nm



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### Preparación de Material



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### Zona de preparación y material



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### Llenado de Ampollas 1ª Fase



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### Llenado de Ampollas 2ª Fase



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### Cerrado de Ampollas 1



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## Cerrado Ampollas 2



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## Ampollas cerradas



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## Envoltorio para autoclavado



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### Cestillo para Autoclave



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### Autoclave



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### Autoclavado a vapor fluente 40 minutos



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### Manómetro autoclave



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### Después de Autoclavado



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### Etiquetado de Ampollas



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### Cerrado Viales 1



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### Cerrado Viales 2



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### Vial y Ampolla cerrados



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