

**Student name:**

**Fac. №**

<b>1. Medicinal product:</b>	Fenistil
<b>2. Dosage form:</b>	Hydrogel
<b>3. Composition:</b>	
<b>3.1. Active ingredients (drugs):</b> Dimethidene maleate	
<b>3.2. Excipients:</b>	<b>Function:</b>
Carbomer	gelling agent
Propylenglycol	co-solvent; water-retention agent
Purified water	liquid base for gelling
Sodium hydroxide	alkalizing agent
Benzalkonium chloride	preservative
Disodium EDTA	preservative, antioxidant
<b>3.3. Rationale for the use of the excipients:</b>	
<p>The purified water is the liquid in which carbomer swells and results in gel formation. Propylenglycol is also liquid, has co-solvent properties and retains water in the final product. Carbomer is a synthetic polymer based on acrylic acid which is used as a gelling agent in the preparation of a hydrogel.</p> <p>Sodium hydroxide is used to achieve the required pH in order for the gelling of carbomer in water.</p> <p>Benzalkonium chloride and disodium EDTA are used to increase the stability of the product and they maintain its microbiological stability.</p>	
<b>4. Suggest technology of preparation:</b>	
<p>The hydrogel preparation includes the following steps:</p> <ul style="list-style-type: none"> <li>- Carbomer swelling in water</li> <li>- Incorporation of the Active ingredient</li> <li>- addition of stabilizing excipients and alkalizing agent</li> </ul>	
<b>5. Control parameters according to Ph.Eur.:</b>	

