Atropine Sulfate Ophthalmic Solution

**DEFINITION**
Atropine Sulfate Ophthalmic Solution is a sterile, aqueous solution of Atropine Sulfate. It contains NLT 93.0% and NMT 107.0% of the labeled amount of atropine sulfate monohydrate \([\text{C}_17\text{H}_{33}\text{NO}_2\cdot\text{H}_2\text{SO}_4\cdot\text{H}_2\text{O}]\). It may contain suitable stabilizers and antimicrobial agents.

**IDENTIFICATION**

- **A.** The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.

**ASSAY**

**Change to read:**

- **ORGANIC IMPURITIES**

  ▲ Buffer A, Buffer B, Mobile phase, Diluent, Standard solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

  System suitability solution: 0.005 mg/mL of atropine sulfate and 0.5 mg/mL of USP Atropine Sulfate RS in Diluent

  System suitability

  Samples: Standard solution and Sample solution

  [NOTE—See Table 1 for the relative response factors.]

  **Suitability requirements**

  | Analysis | Relative standard deviation: NMT 1.0%, Standard solution |

  **Analysis**

  Samples: Standard solution and Sample solution

  Calculate the percentage of each specified and any unspecified degradation product in the portion of Ophthalmic Solution taken:

  \[
  \text{Result} = \left( \frac{r_1}{r_2} \right) \times \left( \frac{C_1}{C_2} \right) \times \left( \frac{M_1}{M_2} \right) \times 100
  \]

  \(r_0\) = peak response of each specified and any unspecified degradation product from the Sample solution

  \(r_1\) = peak response of atropine from the Standard solution

  \(C_1\) = concentration of USP Atropine Sulfate RS in the Standard solution (mg/mL)

  \(C_2\) = nominal concentration of atropine sulfate in the Sample solution (mg/mL)

  \(F\) = relative response factor (see Table 1)

  \(M_1\) = molecular weight of atropine sulfate monohydrate, 694.84

  \(M_2\) = molecular weight of anhydrous atropine sulfate, 676.82

  **Acceptance criteria:** See Table 1.
### Table 1

<table>
<thead>
<tr>
<th>Name</th>
<th>Relative Retention Time</th>
<th>Relative Response Factor</th>
<th>Acceptance Criteria, NMT (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tropic acid</td>
<td>0.69</td>
<td>2.0</td>
<td>7.0</td>
</tr>
<tr>
<td>Atropic acid</td>
<td>0.87</td>
<td>12.2</td>
<td>1.0</td>
</tr>
<tr>
<td>Atropine</td>
<td>1.0</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Apoatropine</td>
<td>2.1</td>
<td>4.3</td>
<td>1.0</td>
</tr>
<tr>
<td>Any individual unspecified degradation product</td>
<td>—</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Total impurities</td>
<td>—</td>
<td>—</td>
<td>7.0</td>
</tr>
</tbody>
</table>

*a* 3-Hydroxy-2-phenylpropanoic acid.

*b* 2-Phenylacrylic acid.

*c* (1R,3r,5S)-8-Methyl-8-azabicyclo[3.2.1]octan-3-yl 2-phenylacrylate.

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### SPECIFIC TESTS

- **pH** (791): 3.5–6.0
- **Sterility Tests** (71): Meets the requirements

### ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.
- **USP Reference Standards** (11)
  - USP Atropine Sulfate RS

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