Travoprost Ophthalmic Solution

**DEFINITION**
Travoprost Ophthalmic Solution is a sterile buffered aqueous solution of Travoprost. It contains NLT 90.0% and NMT 110.0% of the labeled amount of travoprost \((\text{C}_{26}\text{H}_{35}\text{F}_{3}\text{O}_{6})\). It may contain suitable stabilizers, buffers, and antimicrobial agents.

[CAUTION—Great care should be taken when handling the active ingredient to avoid contact with the body.]

**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:**

- **PROCEDURE**
  - **Buffer:** 2.18 mg/mL of sodium 1-octanesulfonate in water. Adjust with phosphoric acid to a pH of 3.5.
  - **Mobile phase:** Acetonitrile and Buffer (17:33)
  - **Standard solution:** 0.04 mg/mL of travoprost from USP Travoprost RS in a mixture of acetonitrile and water (3:7)
  - **Sample solution:** Use Ophthalmic Solution without dilution.

**Chromatographic system**
(See Chromatography (621), System Suitability.)

**Mode:** LC
**Detector:** UV 220 nm
**Column:** 4.6-mm × 15-cm; packing L1
**Flow rate:** 2.0 mL/min
**Injection volume:** 100 µL

**System suitability**
- **Sample:** Standard solution
- **[NOTE—USP Travoprost RS contains a small percentage of the 5,6-trans isomer. The relative retention times for travoprost and the 5,6-trans isomer are 1.0 and 1.1, respectively.]**
  - **Resolution:** NLT 1.5 between travoprost and the 5,6-trans isomer
  - **Column efficiency:** NLT 2000 theoretical plates
  - **Relative standard deviation:** NMT 2.0%

**Analysis**
- **Samples:** Standard solution and Sample solution
  - **Analytical expression:** Calculate the percentage of travoprost related compound A in the portion of Ophthalmic Solution taken:
    
    \[ \text{Result} = \left( \frac{r_0}{r_s} \right) \times \left( \frac{C_s}{C_u} \right) \times 100 \]

  - **Samples:** Standard solution and Sample solution
  - **Analytical expression:** Calculate the percentage of each degradation product in the portion of Ophthalmic Solution taken:
    
    \[ \text{Result} = \left( \frac{r_0}{r_s} \right) \times \left( \frac{C_s}{C_u} \right) \times (1/F) \times 100 \]

**Acceptance criteria:**
- LIQUIDE: NMT 5.5%. It is the sum of all degradation products, including travoprost related compound A, obtained in Limit of Travoprost Related Compound A.
## 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>5,6-trans Isomer</td>
<td>1.1</td>
<td>1.0</td>
<td>5.0</td>
</tr>
<tr>
<td>15-keto Derivative</td>
<td>1.4</td>
<td>1.7</td>
<td>5.0</td>
</tr>
</tbody>
</table>

### ADDITIONAL REQUIREMENTS

- **PH (791):** 5.5–6.5

### SPECIFIC TESTS

- **Sterility Tests (71):** Meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*