Morrhuate Sodium Injunction

Morrhuate Sodium Injection is a sterile solution of the sodium salts of the fatty acids of Cod Liver Oil. It contains, in each mL, not less than 46.5 mg and not more than 53.5 mg of morrhuate sodium. A suitable antimicrobial agent, not to exceed 0.5 percent, and ethyl alcohol or benzyl alcohol, not to exceed 3.0 percent, may be added. NOTE—Morrhuate Sodium Injection may show a separation of solid matter on standing. Do not use the material if such solid does not dissolve completely upon warming.

Packaging and storage—Preserve in single-dose or in multiplet-dose containers, preferably of Type I glass. It may be packaged in 50-mL multiple-dose containers.

USP Reference standards (11)—

Endotoxin RS

Identification—Evaporate about 5 mL of the chloroform solution of the fatty acids obtained in the test for Iodine value of the fatty acids on a steam bath nearly to dryness, dissolve the residue in 1 mL of chloroform, and add 1 drop of sulfuric acid: a transient red color is produced, and it changes to brown-red.

Bacterial endotoxins (85)—It contains not more than 1.4 USP Endotoxin Units per mg of morrhuate sodium.

Acidity and alkalinity—To 5 mL of Injection add 5 mL of alcohol and 2 drops of phenolphthalein TS. If no red color is imparted, it contains not more than 0.50 mL of 0.10 N sodium hydroxide is required to impart a distinct red color. If a red color is produced, not more than 0.30 mL of 0.10 N acid is required to discharge it. For concentrations of morrhuate sodium other than 5%, no larger than proportional volumes of alkali and acid are required.

Iodine value of the fatty acids—Transfer to a tared, 125-mL conical flask the solvent hexane solution of the fatty acids obtained in the Assay. Evaporate at about 60° to dryness, dry the residue in vacuum over silica gel for 18 hours, and weigh. Dissolve the residue in chloroform to make 100.0 mL of solution, and determine the iodine value (see Fats and Fixed Oils (401)) on a 25.0-mL aliquot of the solution: the iodine value is not less than 98.0 percent and not more than 102.0 percent of C21H24FN3O4 · HCl, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight, light-resistant containers. Store at room temperature.

USP Reference standards (11)—

Moxifloxacin Hydrochloride RS

Moxifloxacin Related Compound A RS

Moxifloxacin Related Compound B RS

Moxifloxacin Related Compound C RS

Microbial enumeration tests (61) and Tests for specified microorganisms (62)—The total aerobic microbial count does not exceed 1000 cfu per g, and the total combined molds and yeasts count does not exceed 100 cfu per g.

pH (791) between 3.9 and 4.6, in a solution (0.2 in 100).

Water, Method II (921): not more than 4.5%.

Residue on ignition (281): not more than 0.1%.

Sulfate (221)—A 0.6-g portion shows no more sulfate than corresponds to 0.25 mL of 0.020 N sulfuric acid (0.04%).

Related compounds—[Note—Protect solutions from light.]

Mobile phase and Diluent—Prepare as directed in the Assay. Blank solution—Use the Diluent.

Resolution solution—Prepare as directed in the Assay. Sensitivity solution—Dilute an accurately measured volume of the Standard solution with Diluent to obtain a solution containing about 0.05 µg per mL. [Note—Store the Sensitivity solution under refrigeration and protected from light.]

Standard solution—Dilute an accurately weighed quantity of USP Moxifloxacin Hydrochloride RS in Diluent, and dilute quantitatively, and stepwise if necessary, with Diluent to obtain a solution having a known concentration of about 0.002 mg per mL.
Test solution—Use the Assay preparation.

Chromatographic system (see Chromatography (621))—Prepare the Chromatographic system as directed in the Assay. Chromatograph the Resolution solution, and record the peak responses as directed for Procedure: the resolution, R, between moxifloxacin and moxifloxacin related compound A is not less than 1.5. Chromatograph the Standard solution, and record the peak responses as directed for Procedure: the column efficiency using the moxifloxacin peak is not less than 4000 theoretical plates; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%. In addition, chromatograph the Sensitivity solution, and record the peak response as directed for Procedure. Confirm that the signal-to-noise ratio of the moxifloxacin peak is not less than 10.

Procedure—Separately inject equal volumes (about 25 µL) of the Blank solution, the Standard solution, and the Test solution into the chromatograph, record the chromatograms for at least 2 times the retention time of moxifloxacin, and measure the peak responses, disregarding any peaks corresponding to those obtained from the Blank solution. Calculate the percentage of each impurity in the portion of Moxifloxacin Hydrochloride taken by the formula:

\[
(C_i / C_s)(1/F)(100)(r_i / r_s)
\]

in which \(C_i\) is the concentration, in mg per mL, of USP Moxifloxacin Hydrochloride RS in the Standard solution; \(C_s\) is the concentration, in mg per mL, of Moxifloxacin Hydrochloride in the Test solution; \(F\) is the relative response factor for the individual related compound; \(r_i\) is the peak response of each individual impurity; \(r_s\) is the peak response of moxifloxacin in the Standard solution; and 100 is the conversion factor to percentage. The limits as shown in Table 1 are met.

<table>
<thead>
<tr>
<th>Related Compound</th>
<th>F</th>
<th>Relative Retention Time vs. Moxifloxacin</th>
<th>Limit (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxifloxacin related compound A1</td>
<td>1.0</td>
<td>1.15</td>
<td>0.1</td>
</tr>
<tr>
<td>6,8-Dimethoxy</td>
<td>0.71</td>
<td>1.32</td>
<td>0.1</td>
</tr>
<tr>
<td>8-Ethoxy</td>
<td>1.0</td>
<td>1.48</td>
<td>0.1</td>
</tr>
<tr>
<td>6-Methoxy-8-fluoro</td>
<td>1.0</td>
<td>1.71</td>
<td>0.1</td>
</tr>
<tr>
<td>8-Hydroxy</td>
<td>0.29</td>
<td>1.83</td>
<td>0.1</td>
</tr>
<tr>
<td>Other individual impurity</td>
<td>1.0</td>
<td>—</td>
<td>0.1</td>
</tr>
</tbody>
</table>

\(100(C_i / C_s)(1/F)(100)(r_i / r_s)\)

in which 100 is the conversion factor to percentage; \(C_i\) is the concentration, in mg per mL, of USP Moxifloxacin Hydrochloride RS in the Standard preparation; \(C_s\) is the concentration, in mg per mL, of Moxifloxacin Hydrochloride in the Assay preparation; and \(r_0\) and \(r_i\) are the peak responses obtained from the Assay preparation and the Standard preparation, respectively.

Moxifloxacin Ophthalmic Solution

» Moxifloxacin Ophthalmic Solution is a sterile, self-preserved aqueous solution of Moxifloxacin Hydrochloride. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of moxifloxacin (C₂₃H₂₇FN₃O₄·HCl).

Packaging and storage—Preserve in tight containers. Store between 2° and 25°.

USP Reference standards (11)—

USP Moxifloxacin Hydrochloride RS
USP Moxifloxacin Related Compound A RS

1-Cyclopropyl-8-difluoro-1,4-dihydroxy-6H-pyrrolo[3,4-b]pyridin-6-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid.

\(C_{23}H_{27}F_{2}N_{3}O_{4}\) 389.40

Identification—The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.