Here, \( k \) is the mass delivery rate (\( \mu \text{g/hr} \)), \( Q \) is the volume delivery rate (\( \mu \text{l/hr} \)), and \( C \) is the concentration (\( \mu \text{g/}\mu \text{l} \)) of the agent in the solution.

When the environment in which the pump is to be used differs significantly from that for which it was manufactured (body temperature and osmolality (310 milliosmols/l)), the pumping rate of ALZET pumps will be affected. (Consult the manufacturing data under special temperature and osmolality conditions, refer to the equation in Section VI.)

**II. Checklist for Satisfactory Performance of the ALZET**

1. Flow Moderator
   - Filling Tube
   - Dimensions, overall

2. Filling Tube
   - Diameter
   - Weight (empty)
   - Total Displaced Volume

**III. Instructions for Filling ALZET Micro-Osmotic Pumps**

If you desire the pump to start immediately, are working with a volatile substance, or if you wish to attach a catheter, incubate the pre-filled pump in sterile saliné at 37°C for at least 4 to 6 hours (preferably overnight), refer to Section VI part b for complete instructions.

**IV. Solvent and Agent Compatibility With ALZET Osmotic Pumps**

The pumps are compatible with aqueous solutions, dilute acids and bases, dilute or low concentrations of DMSO and alcohol, and up to 15% ethyl alcohol, ethylene glycol, polyethylene glycol, and ethylene glycolmonoethyl ether.

Polyethylene glycol 300 is compatible with all solvents, except polyethylene glycol 400 and potable water. Polyethylene glycol 400 is not compatible with all solvents, except polyethylene glycol 300.

Note that the solutions listed above are known to be compatible with the reservoir material of ALZET pumps, and caution is recommended. No compatibility is given for solutions containing organic solvents and fluids at the site of administration.

**Table 1**

<table>
<thead>
<tr>
<th>Solvents Known to Be Compatible With the Reservoir Material of ALZET Osmotic Pumps</th>
<th>Solvent</th>
<th>Compatibility</th>
<th>Compatibility Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohols</td>
<td>Ethanol, up to 15% in water</td>
<td>Compatible</td>
<td>No compatibility issues reported.</td>
</tr>
<tr>
<td>Aqueous solutions</td>
<td>Water, distilled</td>
<td>Compatible</td>
<td>No compatibility issues reported.</td>
</tr>
<tr>
<td>Oils</td>
<td>Mineral oil, up to 15%</td>
<td>Compatible</td>
<td>No compatibility issues reported.</td>
</tr>
</tbody>
</table>

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Note that the solutions listed above are known to be compatible with the reservoir material of ALZET pumps, and caution is recommended. No compatibility is given for solutions containing organic solvents and fluids at the site of administration.

**Note:**

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VIII. Verifying the Accuracy of ALZET Micro-Osmotic Pumps

To verify that experimental results are derived from continuous administration of the drug solution, DURECT recommends that ALZET® micro-osmotic pumps be operated at a constant rate (± 0.5% deviation from label rate) over a 800-168-hour (7 day) time period, each pump operates at a constant rate. Output from each pump is analyzed against a standard. Over the 4 to 800-hour period, the rate and within the period indicated when used in accordance with the written instructions delivered with such Product.

IX. Additional Technical Information About ALZET Osmotic Pumps

A. Technical Information Manual

To obtain any of these materials, or if you desire additional information, contact ALZET Technical Support:

• A Technical Information Manual
• A video demonstrating several surgical implantation procedures

ALZET micro-osmotic pumps are slightly larger than that required to assure pumping for the complete 7 days. As a result, at the end of the pumping duration some of the drug solution will remain in the pump. This solution can be aspirated from the pump using the supplied blunt-tipped filling tube and a 1.0 ml syringe. Recovery of the drug solution can be enhanced by flushing the resealable catheter end of the pump with 0.9% saline. The active agent in the solution which was recovered from the reservoir can then be assayed by an appropriate technique. To calculate the average pumping rate, the difference between the amount loaded and the residual amount in the pump is divided by the elapsed time.

Complete your worksheet as directed by the manufacturer. A random sample of 20 ALZET pumps is selected from the same lot of pumps which have been delivered; then the rate falls rapidly to zero. If the solvent you wish to use is not listed in Table 1, an ALZAID® Technical Information Manual is available from Sensient Colors, 2515 N. Jefferson, St. Louis, MO 63103; 1-800-335-8170 x4773; catalog #59601).

Once the catheter is flush with the surface of the pump. The syringe attached to the distal part of the catheter should cover about 3 - 4 mm of the length of the tube. Leave the syringe attached to the distal end of the catheter.

If the reservoir volume of ALZET micro-osmotic pumps is slightly larger than that required to assure pumping for the complete 7 days. As a result, at the end of the pumping duration some of the drug solution will remain in the pump. This solution can be aspirated from the pump using the supplied blunt-tipped filling tube and a 1.0 ml syringe. Recovery of the drug solution can be enhanced by flushing the resealable catheter end of the pump with 0.9% saline. The active agent in the solution which was recovered from the reservoir can then be assayed by an appropriate technique. To calculate the average pumping rate, the difference between the amount loaded and the residual amount in the pump is divided by the elapsed time.

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