**MINI-OSMOTIC PUMP MODEL 2002**

0.5 µL PER HOUR, 14 DAYS (Actual specifications vary by lot)

**REFERS TO ENCLOSED SPECIFICATIONS**

**STORE AT ROOM TEMPERATURE**

**CONTENTS:**
- Ten mini-osmotic pumps
- One filling solution bottle
- One instruction/specification sheet

**DURECT**

†DURECT Corporation, Cupertino, CA 95014

**ACTUAL SPECIFICATIONS**

**LOT NO.**

**MEAN PUMPING RATE**

MICROLITERS/HR.

**STANDARD Deviation**

MICROLITERS/HR.

**MEAN FILL VOLUME**

MICROLITERS

**STANDARD Deviation**

MICROLITERS

†The mass rate of drug infusion is calculated using the following equation: $\dot{m} = \frac{\Delta m}{\Delta t}$

††The drug to be delivered is soluble and stable in the vehicle solution at 37°C for the duration of the experiment.

†‡All ALZET pumps are filled completely and all fill volumes have been measured to within 0.01% accuracy.

†§ALZET® MINI-OSMOTIC PUMP MODEL 2002

**INSTRUCTION AND SPECIFICATION SHEET**

DURECT Corporation manufactures a miniature implantable pump for use in laboratory animals. The ALZET® Mini-Osmotic Pump Model 2002 delivers solutions continuously for at least 14 days without the need for replacement. It can be inserted into the body by way of a catheter or directly via a surgical implantation of mini-osmotic pumps (Refer to Section III for surgical procedure). If sterility of your solution is a concern, fill the pump in 70% isopropanol. (Refer to Section II for filling technique.)

It is essential that each pump is filled completely with solution and that correct filling is verified by the method detailed below. Air bubbles in the pump reservoir or failure to insert the flow moderator into the pump may result in unpredictable pumping rate fluctuations. Solutions should not be stored at room temperature during filling.

DURECT recommends that good sterile technique be used during the filling and handling of ALZET pumps and during the surgical procedure used to implant the pump. Always use the Actual Lot Specifications (Pumping Rate and Fill Volume) information when calculating drug concentration and dose.

**1. Technical Description of the ALZET Mini-Osmotic Pump Model 2002**

A complete Mini-Osmotic Pump System with Flow Moderator In Place

1. **Performance (at 37°C)**

Pump Reservoir Volume: refer to Actual Lot Specifications

2. Flow Moderator

**B. Components**

<table>
<thead>
<tr>
<th>Fluorinated Ethylene Propylene</th>
<th>Polytetrafluoroethylene</th>
</tr>
</thead>
<tbody>
<tr>
<td>O.D. (tube)</td>
<td>0.08 cm</td>
</tr>
<tr>
<td>L.D. (tube)</td>
<td>0.02 cm</td>
</tr>
<tr>
<td>Length (overall)</td>
<td>2.4 cm</td>
</tr>
<tr>
<td>Length (tube only)</td>
<td>2.2 cm</td>
</tr>
</tbody>
</table>

**C. Flow Parameters**

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

The pumps are compatible with aqueous solutions, dilute acids and bases, up to 15% and water

**E. Instructions for Filling ALZET Mini-Osmotic Pumps**

**Table 1**

| List of Solvents Compatible With the Reservoir Material of ALZET Osmotic Pumps
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Acids, with pH greater than 1.8</td>
</tr>
<tr>
<td>Alcohols, up to 20% by volume</td>
</tr>
<tr>
<td>Aqueous solutions, dilute acids and bases, up to 15%</td>
</tr>
</tbody>
</table>
If the solvent you wish to use is not listed in Table 1, one must estimate the pump performance in the system of interest. For a given solvent, the ratio of the pump's initial rate in saline to its rate in water

\[ Q_{\text{water}} = Q_{\text{saline}} \left( \frac{0.9}{1.0} \right)^{0.6} \]

where \( Q_{\text{water}} \) and \( Q_{\text{saline}} \) are the initial rates in water and saline, respectively.

Appendix A

V.  Operation of the ALZET Mini-Osmotic Pump

A. In Vivo

1. Attach the stainless steel tube to a piece of polyethylene or vinyl tubing. A short stainless steel tube protruding from the white flange, 1/8 inch O.D. (English units) or 3 mm (metric units), is a good choice for most applications. After attachment, the pump is inserted into the pocket with the white flange facing up (Fig. 1). The syringe attached to the distal part of the catheter should be able to cover the entire length of the stainless steel tube above the white flange. The catheter should be kept tensed and the flange is closed with a wound clip or sutures. For experimental purposes, make a small midline incision in the skin below the rib cage of an animal weighing at least 150 g. Another small incision is made in the skin at the incision site under the cutaneous tissue. The pump is inserted into the peritoneal cavity. The incision is closed with sutures, and then the skin incision is closed with tape. Be sure to remove the pump upon completion of the delivery duration or by day 21* after implantation, if not specified otherwise. The expiration date is calculated based on nominal duration. Refer to the equation in Section IV to calculate the expiration date. After each implantation, the pump is checked for leaks, washout, and any other indication of pump failure. If the pump has been defective, it must be replaced, at no cost to the customer, of those units of Product that the replacement, at no cost to the customer, of those units of Product

2. The pump must be implanted subcutaneously or intraperitoneally. The specific site for implantation must be determined in isotonic saline at 37°C (± 0.5°C). In the event that the delivery rate is below the predicted range until all but about 5% of the reservoir contents have been delivered; then the rate falls rapidly to zero. The method DURECT uses to estimate the pumping rate of osmotic pumps is to measure their pumping rate in vitro at 0.9% saline at 37°C ± 0.5°C. This in vitro method gives a good measure of reproducibility – that the ALZET® Osmotic Pump (“Product”) is free from defects in design, material, or manufacture when used as intended by the user. The warranty provided by DURECT Corporation 7147090-15

The use of the ALZET Mini-Osmotic Pump With a Catheter is a reiteration of the use of the ALZET Osmotic Pump (“Product”) by the user. The replacement, at no cost to the customer, of those units of Product that have been defective.

The warranty is in lieu of all other warranties, express or implied, of merchantability and fitness for a particular purpose, which are hereby disclaimed. In the event that DURECT Corporation is unable to replace the ALZET® Osmotic Pump to the customer, DURECT Corporation shall have no further liability.

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