MINI-OSMOTIC PUMP MODEL 2002

0.5 µL PER HOUR, 14 DAYS

STANDARD DEVIATION

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When the environment in which the pump is to be used differs significantly from normal mammalian body temperature (37°C) and osmolality (310 mosmol/kg), the pumping rate of ALZET pumps will be affected. (To calculate the pumping rate under specific temperature and osmolality conditions, refer to the equation in Section VI.)

ALZET® MINI-OSMOTIC PUMP

Model 2002, should be removed upon completion of their delivery duration or by day 21* after implantation. After this time, there is no further control of drug delivery into the pump, it may swell and leak a concentrated salt solution, resulting in local inflammation around the pump. (*Refer to the equation in Section VI to calculate the exact delivery duration and maximum explantation date for this lot of mini-osmotic pumps.)

When back pressure is encountered, the filling tube can be cocked at a 90° angle to eliminate the filling. The filling system can also be widened slightly by moving the filling tube back and forth, or by inserting and removing the flow moderator several times before inserting the filling tube.

I. Technical Description of the ALZET Mini-Osmotic Pump

II. Components

3. Pump Body Materials

The vehicle-drug combination to be delivered is compatible with the MONITOR research animals or in vitro.

When filling, hold the pump in upright orientation. The length of time that a pump is at room temperature during filling and handling of ALZET pumps and during the surgical implantation procedure. If sterility of your solution is a concern, fill the pumps through a 0.22 µm syringe-end filter (e.g., Millex®-GV, Millipore Corporate Headquarters, 200 Concord Road, Billerica, MA 01821, 978-715-4321). Solutions should be at room temperature during filling.

TABLE 1

List of Solvents Compatible With the Reservoir Material of ALZET Osmotic Pumps

For solvents compatible with ALZET® pumps, contact: technical support at alzet@durect.com

For use only in laboratory animals. The ALZET mini-osmotic pump Model 2002 is compatible with a wide variety of solvents known to be compatible with the pump. Caution must be taken to avoid using solvents known to be incompatible with the pump.

For instructions on how to prepare the pump for veterinary applications, refer to Section VII.

3. Pump Body Materials

2. Components

3. Pump Body Materials

Water, distilled

Acids, with pH greater than 1 or less than 1.5

Bases, with pH less than 14

Note that the solvents listed above are known to be compatible with the reservoir material of the pump. Caution must be taken to ensure that each solvent does not become incompatible with tissues and fluids at the site of administration.
If the solvent you wish to use is not listed in Table 1, an ALZET® osmotic pump can be filled with another solvent and solvent compatibility with ALZET pumps. The lot you wish to use must be compatible with your experiment, existing agent and solvent compatibility with ALZET pumps. The lot you wish to use must be compatible with your experiment, existing agent and solvent compatibility with ALZET pumps. The lot you wish to use must be compatible with your experiment, existing agent and solvent compatibility with ALZET pumps. The lot you wish to use must be compatible with your experiment, existing agent and solvent compatibility with ALZET pumps. The lot you wish to use must be compatible with your experiment, existing agent and solvent compatibility with ALZET pumps. The lot you wish to use must be compatible with your experiment, existing agent and solvent compatibility with ALZET pumps. The lot you wish to use must be compatible with your experiment, existing agent and solvent compatibility with ALZET pumps.

To order an ALZET® kit, call 877-922-9398 (toll free in the U.S. and Canada).

A solution which generates gases within the pump during use makes the pump rate highly unpredictable. Also, solutions with precipitated solute particles must be filtered before use with osmotic pumps. DURECT strongly recommends the use of this test kit under the following circumstances:

1. When the solvent you wish to use is not listed in Table 1.
2. When the agent is in its free base form.
3. When the solvent you wish to use is not listed in Table 1 and intraperitoneal administration or injection is required.
4. When the agent is known to bind tenaciously to various polymeric materials.
5. When the agent is in its free base form.
6. When the solvent you wish to use is not listed in Table 1 and intraperitoneal administration or injection is required.
7. When the agent is known to bind tenaciously to various polymeric materials.

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This warranty is in lieu of all other warranties, express or implied, including warranties of merchantability and fitness for a particular purpose, which are hereby excluded. IN NO EVENT SHALL DURECT CORPORATION BE LIABLE FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY, INCLUDING BUT NOT LIMITED TO LOST PROFITS, BUSINESS INTERRUPTION, DATA LOSS OR THE LIKE.

VIII. Verifying the Accuracy of ALZET Mini-Osmotic Pumps

To verify that experimental results are derived from continuous administration of the drug solution, DURECT recommends that ALZET pumps be verified at regular intervals to prevent possible loss of drug due to the course of infusion. In the event that determination of circulating blood levels proves possible or is technically undesirable, several alternative techniques will verify correct delivery.

Note that neither a partially empty or discharged pump cannot be used to determine the quantity of drug delivered because the pump imbibes water during operation. Likewise, cutting open a spent pump is not a reliable means of verifying pump performance.

A. Determination of Average Pumping Rate

The ALZET Mini-Osmotic Pump is not a constant pump; the pumping rate is slightly larger than that required to assure pumping for the complete 14 days. As a result, the variance in rates for most applications. After attachment, the catheter should cover the entire length of the stainless steel tube above the white flange.

To fill the catheter and attached stainless steel tube using a syringe, Lea the syringe attached to the distal part of the catheter.

1. Following the instructions above (Section III), fill the ALZET pump.
2. Leave the syringe attached to the catheter, then the fluid flow will cease as the white flange is flush with the surface of the pump. The syringe attached to the distal end of the catheter can now be removed.

3. Place the pump in a water bath at 37°C for at least 4-6 hours (preferably overnight). This will allow the pump to begin operating before implantation, and avoid any problems with occlusion or clotting in the catheter. This step is mandatory in all catheter applications. The pump and catheter can now be implanted.

IX. Additional Technical Information About ALZET Osmotic Pumps

A wealth of information on ALZET osmotic pumps and their uses is available through DURECT Technical Support. To support this complementary service you can request:

• A video of commonly used surgical implantation procedures
• Custom searches of the ALZET osmotic pump bibliography of publications
• Presentation materials for authors presenting their work
• Technical Information Bulletins
• ALZET® osmotic pumps and their uses are available from ALZET Technical Support. (Contact ALZET Technical Support at 408-865-1406 (Facsimile) 800-692-2990 (U.S. and Canada), or P.O. Box 530 Cupertino, CA 95015-0530)

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