The mass rate of drug infusion is calculated using the following equation:

\[ \text{Flow Rate} = \frac{Q \cdot C}{V} \]

where \( Q \) is the pump rate of solution, \( C \) is the concentration of the drug, and \( V \) is the reservoir volume. This equation assumes that the reservoir volume is constant and that the drug is dissolved in a compatible solvent.

For in vitro testing, if the drug solution is not compatible with the pump, the pump may not be used until the drug solution has been replaced. For in vivo testing, if the drug solution is not compatible with the pump, the pump may not be used until the drug solution has been replaced.

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If the solution you wish to use is not listed in Table 1, on a ALZET® chemical compatibility test kit, follow the manufacturer’s instructions and solvent compatibility with ALZET pumps. The test kit provides you with a qualitative assessment of the solute compatibility with your selected vehicle and vehicle-borne solutes and with ALZET pumps. The test kit provides you with a qualitative assessment of the solute compatibility with your selected vehicle and vehicle-borne solutes and with ALZET pumps. The following equation can be used to predict the pumping rate in in vitro conditions, where the bulk of the infused solution is well-mixed and the rate of osmolality and temperature change is slow.

\[ Q = Q_0 \left[ 0.135 e^{0.054T} - 0.004 \right] \]

where:
- \( Q \) is pumping rate in µl/hr,
- \( Q_0 \) is specified pumping rate in µl/hr as given in the specifications,
- \( T \) is environmental temperature in °C.

The following equation can be used to predict the pumping rate in in vivo conditions, where the infused solution is not well-mixed and the rate of osmolality and temperature change is rapid.

\[ Q = \frac{V}{P} \cdot \frac{1}{t} \]

where:
- \( V \) is fill volume in µl,
- \( P \) is osmotic pressure (atm),
- \( t \) is time in hours.

For a period of 12 months from date of shipment, DURECT warrants that the ALZET Mini-Osmotic Pump (“Product”) is free from defects in materials and workmanship, and will, on average, deliver its contents at a uniform delivery rate. DURECT’s sole and exclusive remedy for any breach of warranty shall be, at DURECT’s option, either a refund or repair of the Product. If a refund is elected by the customer, DURECT will (a) credit the purchase price paid by the customer for the defective Product; (b) pay all reasonable costs of return of the Product to DURECT; and (c) pay all reasonable costs of repair of the Product. DURECT Corporation 7147080-14

VII. Verifying the Accuracy of ALZET Mini-Osmotic Pumps

To verify that experimental results are derived from continuous administration of the correct amount of drug, ALZET recommends that all ALZET Mini-Osmotic Pump users verify the biosoluble drug of bivalent microspheres at several points during the course of infusion. This procedure will also be used to verify if the drug concentrations in the solution levels is not possible or is technically undesirable, users should measure the output of the pump by flushing the reservoir with a blunt-end filling tube attached to a syringe to aspirate the remaining solution and measure the volume. 

1. Place the pump in sterile 0.9% saline at 37°C for at least 4-6 hours (preferably overnight) so that the pump will begin to operate before beginning implantation, and minimize the changes of an occlusion or clogging forming in the catheter. This step is mandatory in all catheter applications. The pump and catheter can now be implanted.

2. Determine of Average Pumping Rate

The reservoir volume of ALZET mini-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 reservoir and will be removed from the pump using the supplied blunt-tipped filling tube and a 1 ml syringe. Recovery of the drug solution will be assured by flushing the reservoir with additional saline. The active agent in the solution which was recovered from the reservoir can then be assayed using an appropriate technique. To calculate the average pumping rate, the difference between the amount of drug loaded into the reservoir and the residual amount in the pump is divided by the elapsed time.

3.  Fill the ALZET pump with the indicator solution according to Section B.

4. Place the ALZET pump into a 10 ml test tube prefilled with 7 ml of isotonic saline and pre-incubated at 37°C (± 0.5°C). Cap the tube to prevent evaporation.  

5. Repeat step 5 for 7 days.

6. Stop Repeat Step 5 for 7 days. 

7. Record the time of the starting the incubation.

8. Transfer the ALZET pump to a new test tube filled with 7 ml of isotonic saline and pre-incubated at 37°C (± 0.5°C). Cap the tube to prevent evaporation.

9. Record the time of the starting the incubation.

10. Stop Repeat Step 5 for 7 days.

11. A determination of indicator in each test tube against a standard of known concentration to determine the amount of indicated agent delivered using an appropriate technique. The amount of drug delivered is then divided by the time interval in hours to obtain the hourly pumping rate. 

For a 12 month period from date of shipment, DURECT warrants that the ALZET Mini-Osmotic Pump (“Product”) is free from defects in materials and workmanship, and will, on average, deliver its contents at a uniform delivery rate. DURECT’s sole and exclusive remedy for any breach of warranty shall be, at DURECT’s option, either a refund or repair of the Product. If a refund is elected by the customer, DURECT will (a) credit the purchase price paid by the customer for the defective Product; (b) pay all reasonable costs of return of the Product to DURECT; and (c) pay all reasonable costs of repair of the Product.