User Guide

mdi Stericheck – SVP Dilutor

for Vials with Difficult to Dissolve Powders

Advanced Microdevices Private Ltd.
20-21 Industrial Area, Ambala Cantt - 133006, India
Tel: 0171 - 2699290, 2699274 **Fax**: 0171 - 2699221, 2699008
Mail: info@mdimembrane.com **Web**: www.mdimembrane.com

1. Introduction

Sterility testing is critical to quality control of sterile pharmaceutical product manufacture and has become all the more important because of the regulatory and commercial considerations. International pharmacopoeias recommend use of procedures that ensure elimination of secondary contamination for accurate and reproducible results.

As per USP "Pharmacopeial articles are to be tested by the Membrane Filtration method where the nature of the product permits". The membrane filtration method involves filtration of samples drawn from an aseptically manufactured product lot through the membrane filter followed by washing away of any growth inhibiting substances, cutting the membrane filter into two equal halves and incubating these in nutrient media suitable for growth of aerobic and anaerobic microorganisms.

The sterility of the lot under test is confirmed only if no growth is observed after the specified number of days of incubation. The USP also states that the presence or absence of microbial growth observed as turbidity should not be due to any external contamination (false positives) or presence of any inhibitory substances (false negatives).

Such situations that compromise the reliability of the test is a serious issue as retesting has very limited scope and frequent investigations and revalidations is a highly undesirable activity.

Therefore it is very important for the microbiologist to prevent the presence of any inhibitory substances such as difficult to dissolve antibiotic powders, which may settle on the surface of the membrane and ultimately inhibit the growth of microorganisms which may be present in the drug sample.

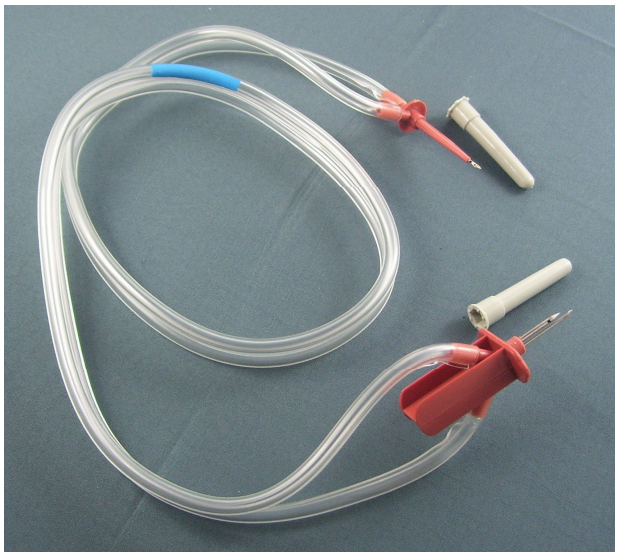
This guide describes the procedure for use of **mdi** SVP Dilutor, the facilitating device for sterility testing of difficult to dissolve powders in vials. This device helps dissolve these powders and the fully dissolved drug is then tested using **mdi** Stericheck SVP1, the sterility testing device for vials.

2.
SVP Dilutor

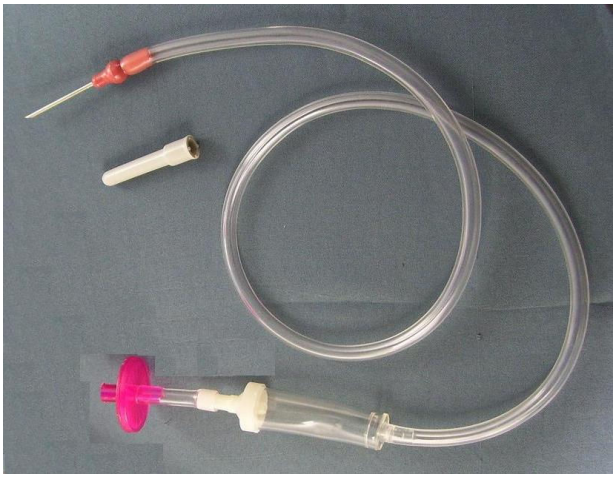
mdi Stericheck SVP Dilutor is used for antibiotics and difficult to dissolve powders in vials. The SVP Dilutor has a 2 way needle set connecting the diluent bottle to the product vial. The circulation of the diluent from the diluent bottle to the product vial allows complete dissolution of the difficult to dissolve drug sample and therefore prevents presence of un-dissolved residual drug particles in the Stericheck canisters. This eliminates the possibility of any inhibitory effect on the growth of microorganisms.

Specifications

Material of Construction of SVP Dilutor	
Tubing	PVC, plain transparent
Needle	Stainless Steel
Filter on Vented expansion chamber	0.2 µm PTFE Membrane
Tubing Length	850 mm
Sterilization	ETO sterilized
Maximum Operating Temperature	45°C continuous
Maximum Operating Pressure	45 psi



Pic. 1 SVP Dilutor : Tubing with Needle Connections



Pic. 2: Vented Expansion Chamber

3. Procedure of Use

3.1 Using **SVP Dilutor:** The set-up requirements and steps to be sequentially followed for using SVP Dilutor are as below.

Requirements:

a. mdi Steripump

b. SVP Dilutor pack, presterilized

c. Product to be tested

d. Aseptic laboratory environment

e. Diluent as recommended in referred pharmacopoeia – USP/EP/IP/Other

Steps

A. Set up the Steripump

B. Position the SVP Dilutor on the pump

C. Prepare the product samples to be tested

D. Dilute the product

A. Set up the Steripump:

Set up the peristaltic pump. Please refer to Steripump User Manual for more details.

Pic.3: mdi Steripump Unit

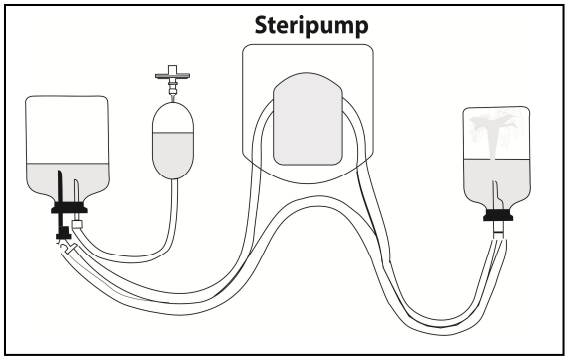
B. Position the SVP Dilutor and Tubing on the Pump:

- Open the pre-sterilized plastic tray that contains the SVP Dilutor set by peeling back the lid in an aseptic environment.

- Remove the SVP Dilutor set from the plastic tray.

Important:

- The middle section of the double tubing for the SVP Dilutor is separated into two single lines of tubing. One of the single lines of tubing has a blue marking and one does not. The line without the blue marking will be loaded into the pump head.



Pic. 4: Schematic Set-up of Stericheck SVP Dilutor

- Insert the Single line of tubing (without the blue marking) into the pump head starting from left to right, with the LVP-type needle on the left side of the pump and the SVP Dilutor product needle on the right side of the pump.

Caution:

- *Do not insert the other line of tubing (with blue marking) in the pump head. This line of tubing mounts outside the pump.*

C. Prepare the Product Samples to be Tested:

Please refer United States Pharmacopoeia (USP)/ European Pharmacopoeia (EP)/ any other international pharmacopoeia for information on the diluent you should use for your application:

I. Swab the surfaces of the product vial with an approved disinfectant, specially the rubber septum which you will pierce with the needle.

II. Disinfect the rubber septum of the diluent fluid bottle as well.

III. Remove the protective cap from the LVP-type needle, and insert it aseptically into the diluent bottle.

IV. Aseptically insert the expansion chamber needle into the diluent bottle. Make sure that the expansion chamber is positioned vertically above the top liquid level in the diluent bottle while it is in the bottle support.

V. Insert the SVP Dilutor product needle aseptically into the upright product vial.

D. Dilute the Product:

To dilute your product in vials:

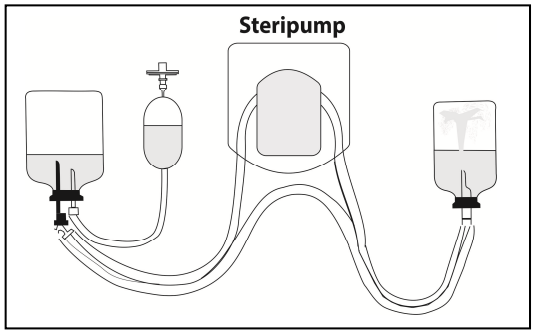
I. Switch on the Steripump unit.

II. Set the pump speed at ≤ 50.

III. Invert the diluent fluid container and place it in the bottle support with the stabilizing bar firmly in place.

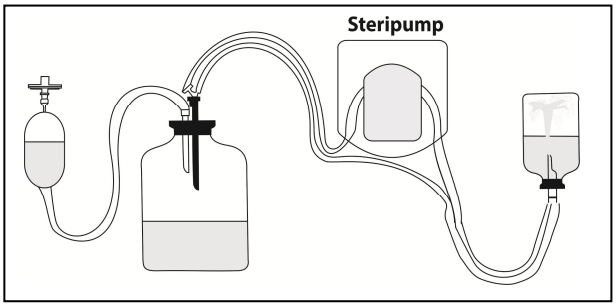
IV. Turn on the pump. If you are using the foot control accessory, press the pedal down with your foot.

V. Allow the diluent fluid to fill the vial. Now invert the sample vial to circulate the product through the diluent bottle and the product vial at a low pump speed.



Pic. 5: Indicative position of product container

VI. After the product is fully dissolved, remove the diluent bottle and place it upright on your work station. Continue pumping until the tubing and product vial are clear of product and all liquid returns to the diluent fluid container.



Pic. 6: Indicative position of product container

VII. Turn off the pump and place the product vial upright on your work station.

VIII. Place the second product vial you want to dissolve and dilute next to the first vial. Decontaminate the vial cap septum before diluting.

IX. Remove the non-vented, SVP Dilutor needle from the first vial and aseptically insert it into the second vial.

Caution:

- *If you are using a flame, quickly flame the needle and allow it to cool before inserting it into the next bottle.*

X. Turn on the pump.

XI. Invert the diluent fluid container and place it in the bottle support as before.

XII. Repeat steps 2-9 until the last sample in the lot is dissolved and transferred to the diluent bottle.

The product sample now pooled in the diluent bottle can be tested for sterility using **mdi** Stericheck SVP 1.