TECHNICAL REPORT

ISO/TR 19727

First edition
2017-08

Medical devices — Pump tube spallation test — General procedure

Dispositifs médicaux — Essai de spallation des tubes de pompes — Mode opératoire général

Reference number
ISO/TR 19727:2017(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

Medical devices — Pump tube spallation test — General procedure

1 Scope

This document provides a method of measuring, analysing and assessing the particle shedding from an infusion pump set during pumping.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Materials and equipment

The following materials and equipment are needed for the test set-up.

— IV-fluid container, container or bag with IV-fluid. A container with high volume is preferable. Maybe several containers or bags are needed depending on volume, flow rate and test time. If a glass or rigid container is used, the container should be sufficiently vented. No air born particles enters the container. Recommendation for the IV-fluid is a 0,9 % NaCl solution.

— IV-filter with 0,2 µm pore size or less which is vented. Several IV-filters may be need depending on the number of IV-fluid container.

— Distributor 1, e.g. electronically driven manifold or a manually driven stopcock manifold.

— Pump set to be tested.

— Infusion pump to be tested.

— Distributor 2, e.g. electronically driven manifold or a manually driven stopcock manifold. The number of output of distributor 2 is $N = N_r + N_s + 1$, where N_r is the number of reference containers, N_s is the number of sample containers and "+1" for the waste container.

— Reference containers, container or bag to collect reference sample IV-fluid. Several containers or bags can be used to collect several reference samples. A container with a volume between 50 ml to 500 ml is preferable. If a glass or rigid container is used then the container should be sufficiently vented. No air born particles enter the container.

— Sample containers, container or bag to collect sample IV-fluid. Several containers or bags are needed depending on volume, flow rate and test time. A container with a volume between 50 ml to 500 ml is preferable. If a glass or rigid container is used then the container should be sufficiently vented. No air born particles enter the container.

— Waste container, container or bag with high volume, depending on volume of the IV-fluid used. A container with high volume is preferable. If a glass or rigid container then the container should be sufficiently vented.

— Timer, if manually driven distributors are used.

Sample containers and reference containers are identical and from the same production batch.

5 Identification

Remove pump set from package and mark each pump set with the date, the initials of tester, the Lab Test Request (LT) number and a reference number. Also note the reference number on a blank area of the set label.

6 Preparation

6.1 General

The test should be conducted at a temperature between (23 ± 2) °C. All IV-fluids, the test set-up, the pump set and the infusion pump should be stored at a temperature between (23 ± 2) °C for at least 24 h.

6.2 Pump set to be tested

Remove (e.g. cut off) the drip chamber of the pump set and replace it by a connector, e.g. female Luer lock, in order to connect the pump set with the distributor 1. The part with the new connector is called the input of the test pump set and the part with the original male Luer connector of the pump set is called the output of the test pump set.

7 Test setup

7.1 Close the distributor 1, no flow allowed.

7.2 Connect the following parts of the test setup according to Figure 1:

— IV-fluid filters to distributor 1;

— IV-fluid filter to IV-fluid container;

— distributor 1 to pump set input (former place of drip chamber);

— do not install pump set into pump;

— pump set output to distributor 2;

— distributor 2 to reference, sample and waste containers.

7.3 Hang up the IV-fluid containers with a height of (1 ± 0,1) m between IV-fluid containers output and pump input.

7.4 The height difference between pump output and sample container input is less than 30 cm.

7.5 Fill each line of the test set-up with IV-fluid by allowing flow from IV-fluid container to the waste container. No air bubble is in the fluid line.

7.6 Flush under gravity conditions (do not use pump) the test set-up from distributor 1 onward to the waste container with minimum 500 ml IV-fluid. Please consider the internal volume of the test set-up for the amount of flushing volume.

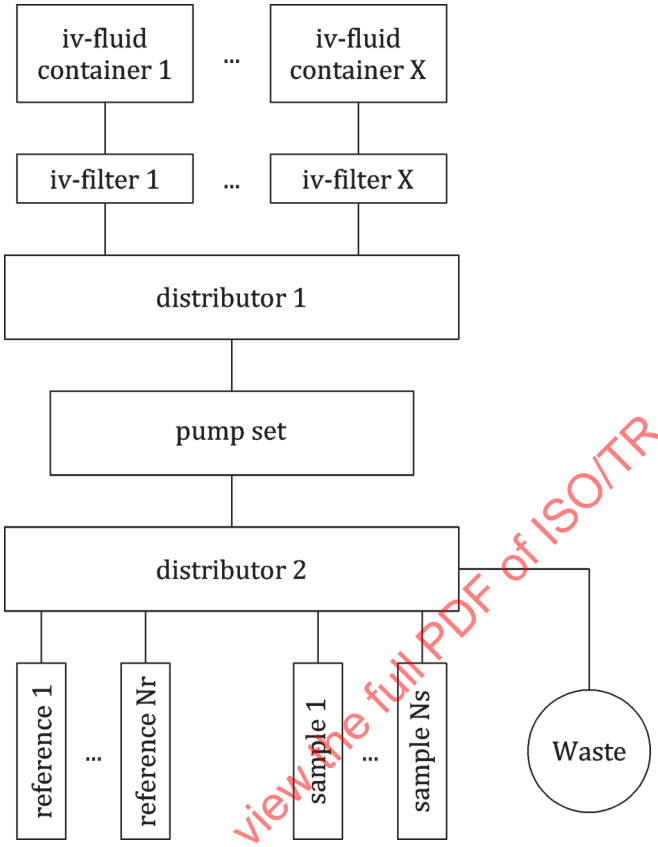

Figure 1 — Flow diagram of test setup

8 Test method

8.1 Sampling

8.1.1 Take reference sample by filling one or more reference sample containers under gravity conditions (do not use pump).

8.1.2 Install pump set into pump.

8.1.3 Set distributor 2 to sample container 1.

8.1.4 Start pump with desired flow rate.

8.1.5 Fill sample container 1, filling time t_s (min) = filling volume (l)/flow rate (l/min).

8.1.6 After sample container 1 is filled set distributor 2 to waste.

8.1.7 Fill waste container, filling time t_w (min).

8.1.8 Repeat steps 8.1.5 to 8.1.7 to fill the sample containers 2 to N_s.

8.1.9 After all sample containers are filled, shut off infusion pump, disconnect the sample container from distributor 2 and close the sample container.

The minimum volume of the IV-fluid ($V_{i,\,min}$) needed for this method is calculated using Formula (1):

$$V_{i,\,min} = \text{flow rate} \times N_s \times (t_s + t_w) + N_r \times V_r \quad (1)$$

where

flow rate is given in l/min;

N_s is the number of sample containers;

t_s is the filling time of the sample container in min;

t_r is the filling time of the reference container in min;

N_r is the number of reference containers;

V_r is the volume of the reference container in l.

This is considered for the selection of the IV-fluid and waste container volume as well as for the layout of the distributor 1.

8.2 Analysing

After 7.1, a number of sample containers (N_s) and reference containers (N_r) have been prepared. The particle concentration as well as the particle distribution of each container should be analysed using a method described in the USP or other corresponding national pharmacopoeia.

9 Test conditions and acceptance criteria

The flow rate to be tested is at least the maximum flow rate of the pump and a typical flow rate of the desired application. The running time of the pump $t_p = N_s \times (t_s + t_w)$. The running time is selected as follows:

a) maximum time for the desired application at maximum flow rate;

b) maximum time for the desired application at the typical flow rate.

The recommended number of samples (N_s) is 10 pieces for each running time.

The reference sample is understood as the blank value for the determination of the particle concentration and distribution.

The impact of the measured particle concentration and distribution is a subject within the framework of the product risk analysis. Risk evaluation can be supported by literature, e.g. pharmacopoeias.

