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.