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Aerosol drug delivery device design verification — Requirements and test methods

Vérification de la conception d'un dispositif d'administration de médicament sous forme d'aérosol — Exigences et méthodes d'essai

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 20072 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

Introduction

This International Standard applies to hand-held aerosol drug delivery devices (ADDD) intended to administer medication to humans. To avoid unnecessarily restricting innovation, given the broad variation in device designs, this International Standard addresses the more general design/labelling requirements rather than specific physical and prescriptive design requirements. However, this International Standard does require the elaboration of a device functionality profile (DFP) specific to the ADDD in question. This International Standard also addresses ADDD design requirements from both the user interface and safety perspectives.

An ADDD is used as part of a system consisting of the ADDD, the container, the medication and the labelling, including the instructions for use. Therefore, design verification of the ADDD includes a final system verification test conducted in accordance with the instructions for use.

From a regulatory perspective, the ADDD system may be reviewed and approved as part of a drug product (combination of ADDD and medication) or as a device by itself. For the purposes of this International Standard, such regulatory distinctions do not alter the intent of the design verification process described herein. As an example, in the European Union (EU), if an ADDD is placed on the market in such a way that the ADDD and the medication form a single integral product (i.e. the system) that is intended exclusively for use in the given combination and which is not refillable, that single product shall be governed by Directive 2001/83/EEC. However, the relevant essential requirements of Annex I of the Medical Device Directive (93/42/EEC) shall apply as far as safety and performance-related ADDD features are concerned, which is the specific objective of this design verification standard.

Regardless of the distinctions (“drug” or “device,” pre-filled or refillable), it is recognised that ADDD design verification is an important component of the overall validation process. Moreover, design verification is iterative, to be conducted at various phases throughout the ADDD’s development and subsequent ADDD post-approval modifications. In all instances, design verification is conducted using the phase-appropriate instructions for use. It is understood that in the early phases of ADDD development an appropriate subset of the requirements contained herein might apply, but that all of the requirements will be satisfied as part of the final design verification exercise. Furthermore, design verification should be considered a minimum requirement for the safe and effective use of the ADDD, and in many instances additional testing may be appropriate as indicated by a risk assessment that shall also be conducted.

This International Standard introduces the requirement for developers and/or manufacturers to create a device functionality profile (DFP) for a given ADDD based on the ISO Standard for device risk assessment (as a part of ISO 14971). The device functionality profile defines the parameters and tolerance intervals used to verify the ADDD's ability to meet the manufacturer's design specifications during in-use conditions and following environmental and electromechanical extreme use conditions. This International Standard also includes a system verification test conducted at standard atmosphere and nominal flow rate as a simple bridge between the device design and the patient interface.

The purpose of this International Standard is to ensure a method and guide for independent testing of the repeatability and reproducibility of ADDD functionality that verifies compliance with its design specification. The design verification process may include use of applicable regulatory agency requirements and/or test methods. The sampling plans for this International Standard are intended to verify the design at a high confidence level. They do not replace the more general manufacturing quality systems, including lot release, which appear in standards on quality systems (e.g. the ISO 9000 series or ISO 13485).

Figure 1 illustrates the process this International Standard advises to use in order to assess and verify whether a design meets the determined DFP.

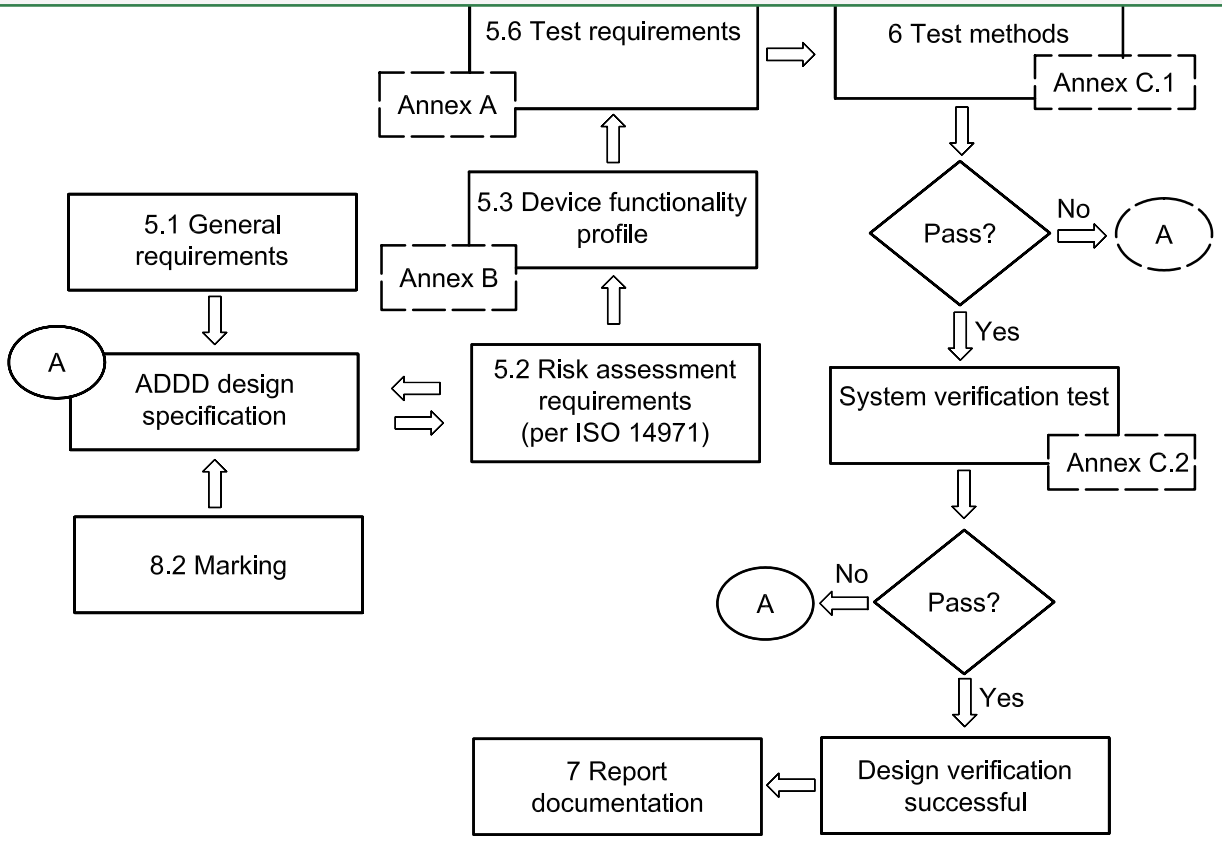

Figure 1 — ADDD design verification process

This International Standard specifically addresses the most basic elements regarding the safe and effective use of ADDD in humans. It does not define the pharmaceutical or clinical performance of an ADDD. Any labelling indicating ADDD use to deliver medication to specific regions of the respiratory tract falls under the authority of national governments or regional agencies regulating the manufacture and marketing of medical devices and pharmaceutical products. In some countries national regulations exist, and their requirements can supersede or complement this International Standard.

For a given manufacturer, existing marketed products and those currently under development might not fulfil some of the requirements. However, manufacturers should comply with this International Standard when improving the functional design of existing ADDDs or developing new ADDDs to obtain an even higher level of quality.

Annex A describes the reasoning for establishing the various requirements in this International Standard.