Sterile hypodermic syringes for single use —
Part 1: Syringes for manual use

Seringues hypodermiques stériles, non réutilisables —
Partie 1: Seringues pour utilisation manuelle
Contents

Foreword ....................................................... v
Introduction .................................................. vi

1 Scope ......................................................... 1
2 Normative references ................................. 1
3 Terms and definitions ................................. 1
4 Nomenclature ............................................. 3
5 General requirements ................................. 5
6 Extraneous matter ....................................... 5
   6.1 General ................................................. 5
   6.2 Limits for acidity or alkalinity .................. 5
   6.3 Limits for extractable metals .................. 5
7 Lubricant .................................................... 6
8 Tolerance on graduated capacity .................. 6
9 Graduated scale .......................................... 7
   9.1 Scale .................................................... 7
   9.2 Numbering of scales ............................... 8
   9.3 Overall length of scale to nominal capacity line .... 8
   9.4 Position of scale ..................................... 9
10 Barrel ....................................................... 9
   10.1 Dimensions ......................................... 9
   10.2 Barrel flanges ....................................... 9
11 Plunger stopper/plunger assembly ............... 9
   11.1 Design ............................................... 9
12 Nozzle ...................................................... 10
   12.1 Conical fitting ...................................... 10
   12.2 Position of nozzle on end of barrel .......... 10
   12.3 Nozzle lumen ...................................... 10
13 Performance ............................................. 10
   13.1 Dead space .......................................... 10
   13.2 Freedom from air and liquid leakage past plunger stopper .... 10
   13.3 Force to operate the piston .................... 10
   13.4 Fit of plunger stopper/plunger in barrel .... 10
14 Packaging ............................................... 11
   14.1 Unit packaging and self-contained syringe units .... 11
      14.1.1 Unit packaging .................................. 11
      14.1.2 Self-contained syringe units ............... 11
   14.2 Multiple unit packs .................................. 11
   14.3 User packaging ..................................... 11
15 Information supplied by the manufacturer ...... 12
   15.1 General .............................................. 12
   15.2 Syringes ............................................. 12
      15.2.1 General .......................................... 12
      15.2.2 Additional marking for self-contained syringe units ... 12
   15.3 Unit packaging ...................................... 12
   15.4 Multiple unit packs ................................ 13
      15.4.1 General .......................................... 13
      15.4.2 Multiple unit packs with self-contained syringes ... 13
   15.5 User packaging ..................................... 13
15.6 Storage container .............................................. 14
15.7 Transport wrapping ........................................... 14

Annex A (normative) Method for preparation of extracts ............................................. 15
Annex B (normative) Test method for air leakage past syringe plunger stopper during aspiration, and for separation of plunger stopper and plunger .................................................... 16
Annex C (normative) Method for determination of dead space ..................................... 18
Annex D (normative) Test method for liquid leakage at syringe plunger stopper under compression .................................................................................................................. 19
Annex E (informative) Test method for the determination of forces required to operate the piston .......................................................................................................................... 21
Annex F (informative) Test method for the quantity of silicone ....................................... 25

Bibliography .................................................................................................................... 28
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b) added new Normative references;

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k) informative annex on materials has been deleted.

A list of all parts in the ISO 7886 series can be found on the ISO website.
Introduction

The ISO 7886 series covers hypodermic syringes primarily intended for human use and provides performance and testing requirements. It permits broader variation in design so as not to limit innovation and methods of packaging. Its appearance and layout are consistent with other related standards which are designed to be more performance-based compared to design prescriptive.

General requirements as design guidelines for manufacturers are introduced in this document. Several limits for requirements which are historic based but confirmed in practice for many years have been kept.

Materials to be used for the construction and lubrication of sterile syringes for single use are not specified as their selection will depend to some extent upon the design, process of manufacture and sterilization method employed by individual manufacturers. The materials of the syringe should be compatible with injection fluids. If this is not the case, the attention of the user should be drawn to the exception by labelling on unit packaging. It is not practicable to specify a universally acceptable test method for incompatibility, as the only conclusive test is that an individual specific injection fluid is compatible with a specific syringe.

Manufacturers of pharmaceuticals use solvents in injectable preparations. Such solvents should be tested by the manufacturer of the injectable preparation for any possible incompatibility with the materials frequently used in syringe construction. If an incompatibility is identified, the injection fluid should be suitably labelled. The impossibility of testing any one injection fluid with all available syringes is recognized and it is strongly recommended that regulatory authorities and relevant trade associations should recognize the problem and take appropriate measures to assist manufacturers of injectable preparations.

Syringes should be manufactured and sterilized in accordance with recognized national or international codes of good manufacturing practice for medical devices.

The sampling plans for inspection selected for the ISO 7886 series are intended to verify the design at a high confidence level. The sampling plans for inspection do not replace the more general manufacturing quality systems requirements that appear in standards on quality systems, for example the ISO 9000 series and ISO 13485.

Manufacturers are expected to follow a risk-based approach and employ usability engineering during the design, development and manufacture of syringes.

Guidance on transition periods for implementing the requirements of ISO 7886 (all parts) is given in ISO/TR 19244.
# ISO 7886-1:2017(E)

This is a preview of "ISO 7886-1:2017". Click here to purchase the full version from the ANSI store.

## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreword</td>
<td></td>
<td>v</td>
</tr>
<tr>
<td>Introduction</td>
<td></td>
<td>vi</td>
</tr>
<tr>
<td>1</td>
<td>Scope</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Normative references</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Terms and definitions</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Nomenclature</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>General requirements</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Extraneous matter</td>
<td></td>
</tr>
<tr>
<td>6.1</td>
<td>General</td>
<td></td>
</tr>
<tr>
<td>6.2</td>
<td>Limits for acidity or alkalinity</td>
<td></td>
</tr>
<tr>
<td>6.3</td>
<td>Limits for extractable metals</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Lubricant</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Tolerance on graduated capacity</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Graduated scale</td>
<td></td>
</tr>
<tr>
<td>9.1</td>
<td>Scale</td>
<td></td>
</tr>
<tr>
<td>9.2</td>
<td>Numbering of scales</td>
<td></td>
</tr>
<tr>
<td>9.3</td>
<td>Overall length of scale to nominal capacity line</td>
<td></td>
</tr>
<tr>
<td>9.4</td>
<td>Position of scale</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Barrel</td>
<td></td>
</tr>
<tr>
<td>10.1</td>
<td>Dimensions</td>
<td></td>
</tr>
<tr>
<td>10.2</td>
<td>Barrel flanges</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Plunger stopper/plunger assembly</td>
<td></td>
</tr>
<tr>
<td>11.1</td>
<td>Design</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Nozzle</td>
<td></td>
</tr>
<tr>
<td>12.1</td>
<td>Conical fitting</td>
<td></td>
</tr>
<tr>
<td>12.2</td>
<td>Position of nozzle on end of barrel</td>
<td></td>
</tr>
<tr>
<td>12.3</td>
<td>Nozzle lumen</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Performance</td>
<td></td>
</tr>
<tr>
<td>13.1</td>
<td>Dead space</td>
<td></td>
</tr>
<tr>
<td>13.2</td>
<td>Freedom from air and liquid leakage past plunger stopper</td>
<td></td>
</tr>
<tr>
<td>13.3</td>
<td>Force to operate the piston</td>
<td></td>
</tr>
<tr>
<td>13.4</td>
<td>Fit of plunger stopper/plunger in barrel</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Packaging</td>
<td></td>
</tr>
<tr>
<td>14.1</td>
<td>Unit packaging and self-contained syringe units</td>
<td></td>
</tr>
<tr>
<td>14.1.1</td>
<td>Unit packaging</td>
<td></td>
</tr>
<tr>
<td>14.1.2</td>
<td>Self-contained syringe units</td>
<td></td>
</tr>
<tr>
<td>14.2</td>
<td>Multiple unit pack</td>
<td></td>
</tr>
<tr>
<td>14.3</td>
<td>User packaging</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Information supplied by the manufacturer</td>
<td></td>
</tr>
<tr>
<td>15.1</td>
<td>General</td>
<td></td>
</tr>
<tr>
<td>15.2</td>
<td>Syringes</td>
<td></td>
</tr>
<tr>
<td>15.2.1</td>
<td>General</td>
<td></td>
</tr>
<tr>
<td>15.2.2</td>
<td>Additional marking for self-contained syringe units</td>
<td></td>
</tr>
<tr>
<td>15.3</td>
<td>Unit packaging</td>
<td></td>
</tr>
<tr>
<td>15.4</td>
<td>Multiple unit packs</td>
<td></td>
</tr>
<tr>
<td>15.4.1</td>
<td>General</td>
<td></td>
</tr>
<tr>
<td>15.4.2</td>
<td>Multiple unit packs with self-contained syringes</td>
<td></td>
</tr>
<tr>
<td>15.5</td>
<td>User packaging</td>
<td></td>
</tr>
</tbody>
</table>

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