BS EN 15384-1:2017

BSI Standards Publication

Packaging — Test method to determine the porosity of the internal coating of flexible aluminium tubes

Part 1: Sodium chloride test

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National foreword

This British Standard is the UK implementation of EN 15384-1:2017. Together with BS EN 15384-2:2017, it supersedes BS EN 15384:2007 which is withdrawn.

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A list of organizations represented on this subcommittee can be obtained on request to its secretary.

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English Version

Packaging - Test method to determine the porosity of the internal coating of flexible aluminium tubes - Part 1: Sodium chloride test

Emballage - Méthode d'essai pour déterminer la porosité du revêtement intérieur des tubes souples en aluminium - Partie 1 : Méthode au chlorure de sodium

Packmittel - Prüfverfahren zur Bestimmung der Porosität der Innenbeschichtung von Aluminiumtuben - Teil 1: Natriumchlorid-Verfahren

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Page

European foreword

This document (EN 15384-1:2017) has been prepared by Technical Committee CEN/TC 261 "Packaging", the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2017, and conflicting national standards shall be withdrawn at the latest by July 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 15384:2007.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

1 Scope

This European Standard is applicable for internally coated cylindrical and conical aluminium tubes, mainly used for the packing of pharmaceutical, cosmetic, hygiene, food or other household products.

The internal coating is used as a barrier and should avoid any contact between aluminium and the product. This standard defines the sodium chloride method to detect the electrolyte conductivity as one criterion for the quality of the internal coating.

NOTE The electrolyte conductivity of the internal coating is only one criterion for evaluation of the quality of an internal coating. It does not give any information on the quantity or size of any pores or uncoated areas, nor any hint on possible reactions between the aluminium tube and the product.

The electrolyte conductivity should never be used as the sole criterion for quality evaluation of the internal coating, but always with other parameters e.g. film thickness, acetone and/or ammonia resistance and of course results of enhanced stability studies.

2 Principle

The electrolyte conductivity of internally coated aluminium tubes is tested by an enamel conductometer. The aluminium tubes are filled with an electrolyte solution up to a fixed level at its open end. One electrode is connected to the tube nozzle, the second electrode is dipped into the solution. A defined voltage is applied for a fixed time. The induced current is a measure for the quality (pores and/or film thickness) of the internal coating.

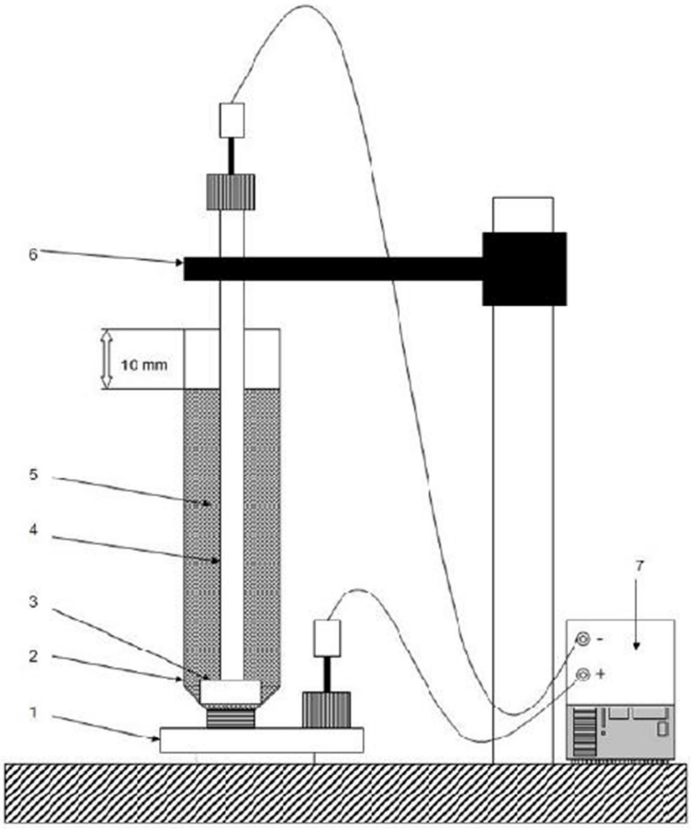
3 Apparatus

3.1 Enamel conductometer

3.2 Moveable electrode

3.3 Electrolyte

NOTE A schematic diagram of the test equipment is given in Figure 1.



Key

1 electrode (positive pole)
2 aluminium tube
3 insulating spacer
4 movable electrode (negative pole)
5 electrolyte
6 electrode holder
7 processor unit

Figure 1 — Test device

4 Procedure

All parameters having a significant influence on the test results for sodium chloride methods are listed in Table 1.

Table 1 — Test conditions for the sodium chloride method

Parameter	Sodium chloride method
Temperature	23 ± 2 °C
Voltage and measuring interval internal resistance	6 300 mV DC 4,0 s voltmeter 20 kΩ/V ammeter 2,5 Ω at 100 mA
Electrodes - polarity - material - diameter	dipping electrode is the negative pole dipping electrode stainless steel (a round insulating spacer of 5 ± 2 mm has to be mounted on the bottom of the electrode to avoid direct contact between electrode and tube shoulder) adapter electrode stainless steel 6 mm ± 0,3 mm for all tube sizes
Electrolyte	Sodium chloride solution (10,2 ± 0,01) g Sodium chloride p.a. NaCl, CAS [a] 7647–14–5 Dissolve the NaCl in deionized water and make up to (1 000 ± 2) ml with deionized water.
[a] CAS is Chemical Abstracts Service – CAS registry numbers are unique numerical identifiers for chemical compounds, polymers, biological sequences, mixtures and alloys.	

Depending on the method and the kind of apparatus (different apparatus are available) specific adjustments and calibrations may be necessary and should be done as described in the user manuals prior to use. To take a measurement put the tube into the adapter electrode, ensuring there is an electric circuit between the tube and electrode. Insert the dipping electrode centrally into the tube until it touches the tube shoulder, avoiding any contact between the tube wall / tube shoulder and the dipping electrode. Fill the tube with electrolyte up to 10 mm from the end after inserting the electrode. Start the measurement – application of voltage – immediately. Read the result in mA on the display after the measuring interval. The electrolyte can be used for testing 10 tubes. Measurements on one tube are repeatable.

5 Tolerances

The tolerances given in this standard are based on long-term experiences and are valid only for membrane tubes. For tubes with special conification angles and nozzles, e.g. without membrane or cannula, higher tolerance limits may be required.

In addition, for some specific internal coatings but also depending on the product, different tolerance limits may be required. Any deviations from this standard shall be agreed mutually between both parties.

Tolerances for the sodium chloride method are given in Table 2:

Table 2 — Tolerances for the sodium chloride method

Tube diameter Ø [mm]	**Maximum electrolyte conductivity [mA]**			
	Cylindrical tubes		**Conical tubes**	
	Mean value	Single value	Mean value	Single value
Ø ≤ 20	10	25	15	30
20 < Ø ≤ 30	15	30	20	40
30 < Ø ≤ 40	20	40	25	50
40 < Ø ≤ 45	25	50	30	60
45 < Ø ≤ 50	35	80	-	-

NOTE 1 Test apparatus from different suppliers may give different results. In this case, comparative measurements and correlations factors may be required.

NOTE 2 The tolerances given in Table 2 are only valid for standard tubes and not for tubes with additional treatment such as sterilization.

6 Test report

Unless otherwise agreed between both parties the test report shall contain the following information:

a) reference to this standard and – if necessary – a specification for the method of sampling and acceptance of the batch,

b) complete identification of the batch and of the tubes checked,

c) description of the samples,

d) registering number of the apparatus and the selected test parameters,

e) type of internal coating,

f) test results,

g) number of tested tubes,

h) number of defects,

i) if applicable the decision for acceptance or rejection,

j) all factors, that may have had an influence on the test results and which are not covered by this standard,

k) date, place and name of the inspector.

Bibliography

[1] EN 12374, *Packaging - Flexible tubes - Terminology*

[2] EN 13046, *Packaging - Flexible cylindrical metallic tubes - Dimensions and tolerances*

[3] EN 13047, *Packaging - Flexible conical metallic tubes - Dimensions and tolerances*

[4] ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

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