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Dentistry — Pre-capsulated dental amalgam

Médecine bucco-dentaire — Amalgame dentaire en capsules prédosées

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Foreword

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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 document 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).

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For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 20749:2017), which has been technically revised.

The main changes are as follows:

— a requirement for corrosion resistance has been added;

— the roughness measure used to specify the finish required on working surfaces of test piece moulds has been changed from R_k to R_a;

— an instruction to abrade lightly the ends of the cylindrical test pieces, if required, for removing flash has been deleted;

— the requirement for early compression fracture stress has been altered; measurement of the value is made at 2 h and not at 1 h;

— the thickness of the sheet specified for the mould to test for the consistency of dental amalgam from capsule to capsule has been reduced to 2,5 mm;

— a 20 min cooling time before weighing has been added for the determination of the yield of dental amalgam from a capsule;

— additional items of information have been added to each of the test reports;

— the edition number of the manufacturer's instructions and information, and the date of its introduction have been added as a requirement to the manufacturer's instructions;

— for each test method used to determine conformity to a requirement, a new subclause, "Principle", has been added in which a brief summary explains the method adopted;

— for each test method used to determine conformity to a requirement, a new subclause, "Report", has been added;

— a new Clause 7, "Report", has been added which provides details of the evaluation that are to accompany a statement of conformity to this document overall.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this document and it is recommended that, for the assessment of possible biological hazards, reference is made to ISO 10993-1 and ISO 7405.

Dentistry — Pre-capsulated dental amalgam

1 Scope

This document specifies the requirements and test methods for dental amalgam products supplied to the user in capsules, pre-dosed with dental amalgam alloy powder and dental mercury in quantities suitable for the creation of a single dental restoration.

This document specifies the requirements and test methods for the capsule and the requirements for packaging and marking.

This document is not applicable to other metallic materials in which an alloy powder reacts with an alloy that is liquid at ambient temperature to produce a solid metallic material intended for dental restoration.

This document is restricted to dental amalgam products marketed in pre-capsulated form, alone. Other products intended for use in the production of dental amalgam restorations (dental amalgam alloy as a free-flowing powder supplied in bulk masses, dental amalgam alloy powder supplied as compressed tablets and dental mercury sachets) are described in ISO 24234.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 286-2, *Geometrical product specifications (GPS) — ISO code system for tolerances on linear sizes — Part 2: Tables of standard tolerance classes and limit deviations for holes and shafts*

ISO 1942, *Dentistry — Vocabulary*

ISO 3310-1, *Test sieves — Technical requirements and testing — Part 1: Test sieves of metal wire cloth*

ISO 3864-2, *Graphical symbols — Safety colours and safety signs — Part 2: Design principles for product safety labels*

ISO 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000*

ISO 21920-2, *Geometrical product specifications (GPS) — Surface texture: Profile — Part 2: Terms, definitions and surface texture parameters*

ISO 7488, *Dentistry — Mixing machines for dental amalgam*

ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 23325:2020, *Dentistry — Corrosion resistance of dental amalgam*

Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations, New York and Geneva, 9th Revised Edition, 2021, eISBN 978-92-1-005213-9

Recommendations on the Transport of Dangerous Goods, Model Regulations. United Nations, New York and Geneva, 22st Edition (Vol.1), 2022, eISBN 978-92-1-005219-1

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

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

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

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

3.1
dental amalgam alloy
alloy in fine particles, composed mainly of silver, tin and copper, which when mixed with *dental mercury* (3.2) produces a dental amalgam for dental restoration

[SOURCE: ISO 24234:2021, 3.1]

3.2
dental mercury
mercury supplied for use in the preparation of dental amalgam

[SOURCE: ISO 24234:2021, 3.2]

3.3
pre-capsulated product
product supplied in a sealed capsule that contains measured amounts of *dental amalgam alloy* (3.1) powder and *dental mercury* (3.2) with masses that are appropriate for the production of a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth

Note 1 to entry: The dental amalgam alloy powder and dental mercury are separated by a barrier that is broken immediately prior to mixing, allowing their contact. The capsule remains sealed until mixing has been completed.

[SOURCE: ISO 24234:2021, 3.3]

3.4
self-activating capsule
pre-capsulated product (3.3) capsule in which contact between the *dental amalgam alloy* (3.1) powder and the *dental mercury* (3.2) occurs automatically during mixing

3.5
mechanically-activated capsule
pre-capsulated product (3.3) capsule in which force is applied to the ends of the capsule to rupture the barrier between the *dental amalgam alloy* (3.1) powder and the *dental mercury* (3.2) for *activation* (3.6), before placing the capsule in the mechanical mixing machine

3.6
activation
action that renders the capsulated *dental amalgam alloy* (3.1) powder and *dental mercury* (3.2) mixable

3.7
dental amalgam pellet
coherent mass of dental amalgam that is produced by mixing and either drops from the opened and upended capsule, or is dislodged from the same when the rim of the open capsule is tapped lightly on a hard surface

3.8
mixing machine for dental amalgam
DEPRECATED: amalgamator
electrically-powered mixing machine that operates using an oscillating action for mixing *dental amalgam alloy* (3.1) powder and *dental mercury* (3.2) (in a capsule) to produce a dental amalgam

[SOURCE: ISO 24234:2021, 3.6, modified — the word "powder" has been added in the definition.]

4 Requirements

4.1 Package and capsule contamination

The interior of the packaging container and the outer surface of the capsules shall be free of both dental mercury and dental amalgam alloy powder contamination when tested in accordance with 6.1.

4.2 Chemical composition and purity of the dental amalgam alloy

The manufacturer shall declare every element that is present in a concentration greater than, or equal to a mass fraction of 0,1 %. All alloying elements present in concentrations greater than a mass fraction of 0,5 % shall be given by name with mass fraction values rounded to the nearest whole percentage point. Alloying elements that are present in concentrations between a mass fraction of 0,1 % and 0,5 % shall be named without a percentage value.

Test in accordance with 6.2.

The chemical composition shall comply with Table 1.

The total mass fraction for other elements present in concentrations greater than a mass fraction of 0,01 % but below a mass fraction of 0,1 % that are not declared as alloying elements, shall not exceed a mass fraction of 0,1 %.

Table 1 — Requirements for chemical composition of the dental amalgam alloy

Element	Mass fraction %
Silver	≥40
Tin	≤32
Copper	≤30
Indium	≤5
Palladium	≤1
Platinum	≤1
Zinc	≤2
Mercury	≤3

4.3 Large particles in the dental amalgam alloy powder

When conformity to this requirement is determined in accordance with 6.3, the proportion of the dental amalgam alloy powder that occurs as particles that have a size greater than 150 µm shall not exceed a mass fraction of 0,1 %.

4.4 Loss of mass from the capsule during mixing

When conformity to this requirement is determined in accordance with 6.4, the mean loss in mass of dental mercury and dental amalgam alloy powder from a capsule (for the sample of 15 capsules), during mixing in accordance with the manufacturer's instructions, shall not exceed 0,5 mg.

Also, the loss from any one capsule shall not exceed 1 mg.

4.5 Yield of dental amalgam from the capsule

When conformity to this requirement is determined in accordance with 6.5, the mean mass of the pellet of dental amalgam obtained from a capsule (for the sample of 15 capsules) shall not be less than 95,0 %

of the sum of the manufacturer's stated masses for dental mercury and dental amalgam alloy powder in the capsule.

Also, no capsule shall yield a pellet of dental amalgam that is less than 90,0 % of the sum of the manufacturer's stated masses for dental mercury and dental amalgam alloy powder in the capsule.

There can be some small free pieces of dental amalgam as well as the pellet. These are available for use and are regarded as part of the yield, i.e. their mass should be added to that of the pellet.

4.6 Consistency of the dental amalgam from capsule to capsule

When conformity to this requirement is determined in accordance with 6.6, the mean value for the hardness of dental amalgam produced from the content of any one capsule shall not be less than 85 % of the overall mean value of the hardness of the dental amalgam obtained from a sample of 10 capsules.

The content of one capsule is used to make one test piece only.

The mean value for the hardness of a test piece is calculated from all measurements made on that test piece. The overall mean value for hardness is calculated from all measurements made on all 10 test pieces.

4.7 Properties of the dental amalgam

4.7.1 General

The following properties are required, regarding creep, dimensional change during hardening and compressive fracture stress.

Table 2 — Properties of the dental amalgam

Maximum creep	Permitted dimensional change during hardening	Minimum compressive fracture stress at 2 h	Minimum compressive fracture stress at 24 h
%	%	MPa	MPa
2,0	−0,10 to +0,15	100	350

4.7.2 Creep

When conformity to this requirement is determined in accordance with 6.7, the results for either three out of three or four out of five test pieces shall meet the requirement in Table 2.

4.7.3 Dimensional changes during hardening

When conformity to this requirement is determined in accordance with 6.7, the results for at least four out of five test pieces shall meet the requirement in Table 2.

4.7.4 Compressive fracture stress at 2 h

When conformity to this requirement is determined in accordance with 6.7, the results for at least four out of five test pieces or eight out of 10 test pieces shall meet the requirement in Table 2.

4.7.5 Compressive fracture stress at 24 h

When conformity to this requirement is determined in accordance with 6.7, the results for at least four out of five test pieces or eight out of 10 test pieces shall meet the requirement in Table 2.

4.8 Appearance of mixed dental amalgam before setting

When conformity to this requirement is determined in accordance with 6.8, the dental amalgam alloy and dental mercury being mixed according to the manufacturer's instructions, the dental amalgam shall form a coherent plastic mass with a shiny surface before packing and remain a coherent body after packing is completed.

4.9 Corrosion resistance of the dental amalgam

When conformity to this requirement is determined in accordance with 6.9, the mean value (in newtons) of 10 valid results for corrosion test pieces shall not be less than 80 % of the mean value (in newtons) of 10 valid results for control test pieces.

4.10 Length tolerance for the capsule

When conformity to this requirement is determined in accordance with 6.10, the overall length of the activated capsule shall be within ±1 mm of the length specified by the manufacturer. All 10 capsules in the sample tested shall meet the requirement.

5 Sampling

Procure material in packages that have been produced for retail and that are from a single lot.

Procure a sufficient number of capsules to conduct all the testing needed to evaluate the alloy, the capsules and to make the required number of dental amalgam test pieces, including the maximum number of test pieces allowed to replace any that are rejected.

NOTE The number of capsules required depends on the masses of dental amalgam alloy powder and dental mercury in each.

6 Test methods

6.1 Package and capsule contamination

6.1.1 Principle

Any loss of either component from a capsule between production and receipt by the user is of concern. Such a loss can be detected by visual examination of capsule and container surfaces at low power magnification.

6.1.2 Test sample

All the containers holding capsules from the sample procured for testing the product for conformity to all other requirements, as well as 25 capsules selected at random from the same sample.

6.1.3 Apparatus

Stereomicroscope, ×10 magnification.

6.1.4 Procedure

Using the stereomicroscope, inspect the interior surfaces of all the containers holding capsules and the external surfaces of the 25 capsules. Examine these for traces of dental amalgam alloy powder and visible beads of dental mercury.