

# Specification for Ampoules

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| Department of Trade                                | Society of Glass Technology                       |
| Honey Importers and Packers Association            | Wine and Spirit Association of Great Britain      |
| Medical Research Council                           | Coopted member                                    |

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# Contents

|                                                            | Page               |
|------------------------------------------------------------|--------------------|
| Cooperating organizations                                  | Inside front cover |
| Foreword                                                   | ii                 |
| 1 Scope                                                    | 1                  |
| 2 Type references                                          | 1                  |
| 3 Nomenclature and letter symbols                          | 1                  |
| 4 Materials                                                | 2                  |
| 5 Dimensions and performance requirements                  | 2                  |
| 6 Test methods                                             | 4                  |
| 7 Gauging code                                             | 5                  |
| 8 Printing and packaging                                   | 5                  |
| 9 Marking                                                  | 6                  |
| Appendix A Recommended ampoule seal characteristics        | 22                 |
| Appendix B Recommended method to open “easy-open” ampoules | 22                 |
| Figure 1 — Nomenclature and letter symbols                 | 2                  |
| Figure 2 — Type B ampoule                                  | 6                  |
| Figure 3 — Type C ampoule                                  | 6                  |
| Figure 4 — Type H ampoule                                  | 8                  |
| Figure 5 — Type J ampoule                                  | 8                  |
| Figure 6 — Type K ampoule                                  | 9                  |
| Figure 7 — Type L ampoule                                  | 10                 |
| Figure 8 — Type M ampoule                                  | 10                 |
| Figure 9 — Type N ampoule                                  | 11                 |
| Figure 10 — Type P ampoule                                 | 13                 |
| Figure 11 — Type Q ampoule                                 | 14                 |
| Figure 12 — Type R ampoule                                 | 15                 |
| Figure 13 — Type S ampoule                                 | 16                 |
| Figure 14 — Type V ampoule                                 | 17                 |
| Figure 15 — Type W ampoule                                 | 18                 |
| Figure 16 — Type X ampoule                                 | 19                 |
| Figure 17 — Type Y ampoule                                 | 20                 |
| Figure 18 — Torque testing device for break force test     | 21                 |
| Table 1 — Type references                                  | 1                  |
| Table 2 — Dimensions of type B ampoules                    | 7                  |
| Table 3 — Dimensions of type C ampoules                    | 7                  |
| Table 4 — Dimensions of type H ampoules                    | 8                  |
| Table 5 — Dimensions of type J ampoules                    | 9                  |
| Table 6 — Dimensions of type K ampoules                    | 9                  |
| Table 7 — Dimensions of type L ampoules                    | 10                 |
| Table 8 — Dimensions of type M ampoules                    | 11                 |
| Table 9 — Dimensions of type N ampoules                    | 12                 |
| Table 10 — Dimensions of type P ampoules                   | 13                 |
| Table 11 — Dimensions of type Q ampoules                   | 14                 |
| Table 12 — Dimensions of type R ampoules                   | 15                 |
| Table 13 — Dimensions of type S ampoules                   | 16                 |
| Table 14 — Dimensions of type V ampoules                   | 17                 |
| Table 15 — Dimensions of type W ampoules                   | 18                 |
| Table 16 — Dimensions of type X ampoules                   | 19                 |
| Table 17 — Dimensions of type Y ampoules                   | 20                 |
| Publications referred to                                   | Inside back cover  |

## Foreword

This British Standard, prepared under the direction of the Packaging and Freight Containers Standards Committee, was first published in 1938 and revised in 1953 and 1961. This third revision has been prepared at the request of the Department of Health and Social Security and includes performance requirements, notably for the force required to open the “easy-open” ampoules that are now in general use. Easy-open ampoules are characterized by a ceramic band at the constriction which has a differential coefficient of thermal expansion, and do not require the filing of a notch at the constriction to facilitate opening. Since the introduction of easy-open ampoules, the use of ampoules that require notching has declined.

In recent years ampoule filling technology has become increasingly sophisticated and more stringent regulatory controls have been introduced. The ampoule manufacturer is required to maintain a consistently high standard of quality and dimensional accuracy. It is therefore considered necessary to provide guidance for defect classification, acceptable quality levels, and sampling methods, although certain requirements, such as the glass type, are a matter of agreement between the purchaser and the supplier.

Four new ampoule designs have been included in this revision which, in recent years, have become widely used. The reference letters V, W, X and Y have been allocated, on an arbitrary basis, to avoid confusion with the existing reference letters. The dimensions of wider-stem ampoules, types V and W, developed for use with larger diameter needles in order to achieve faster filling speeds, are specified with tightened tolerances. Types X and Y originated in Germany and are based closely on forms B and D respectively in DIN Standard 58 377-1 (1977).

Other ampoule designs are currently used, although many of these are specific to only one manufacturer or user and little benefit could therefore be gained by specifying their dimensions in this standard. The performance requirements given in this standard, however, would be equally applicable to these ampoules.

The original designs have been retained with no dimensional changes, as they continue to be used. Eccentricity and certain additional dimensional requirements have been included for the four new designs as the necessary data are available, but these dimensions have not been specified for the original designs as the data are not readily available. Although no changes have been made to the dimensions of the original designs, advances in technology have facilitated a tightening of tolerances; for instance, the tolerance specified on the body diameter is  $\pm 0.2$  mm or  $\pm 0.3$  mm (dependent on capacity), although the nominal body diameter may be varied within the tolerance specified in the tables.

Appendix A and Appendix B give guidance on the sealing of ampoules and opening of easy-open ampoules respectively.

This standard supersedes BS 795:1961, which is withdrawn.

This British Standard calls for the use of substances and/or procedures that may be injurious to health if adequate precautions are not taken. It refers only to technical suitability and in no way absolves the user from statutory obligations relating to health and safety at any stage of manufacture or use. In particular, attention is drawn to the break force test (6.6) and the use of monochlorobenzene in the test for light transmission (6.1).

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

**Compliance with a British Standard does not of itself confer immunity from legal obligations.**

### Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv pages 1 to 22, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.



## 1 Scope

This British Standard specifies the materials, dimensions and performance requirements for the types of glass ampoule listed in Table 1 and specifies a sampling procedure for ampoules that are normally manufactured and sold in bulk. Pre-scored ampoules are not covered by this standard because of the inherent risk of perforation at the score and the possibility of cracks propagating from the score line.

The following performance requirements are specified in this standard:

- light transmission of amber ampoules
- residual stress
- freedom from internal impurities
- freedom from cracks
- eccentricity
- verticality
- hydrolytic resistance
- break force for easy-open ampoules
- quality of break for easy-open ampoules

NOTE The titles of the publications referred to in this standard are listed on the inside back cover.

## 2 Type references

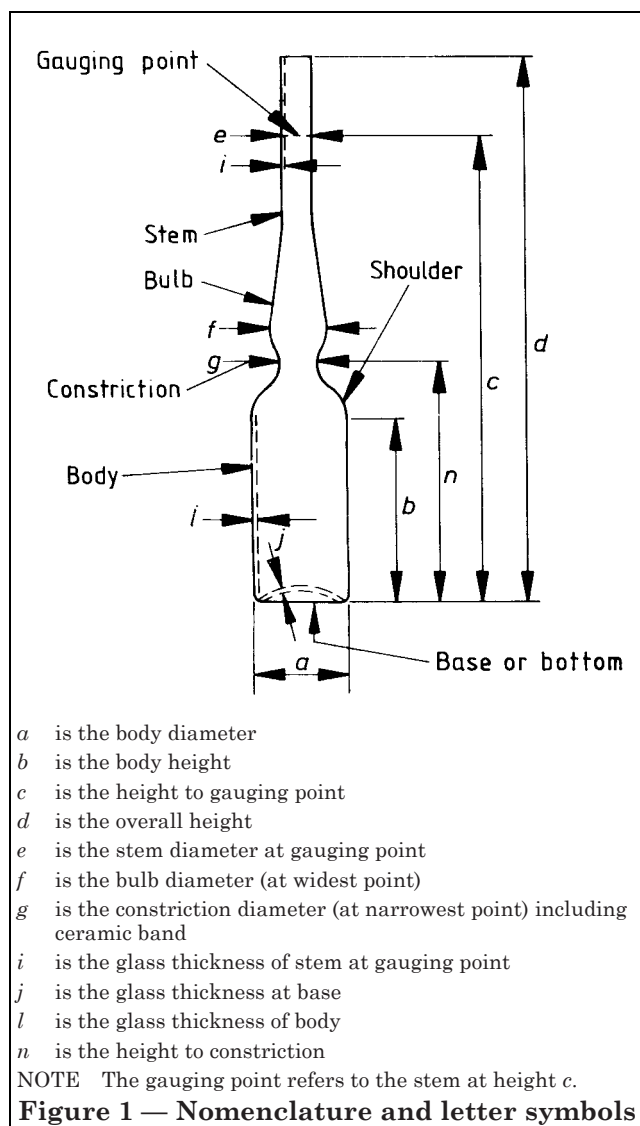
Ampoules shall be classified according to the type references given in Table 1.

## 3 Nomenclature and letter symbols

The various parts of the ampoule shall be referred to as shown in Figure 1. A type Q ampoule is shown for convenience. The letter symbols used in the Table 2 to Table 17 represent the dimensions shown in Figure 1. Dimensions that are specific to particular types of ampoule are shown in the appropriate figures.

**Table 1 — Type references**

| Reference letter                               | Description of ampoule                                                          | Figure/ table no. |
|------------------------------------------------|---------------------------------------------------------------------------------|-------------------|
| <b>Designs included in BS 795:1961</b>         |                                                                                 |                   |
| B                                              | Flat bottom, narrow stem ampoule, with constriction                             | 2                 |
| C                                              | Flat bottom, wide stem ampoule                                                  | 3                 |
| H                                              | Double-pointed ampoule                                                          | 4                 |
| J                                              | Friable (crushable) ampoule                                                     | 5                 |
| K                                              | Freeze-drying ampoule                                                           | 6                 |
| L                                              | Freeze-drying ampoule                                                           | 7                 |
| M                                              | Flat bottom, wide stem ampoule, with constriction                               | 8                 |
| N                                              | Flat bottom, open-funnel, narrow stem ampoule, with constriction                | 9                 |
| P                                              | Flat bottom, narrow stem, cut ampoule (for tip sealing), with constriction      | 10                |
| Q                                              | Flat bottom, narrow stem, cut ampoule (for draw-off sealing), with constriction | 11                |
| R                                              | Flat bottom, wide stem, cut ampoule, with constriction                          | 12                |
| S                                              | Flat bottom, open-funnel, wide stem ampoule, with constriction                  | 13                |
| <b>New designs not included in BS 795:1961</b> |                                                                                 |                   |
| V                                              | Modification of type Q with wider stem and increased wall thickness             | 14                |
| W                                              | Modification of type Q with wider and longer stem and increased wall thickness  | 15                |
| X                                              | Modification of type Q (DIN form B)                                             | 16                |
| Y                                              | Domed closed ampoule (DIN form D)                                               | 17                |



## 4 Materials

**4.1 Glass type.** Ampoules shall be manufactured from a type of glass appropriate to their end use.

NOTE Ampoules for injectable preparations will normally be required to be manufactured from a type of glass specified for that purpose in the European Pharmacopoeia<sup>1)</sup>, which includes requirements for hydrolytic resistance.

**4.2 Colour.** Ampoules shall be made from either uncoloured or amber glass. When tested as described in 6.1, the logarithm of the percent transmission of light at wavelengths below 500 nm of the glass from which amber ampoules are made shall satisfy the following formula:

$$\log_{10} T \leq x(0.01\lambda - 5) + 1$$

where

*T* is the percent transmission;

*x* is the thickness (in mm) of the glass;

$\lambda$  is the wavelength (in nm).

NOTE Amber glass can only give a limited measure of protection against light. Preparations that are particularly photosensitive or are likely to be exposed to sunlight for extensive periods should be packaged and stored in such a manner as to afford increased protection.

**4.3 Annealing.** All ampoules shall be annealed.

**4.4 Residual strain.** The maximum residual strain of uncoloured ampoules after annealing shall not produce an optical retardation exceeding 50 nanometres per millimetre of glass thickness when tested as described in 6.2.

NOTE The test described in 6.2 cannot be applied quantitatively to amber ampoules, although such ampoules should be assessed qualitatively, under polarized light, for residual strain.

## 5 Dimensions and performance requirements

**5.1 Dimensions.** The dimensions of the ampoules shown in Figure 2 to Figure 17 inclusive shall be as specified in the appropriate tables.

NOTE For types B to S inclusive, dimension *a* in Table 2 to Table 13 is given with a "tolerance" that specifies the permitted range for the nominal body diameter. The nominal body diameter may be any value within this range agreed between the purchaser and the supplier.

A tolerance of  $\pm 0.2$  mm (for ampoules of up to and including 10 ml capacity) or  $\pm 0.3$  mm (for ampoules of greater than 10 ml capacity) shall be applied to the nominal body diameter, and the diameter shall not be outside the permitted range, even at the extremes of the tolerances.

For types B and M the top shall be sealed.

For types C and J the top shall be open, as shown in Figure 3 and Figure 5 respectively.

The top of type C shall be glazed, but the bore of the stem shall not be reduced.

For type Y, dimension *a* shall exceed dimension *h*.

For types B, M, N, P, Q, R and S, the internal diameter at the constriction shall be not less than the minimum internal diameter of the stem at the gauging point.

For types B, N, P and Q, dimension *f* shall be approximately twice dimension *e*.

**5.2 Sampling.** General Inspection Level I of BS 6001:1972 shall be used for assessing visual and dimensional defects. Special Inspection Level S-4 shall be used for assessing functional defects (see 5.4), as shown in Tables I and IIA of BS 6001:1972. The expression of non-conformance shall be in terms of percent defective, as defined in 3.2 of BS 6001:1972.

<sup>1)</sup> Published by the European Pharmacopoeia Commission, Council of Europe, BP 431, R6 — 67006, Strasbourg Cedex, France.

### 5.3 Visual and dimensional defects

**5.3.1 Defect classification — Major 1.** The acceptable quality level (AQL) for any individual defect shall be 0.65 %. The AQL for the total number of defects shall be 1.5 %.

- a) Cracks on any part of the ampoule.
- b) Internal impurities that cannot be removed by rinsing (applicable only to types B to X inclusive) when tested as described in 6.3.
- c) Internal impurities, including glass particles (applicable only to type Y), when tested, without rinsing, as described in 6.3.
- d) Ceramic band not circumscribing at least 95 % of the constriction.
- e) Ceramic band removable by scratching with the finger nail.

**5.3.2 Defect classification — Major 2.** The AQL for any individual defect shall be 1.5 %. The AQL for the total number of defects shall be 4.0 %.

- a) Verticality. Deviation from vertical greater than 2°, when tested as described in 6.4.
  - b) Body diameter (dimension *a*) outside limits.
  - c) Body height (dimension *b*) outside limits.
  - d) Overall height (dimension *d*) outside limits.
  - e) Stem diameter at gauging point (dimension *e*) outside limits.
  - f) Dome diameter (dimension *h*) (applicable only to type Y) outside limits.
  - g) Pip thickness (dimension *k*) (applicable only to type Y) outside limits.
  - h) Dome wall thickness (dimension *p*) (applicable only to type Y) outside limits.
  - i) Glass thickness of stem at gauging point (dimension *i*) outside limits.
  - j) Glass thickness of body (dimension *l*) outside limits.
  - k) Glass thickness at base (dimension *j*) (applicable only to types V, W, X and Y) below the limit.
  - l) Eccentricity (applicable only to types V, W, X and Y) in excess of the limit, when tested as described in 6.5.
- NOTE The maximum eccentricity is given at the foot of the appropriate table of dimensions.
- m) Stem diameter (dimension *e*) not parallel to within 0.25 mm, for a distance of 2 mm either side of the gauging point.

**5.3.3 Defect classification — Minor.** The AQL for any individual defect shall be 4.0 %. The AQL for the total number of defects shall be 6.5 %.

- a) Bulb diameter (dimension *f*) (applicable only to types V, W, X and Y) outside limits.
- b) Constriction diameter (dimension *g*) (applicable only to types V, W, X and Y) outside limits. For easy-open ampoules the upper limit shall be increased by 0.05 mm to allow for the thickness of the ceramic band.
- c) Height to constriction (dimension *n*) outside limits.
- d) Glazing of the open end not sufficient to remove all sharp edges.
- e) Internal lip (which may be formed when the open end of the stem is glazed) in excess of 0.15 mm.
- f) Ampoule base slightly rocky.
- g) Internal impurities that *can* be removed by rinsing when tested as described in 6.3.
- h) Distortions or blemishes or external marks that do not affect function.

**5.4 Functional defects** (applicable only to easy-open ampoules).

**5.4.1 Defect classification — Major 1.** The AQL shall be 0.65 %.

- a) Shattered body or stem when opened as described in 6.6.

**5.4.2 Defect classification — Major 2.** The AQL for any individual defect shall be 1.5 %. The AQL for the total number of defects shall be 4.0 %.

- a) Cracks that extend into the body when opened as described in 6.6.
- b) Break force outside the following limits for individual ampoules or average of sample, when tested in accordance with 6.6.

| Ampoule capacity | Limit for individual ampoule | Limit for average of sample |
|------------------|------------------------------|-----------------------------|
| ml               | N m                          | N m                         |
| 1                | 0.3 to 1.3                   | 0.4 to 0.9                  |
| 1.5              | 0.3 to 1.3                   | 0.4 to 0.9                  |
| 2                | 0.3 to 1.3                   | 0.4 to 0.9                  |
| 3                | 0.3 to 1.4                   | 0.5 to 1.0                  |
| 5                | 0.6 to 1.7                   | 0.7 to 1.2                  |
| 10               | 0.6 to 1.7                   | 0.7 to 1.2                  |
| 20               | 0.7 to 2.0                   | 1.0 to 1.6                  |

**5.4.3 Defect classification — Minor.** The AQL shall be 6.5 %.

- a) Cracks not extending beyond the shoulder when opened by the method described in 6.6.