

Containers for pharmaceutical dispensing —

**Part 8: Specification for glass and
plastics containers for solid dosage
forms, semi-solids and powders**

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Packaging and Freight Containers Standards Policy Committee (PKM/-) to Technical Committee PKM/27, upon which the following bodies were represented:

- Association of British Health-care Industries
- Association of Clinical Pathologists
- British Box and Packaging Association
- British Glass Manufacturers' Confederation
- College of Ophthalmologists
- Department of Health
- Guild of Hospital Pharmacists
- Metal Packaging Manufacturers' Association
- National Pharmaceutical Association
- Pharmaceutical Services Negotiating Committee
- Pira International
- Public Health Laboratory Service
- Royal Pharmaceutical Society of Great Britain

The following bodies were also represented in the drafting of the standard, through subcommittees and panels:

- British Plastics Federation
- Chemical Industries' Association
- Institute of Packaging

This British Standard, having been prepared under the direction of the Packaging and Freight Containers Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 December 1992

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Foreword

This Part of BS 1679 has been prepared under the direction of the Packaging and Freight Containers Standards Policy Committee. It will supersede Part 2 of BS 1679:1965 and BS 1679-4:1969 which are to be withdrawn.

NOTE It is intended that following publication of this revision there will be a twelve month period during which Part 2 of BS 1679:1965 and BS 1679-4:1969 remain in existence to enable manufacturers to put the new requirements into effect.

This revision combines the specification for glass and plastics containers in one British Standard since it is considered that the essential requirements for a satisfactory dispensing container are the same irrespective of the material from which it is constructed.

A new requirement and a method of test for resistance to bite forces have been introduced, following reported instances of children having ingested medical products after biting into containers.

Requirements for moisture transmission are now related to the capacity of the container. These requirements provide a classification by grades to assist selection of the container which affords the necessary degree of protection for the particular product to be dispensed. The introduction of a range of quantitative values for the moisture barrier properties of containers should facilitate the early establishment of links between these values and terms such as “airtight” and “well-closed” which are currently used in pharmacopoeias to describe pharmaceutical containers.

Major changes to the pattern of pharmaceutical dispensing are currently in prospect and a consequence of their implementation will be a shift in the onus for providing dispensing containers from the pharmacist to manufacturers of pharmaceutical products. These impending changes have been anticipated in the revised specification which provides performance requirements appropriate to most reclosable dispensing containers.

In view of the importance of the closure component of the container in relation to water vapour transmission performance, a further requirement has been introduced for instances where the closure is not supplied together with the container body. This requires the supplier to provide the purchaser with details of closures which ensure that the container conforms to the relevant requirements.

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 and ii, pages 1 to 8, 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.

Introduction

Containers used for the dispensing of solid dosage forms, such as capsules, lozenges, solution tablets and tablets, are normally rectangular, cylindrical, or oval in shape and are closed with a child-resistant device, a screw cap or other close-fitting closure.

Semi-solids, such as applications, creams, gels, ointments and pastes, are normally dispensed in wide-mouth, cylindrical containers, closed with a screw cap or other close-fitting closure.

Both the above types of container are normally amber in colour, although opaque and natural plastics containers are also used.

Dusting powders, granules, insufflations and bulk powders (for oral ingestion) are normally dispensed in wide-mouth, cylindrical containers, closed with a screw cap or other close-fitting closure. Glass containers may be clear or amber in colour, while plastics containers may be natural, opaque or amber in colour.

The capacity ranges of containers normally used for pharmaceutical dispensing are as follows.

Solid dosage forms	10 ml to 125 ml with occasional use of capacities up to 500 ml
Semi-solids	15 ml to 800 ml
Powders	15 ml to 1 000 ml

1 Scope

This Part of BS 1679 specifies requirements for materials, construction, capacity, neck finish and performance for glass and plastics containers and their closures intended for dispensing solid dosage forms, semi-solids, powders and similar non-liquid pharmaceutical preparations.

Methods of test are included for light transmission, mechanical strength, resistance to bite forces and water vapour transmission.

No requirements are specified for shape or dimensions of containers for solid dosage forms and powders but the shape and proportions of containers for semi-solids are defined.

2 References

2.1 Normative references

This Part of BS 1679 incorporates, by reference, provisions from specific editions of other publications. These normative references are cited at the appropriate points in the text and the publications are listed on the inside back cover. Subsequent amendments to, or revisions of, any of these publications apply to this Part of BS 1679 only when incorporated in it by updating or revision.

2.2 Informative references

This Part of BS 1679 refers to other publications that provide information or guidance. Editions of these publications current at the time of issue of this standard are listed on the inside back cover, but reference should be made to the latest editions.

3 Definitions

For the purposes of this Part of BS 1679 the following definitions apply.

3.1 container

the receptacle which encloses and protects the dispensed pharmaceutical products

NOTE The closure is a component of the container.

3.2 closure

a device that permits opening and resealing of the container body to maintain its enclosing and protective functions. The seal may be an integral part of the closure or may be achieved by a liner or wad

3.3 liner

a compressible gasket which may be faced

NOTE The term "wad" is also used.

3.4 nominal capacity

the volume which a container should hold when filled to the appropriate filling point

3.5 point of fill

the level to which a glass container is intended to be filled

4 Materials

4.1 Container bodies shall be manufactured from either:

- a) amber or white flint soda lime silica glass; or
- b) plastics materials that are natural, coloured or opaque.

4.2 Closures shall be manufactured either from metal, which may be lacquered, or from a coloured or opaque plastics material.

4.3 Liners, if fitted, shall be of suitable resilience (see 7.4) and may have a facing.

NOTE Further guidance on the selection of materials of construction for containers and closures is given in Annex A.