Australian Standard®

MEDICINE MEASURES (including PEDIATRIC DROPPERS)—

Part 1—GLASS— FOR GENERAL USE

This Australian standard was prepared by Committee CH/1, Laboratory Glassware and Related Apparatus. It was approved on behalf of the Council of the Standards Association of Australia on 28 October 1985 and published on 3 February 1986.

The following interests are represented on Committee CH/1:

Chambers of Commerce, NSW, Vic.
Commonwealth Scientific and Industrial Research Organization
Commonwealth Serum Laboratories
Confederation of Australian Industry
Department of Agriculture, NSW
Department of Health (Commonwealth)
Department of Science and Technology
Government Chemical Laboratories, WA
National Standards Commission
Railways of Australia Committee
Royal Australian Chemical Institute
University of Sydney

The following additional interests participated in the production of this standard:

Australian Medical Association
Department of Government Supply, NSW
Department of Veterans Affairs
Manufacturers of Medicine Measures
National Biological Standards Laboratory
Pharmacy Guild of Australia, NSW Branch
Society of Hospital Pharmacists of Australia

This Standard was issued in draft form for comment as DR 83202.

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Part 1—GLASS— FOR GENERAL USE

First published (AS 2224) 1978
AS 2224.1 first published 1986

PUBLISHED BY STANDARDS AUSTRALIA
(STANDARDS ASSOCIATION OF AUSTRALIA)
1 THE CRESCENT, HOMEBUSH, NSW 2140

ISBN 0 7262 3991 7

PREFACE

This standard was prepared by the Association's Committee on Laboratory Glassware and Related Apparatus to supersede AS 2224—1978, as a result of requests by manufacturers who wished to place the Standards Mark on medicine measures which complied with that Australian Standard.

After due deliberation, the Association decided that specifications contained in the 1978 edition of the Standard were not sufficiently precise to permit testing of the product for compliance and therefore that Standard was not regarded as a suitable basis for Standards marking. Furthermore, as the specific products cited were made of plastics material, whose relevant properties were not well documented, it was felt that extensive investigations would be required with regard to materials of manufacture, resistance to elevated temperature, transparency, rigidity and toxicity testing, if eligibility of Standards marking was to be incorporated.

To this end, the drafting committee drew on a diversity of recently published standards and regulatory guidelines to revise AS 2224 and to incorporate new, sound tests of direct practical value to validate the specifications contained in this Standard. To meet the demands of the wide range of users, it was also decided to divide the standard into three parts—Glass Measures, Plastics Measures for Domestic Use and Plastics Measures for Hospital Use. This was necessary because although many plastics products could readily withstand domestic handwashing conditions, only certain plastics products could withstand the high temperature autoclaving and/or sterilization procedures routinely carried out in many hospitals and medical institutions.

It must be emphasized that the tests were devised on the basis of their relationship to practical usage, and every effort has been made to avoid the inclusion of those tests or techniques of testing which have little value or meaning to the user. For example, it was successfully argued that it would be an academic exercise only if a measure is tested for its resistance to leaching by cutting it up into small pieces and extracting any toxic materials from those pieces over a 24 h period. In real life situations (a) it is only the surface of the measure that comes into direct contact with its contents and (b) the contents are in contact with the measure for perhaps only a few minutes at a time or in extreme cases for up to 8 h or 12 h in the overnight situation in a hospital. An acceptable test would have to show cognizance of such practical situations and indeed this has been the philosophy of the drafting committee throughout the production of this standard.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
MEDICINE MEASURES (including PEDIATRIC DROPPERS)

PART 1—GLASS—FOR GENERAL USE

1 SCOPE. This standard specifies requirements for two types of glass medicine measure—one of tumbler form and one of conical form.

NOTE: Pediatric droppers are not manufactured from glass.

2 REFERENCED DOCUMENTS. The following documents are referred to in this standard:

AS 1199	Sampling Procedures and Tables for Inspection by Attributes
AS 1399	Guide to AS 1199, Sampling Procedures and Tables for Inspection by Attributes
AS 1520	Fibreboard Containers for General Purposes
AS 1821-23	Suppliers Quality Control Systems, Levels 1, 2 and 3
AS 2000	Guide to AS 1821—1823, Suppliers Quality Control Systems
AS 2007	Electric Dishwashers for Household Use
AS 2243	Safety in Laboratories Part 1 General Part 2 Chemical
AS 2490	Sampling Procedures and Charts for Inspection by Variables for Percent Defective
AS 2508	Safe Storage and Handling Information Cards for Hazardous Materials 3.017 Ethanol/Methylated Spirits 8.002 Hydrochloric Acid (Muriatic acid, spirits of salts) 8.003 Sodium Hypochlorite (aqueous) 8.006 Sodium Hydroxide (Caustic soda) (Solid and solution)
BS 612 (1966)	Specification for Nessler Cylinders (with amendment slips effective from 31 March 1981)

British Pharmacopoeia (1980)*

3 DEFINITIONS. For the purpose of this standard, the following definitions apply:

3.1 Capacity at any graduation line—the volume of distilled water at 20°C, expressed in millilitres, contained by the relevant measure at 20°C, when filled to the graduation line under test.

NOTE: The determination of the capacity of measures is described in Appendix E.

3.2 Permanently marked—markings which shall endure for the life of measure when it is used in dispensing medicaments as well as in associated cleaning processes. Such markings may be applied by any suitable process, e.g. moulding, etching, chemical adhesion. The method for assessing the permanence of markings is described in Appendix G.

NOTES:

1. Although markings defined here are intended to include both the glass-etched type and the pigmented type, the method of test set out in Appendix G is most unlikely to be meaningful in relation to the first type of marking as this would require dissolution of the glass surface. However, it is considered to be a minimal requirement that the second type of marking does not show deterioration when exposed to that test (see also NOTE to Clause 8.8.2).
2. Engraving of glass is particularly advised against as it causes local weakening of the glass and facilitates production of fracturing and breakage when exposed to mechanical and thermal stresses.

4 MATERIALS OF CONSTRUCTION. The measure shall be formed from colourless, high grade, annealed glass, free of particulate matter. In accordance with the requirements for Glass Types I and II of the current British Pharmacopoeia and Appendix C, the material shall not be a source of contamination to liquids contained within the measure.

Lead glass shall not be used.

NOTE: At the time of issue of this standard, Appendix XVIII B of the B.P. (1980) was applicable.

5 DESIGN AND DIMENSIONS.

5.1 Design. The measure shall be of either the tumbler type or the conical type as shown in Fig. 1.

5.2 Dimensions. Dimensions of the measure shall be in accordance with those shown for the appropriate type in Fig. 1.

6 CONSTRUCTION.

6.1 General. The measure shall be constructed so that it exhibits no distortion, strain, cracking, chipping, loss of clarity, staining or other defect likely to interfere with its normal use. When a clean measure is filled with water, its internal surface shall resist the formation and adherence of air bubbles.

6.2 Stability. The base of the measure shall be constructed so that it shall stand on a flat surface without rocking or spinning.

6.3 Wall thickness. The wall thickness shall be uniform to within 10 percent of the mean wall thickness.

6.4 Pouring lip. If fitted, the pouring lip shall be so formed as to enable the contents of the measure to be poured in a narrow stream without spilling or without running down the outside of the measure.

6.5 Finish. All parts of the medicine measure shall be free from sharp edges, projections or roughness likely to cause accidental cutting, puncturing or abrasion of the skin of the user.

* Refer also to Clause 4.

AS 2224.1-1986 Medicine measures (including paediatric droppers) - Glass - For general use