Australian Standard®

MEDICINE MEASURES (including PAEDIATRIC DROPPERS)

Part 2—PLASTICS— FOR DOMESTIC 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 9 September 1986 and published on 3 November 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, NSW
Department of Science and Technology
Government Chemical Laboratories, WA
National Standards Commission
Railways of Australia Committee
Royal Australian Chemical Institute
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The following additional interests participated in the preparation of this standard:

Australian Medical Association
Department of Government Supply, NSW
Department of Veterans Affairs
Manufacturers of Medicine Mixture
National Biological Standards Laboratory
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Part 2—PLASTICS—FOR DOMESTIC USE

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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 StandardsMark 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 StandardsMarking. 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 to carry the StandardsMark was to be incorporated.

To this end the drafting committee drew on a number 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 some plastics products could readily withstand domestic handwashing conditions, only certain plastics products can withstand the high temperature autoclaving and/or sterilization procedures routinely carried out in many hospitals and medical institutions.

It is emphasized that the tests described in the Appendices 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 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 plastics 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 overnight 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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Australian Standard
for
MEDICINE MEASURES (including PAEDIATRIC DROPPERS)

PART 2—PLASTICS—FOR DOMESTIC USE

1 SCOPE. This standard specifies requirements for three types of plastics medicine measures—tumbler, conical and dropper.

2 REFERENCED DOCUMENTS. The following standards 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 2070	Plastics Materials for Food Contact 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 2508.3.017— Ethanol/Methylated Spirits 2508.8.002— Hydrochloric Acid (Muriatic acid, spirits of salts) 2508.8.003— Sodium Hypochlorite (Aqueous) 2508.8.006— Sodium Hydroxide (Caustic soda) (Solid and solution)
BS 612(1960)	Specification for Nessler Cylinders (with amendment slips effective from 31 March 1981)

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 or dropper at 20°C, when filled to the graduation line under test.

NOTE: The determination of the capacity of a measure and dropper is described in Appendix D.

3.2 Measure—unless otherwise indicated, this term applies generally to the three types of containers specified in this standard, viz. tumbler, conical or dropper.

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

4 MATERIALS.

4.1 Body of measure. The measure shall be formed from colourless, high grade, rigid plastics material free of particulate matter, and shall be inert to the mouth of the user and to medicaments contained therein. The material of manufacture shall meet the requirements of the relevant part of AS 2070 or the equivalent as approved by the relevant Regulatory Authority.

4.2 Teat (dropper only). The teat shall be made of natural or synthetic elastomer formulated to resist degradation such as cracking, hardening, discolouration, stickiness or shedding of surface fragments (see also Clause 9.11). It shall be inert as described in Clause 4.1 and shall meet the requirements of AS 2070, if appropriate, or the equivalent as approved by the relevant Regulatory Authority.

5 DESIGN.

5.1 General. The measure shall be of the appropriate form as designated in Fig 1.

5.2 Dropper type measures. In addition to the requirements of Clause 5.1 the following design requirements shall also be met by dropper type measures:

(a) *Body of dropper*. There shall be sufficient space above the highest graduation mark to minimize the entry of medicament into the teat when held under normal conditions of medicament administration.

(b) *Teat of dropper*. The teat shall be designed so that it provides an airtight grip between the teat and the body of the dropper, and this shall be facilitated by the presence of an internal groove inside its mouth which fits over a flange on the body of the dropper (see Fig. 1(c)).

6 DIMENSIONS. Dimensions of the measure shall be in accordance with those shown for the appropriate type as indicated in Fig. 1.