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Australian Standard 2491—1981

ALL-GLASS SYRINGES FOR THE INJECTION OF 100 UNITS PER MILLILITRE INSULIN (U-100)

[Title allocated by Defence Cataloguing Authority: SYRINGE, HYPODERMIC (All-Glass, For U-100 Strength Insulin Injection)]

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THE FOLLOWING SCIENTIFIC, INDUSTRIAL AND GOVERNMENTAL ORGANIZATIONS and departments were officially represented on the committee entrusted with the preparation of this standard:

Australian Chamber of Commerce

Australian Dental Standards Laboratory

Australian Diabetes Society

Australian Medical Association

Commonwealth and State Departments of Health

Confederation of Australian Industry

Diabetes Federation of Australia

Hospitals and Hospital Associations

New South Wales Government Stores Department

The Pharmacy Guild of Australia

This standard, prepared by Committee MD/1 Hypodermic Equipment for Insulin Injection, was approved on behalf of the Council of the Standards Association of Australia on 23 July 1981, and was published on 12 October 1981.

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This standard was issued in draft form for public review as DR 80117.

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AUSTRALIAN STANDARD

ALL-GLASS SYRINGES FOR THE INJECTION OF 100 UNITS PER MILLILITRE INSULIN (U-100)

AS 2491—1981

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PREFACE

This standard was prepared by the Association's Committee on Hypodermic Equipment for Insulin Injection under the direction of the Medical Materials and Equipment Standards Committee to supersede AS T29—1968. Preparation of the new standard was necessary because of the introduction of U-100 strength insulin in Australia in August 1980. The standard has been prepared in a manner intended to make it suitable for adoption as a statutory standard under the Federal Therapeutic Goods Act.

This standard differs principally from AS T29 in that requirements are included for re-usable syringes for paediatric use, in the light of comment received at public review. Thus, requirements for syringes of 0.5 mL and 0.35 mL sizes have been specified. In the case of the 1 mL syringe, the maximum permitted length of the syringe is longer than that specified in AS T29, and the labelling requirements are also different. Being an 'all-glass' syringe, there is no test for corrosion.

Facilities for testing for compliance with this standard are available at the Australian Dental Standards Laboratory, 240 Langridge Street, Abbotsford, Victoria, 3067.

This standard requires reference to the following standards:

AS 1600*	Conical Fittings with 6 Percent (Luer) Taper for Hypodermic and Other Surgical Equipment
AS 2193	Methods for Calibration and Grading of Force Measuring Systems of Testing Machines
AS K185	Colours for Specific Purposes

*In course of revision.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
ALL-GLASS SYRINGES FOR THE INJECTION OF 100 UNITS PER MILLILITRE INSULIN (U-100)

1 SCOPE. This standard specifies requirements for 1 mL, 0.5 mL and 0.35 mL all-glass syringes intended for use solely with 100 units per millilitre (U-100) insulin. The 1 mL syringe is graduated to 100 'units' in 2-unit intervals. The 0.5 mL and the 0.35 mL syringes are graduated to 50 'units' and 35 'units' respectively, and in 1-unit intervals, and are suitable for paediatric use. The syringes have a 6 percent (Luer) fitting.

2 DESCRIPTION OF SYRINGE.

NOTE: The terms in italic type are illustrated in Fig. 1.

The components of the syringe are the *plunger* and the *barrel*. The term *proximal* refers to the end of the plunger which protrudes from the barrel, and to the corresponding end of the barrel and syringe. The term *distal* refers to the end of the plunger, barrel or syringe opposite to the proximal end. The plunger is *fully inserted* when seated firmly but not under pressure against the distal end of the barrel. Round the proximal end of the barrel is an outward projection termed the *flange*. Around the flange a brake may be provided to arrest the movement of the plunger. The space enclosed by the inside walls of the barrel is termed the *lumen*.

The syringe has a *nozzle* for attaching the needle onto the distal end of the barrel.

Graduation lines and numbering, which comprise the scale, are marked on the barrel. The graduation line nearest the distal end of the barrel is termed the *zero line*. The graduation line nearest the proximal end is termed the *capacity line*. The proximal end of the plunger is formed into a *push button*. The distal end of the plunger forms the *fiducial line* or a fiducial line is marked on the plunger, which provides the reference position for setting the plunger against the scale.

3 DEFINITIONS.

For the purpose of this standard, the following definitions apply:

3.1 Syringe—a syringe without needle having a barrel and plunger made entirely of glass, the plunger being inserted in the barrel.

3.2 Unit (in relation to marking)—the international unit of insulin.

3.3 Unit (in relation to packing)—an all-glass syringe.

3.4 Unit pack—a pack containing a single unit.

3.5 Water—distilled water.

4 DIMENSIONS OF SYRINGE.

4.1 Length. The length of the syringe with the plunger fully inserted (dimension A in Fig. 2) shall be as specified in Table 1.

4.2 Length of Projection of Plunger from Barrel. The length of projection of the fully inserted plunger from the barrel of the syringe (dimension E in Fig. 2) shall not be less than 10 mm.

5 REQUIREMENTS FOR BARREL

5.1 Composition.

(a) The barrel of the syringe shall be made of glass which—

(i) is transparent or sufficiently translucent to afford good visibility of the fiducial line and any air/liquid interface in the barrel; and

(ii) does not affect the therapeutic efficacy of insulin when the syringe is used to inject a preparation of insulin.

(b) The glass shall be well annealed and free from striae and similar defects. Soda glass shall not be used.

(c) When tested in accordance with Appendix A, the pH value of the syringe extract shall be within one unit of pH of that of the control fluid.

5.2 Shape. The barrel shall be essentially cylindrical between the zero line and the flange.

5.3 Lumen. The lumen of the barrel shall, except for any widening at the proximal end, be essentially cylindrical between the cross-sectional planes of the zero line and the proximal end.

5.4 Flange.

(a) The proximal end of the barrel shall be provided with a flange extending outwards from the barrel.

(b) The flange shall be shaped so that it—

(i) prevents the syringe from rolling when the syringe is placed on a plane surface inclined at 10 degrees to the horizontal with the graduated scale upwards; and

(ii) affords good support for the fingers when the syringe is held in the injecting position with the graduated scale in full view.

(c) The dimensions of the flange (designated C and D in Fig. 2) shall be equal and shall each be not less than 3 mm.

5.5 Nozzle. There shall be on the distal end of the barrel a nozzle which—

(a) complies with the appropriate test gauges of AS 1600;

(b) is coaxial with the barrel; and

(c) exhibits no obstruction to the flow of liquid through the nozzle.

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