IS 12227: 2002 ISO 8537: 1991

Indian Standard

STERILE SINGLE-USE SYRINGES, WITH OR WITHOUT NEEDLE, FOR INSULIN

(First Revision)

1 Scope

This International Standard specifies requirements and test methods for sterile syringes with or without needles intended for single use solely for the injection of insulin and primarily in humans It covers syringes for use with 40 units of insulin/ml (U-40) and 100 units of insulin/ml (U-100)

Sterile syringes specified in this International Standard are intended for use soon after filling as they are not suitable for containing insulin over extended periods of time

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard At the time of publication, ihe editions indicated were valid All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below Members of IEC and ISO maintain registers of currently valid International Standards

ISO 594-1 1986, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1 General requirements

ISO 7864 1988, Sterile hypodermic needles for single use