(1807)

SYNOPSIS

Doc: MHD 12 (13026) IS/ISO 11418-7: 2016 Containers and accessories for pharmaceutical preparations Part 7 Screw-neck vials made of glass tubing for liquid dosage forms

a) Scope:

This Indian Standard specifies the design, dimensions, material and requirements of screw-neck vials for pharmaceutical preparations. Screw-neck vials are applicable to primary packs used in direct contact with a drug. This Indian Standard applies to colourless or amber glass vials made from borosilicate or soda-lime-silica glass, made from glass tubing and intended to be used in the packaging, storage or transportation of pharmaceutical products.

Note: The potency, purity, stability and safety of a drug during its manufacture and storage can be strongly affected by the nature and performance of the primary pack.

b) Salient features of content:

This Indian Standard specifies the dimensions, capacities, form and requirements of screw-neck vials made from tubular glass intended for medical use. Vials made from glass tubing are considered to be suitable for the packaging and storage of pharmaceutical preparations until they are administered for medicinal purposes. Such vials may be made of different types of glass which can affect chemical resistance properties. For example, those made from borosilicate glass will have a very high level of chemical resistance where others made from soda-lime-silica glass will have a lower but adequate chemical resistance for the purposes for which they are intended. Because vials may be made from different types of glass and because it is the chemical behaviour of the internal surface which is important when they are filled with pharmaceutical preparations, it is essential to specify the test procedures by which the performance can be measured.

- c) Type/grades/classes, if any covered in the standard: Nil.
- d) Disclaimer (to be automatically provided by the program/software) ----
