



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

Therapeutic Goods Order No. 89 Standard for water for injections for parenteral medicines

I, Rohan Hammett, delegate of the Minister for Health and Ageing for the purposes of section 10 of the *Therapeutic Goods Act 1989* ('the Act') and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of the Act, HEREBY DETERMINE that matters specified in this Order constitute a standard for water for injections:

- a. for therapeutic use as a parenteral medicine; or
- b. for use as an ingredient or component in the manufacture of a parenteral medicine other than for:
- c. an export only medicine; or
- d. a personal import as described under Item 1 of Schedule 5 of the Therapeutic Goods Regulations 1990.

Standard

Water for injections must comply with the monograph for Water for Injections in the British Pharmacopoeia or the European Pharmacopoeia.

Definitions

In this Order:

monograph means the requirements of, and definitions within, an individual or general monograph of the British Pharmacopoeia or the European Pharmacopoeia, read in conjunction with the General Notices contained in the same edition that are applicable to that monograph.

parenteral medicine means a sterile medicine intended for administration by injection, infusion or implantation into the body.

Commencement

This Order commences from the day after the day it is registered on the Federal Register of Legislative Instruments.

Dated this 18th day of October 2011

(signed by)

Rohan Hammett
Delegate of the Minister for Health and Ageing