# Compositional guidelines



#### Australian Government

Department of Health and Ageing Therapeutic Goods Administration

## **Compositional guidelines**

Compositional guidelines are intended to provide clarity to the specific form or type of substances that the Therapeutic Goods Administration (TGA) approves for use in listed medicines, as either an active substance or an excipient.

A compositional guideline is a summary of descriptions, tests and limits that define the composition and characteristics of a substance approved for use in listed medicines. Compositional guidelines are required where there is no standard for the substance in any of the default standards identified in the *Therapeutic Goods Act 1989* (i.e. the British Pharmacopoeia, United States Pharmacopoeia or the European Pharmacopoeia).

### About compositional guidelines

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• Questions & answers about compositional guidelines

### **Current compositional guidelines**

- Compositional guideline: Alpha-casozepine enriched hydrolysed milk protein
- Compositional guideline: Arthrospira maxima
- Compositional guideline: Arthrospira platensis
- Compositional guideline: Black boned chicken powder
- Compositional guideline: Bovine colostrum powder
- Compositional guideline: Conifer phytosterol complex
- Compositional guideline: Demineralised fish proteoglycan extract
- Compositional guideline: DHA-rich oil derived from microalgae Schizochytrium sp.
- Compositional guideline: Fish oil natural
- <u>Compositional guideline: Hydroxycitrate complex</u>
- Compositional guideline: Larix arabinogalactan
- Compositional guideline: Steviol glycosides
- Compositional guideline: Sugar cane wax alcohols (SCWA)
- Compositional guideline: Zeaxanthin

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