Compositional guideline for bovine colostrum powder

Name of the ingredient

Bovine colostrum powder (ABN)

Definition of the ingredient

Bovine colostrum powder (BCP) is derived from the milk of cows (*Bos taurus*) after calving. BCP is a lactose- and fat-reduced, high protein product, which is manufactured without addition of additives or artificial ingredients. BCP contains a number of bioactive components, which are not present or are present in very low amounts in normal cow's milk. These include a number of growth factors (e.g. insulin-like growth factors I and II), antimicrobial factors (e.g. immunoglobulins), cytokines, enzymes, hormones, and other components.

Specific conditions

The colostrum must be obtained either from Australian herds or herds from countries that are considered BSE-free, which are registered for milk production for human consumption. Animal origin information would need to be provided with all new applications to list medicines containing BCP. In some instances, further information may be required for evaluation by the TGA in relation to products containing this substance (see Supplementary information on Transmissible Spongiform Encephalopathies (TSEs) regulation).

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Free-flowing, pale yellow powder
Odour	Organoleptic	Mild odour of milk when contacted with moisture
Characteristics		
Loss on drying	AS 2300.1.1	Not more than 7% w/w

Test	Method reference	Acceptance criteria
Ash	AS 2300.1.5 (1988) (@550oC)	Not more than 8% w/w
Solubility	BP (General notice)	Soluble in water
Identification		
IgG	Chromatographic*	Not less than 10% w/w
Assay		
Total nitrogen (TN)**	AS 2300.1.2 (1991)	For information
Non-protein nitrogen (NPN)**	AS 2300.1.2.2 (1988)	For information
True protein	(TN-NPN) x 6.38	Not less than 60% w/w
Protein	AS 2300.1.2 (1991)	Not less than 60% w/w
Lactose (monohydrate)	UV assay following enzymatic hydrolysis and oxidation (Boehringer Mannheim)	Not more than 15% w/w
Notes		
*The chromatographic method should be validated for the specific quantitation of the IgG component. A typical procedure could be to use affinity chromatography involving a protein A-sepharose column. **used to calculate the value of true protein		

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Incidental metals and non-metals		
Total heavy metals	Subject to the Australia New Zealand Food Standards Code for dairy products, or where there is no applicable Food Standard, BP (Appendix VII, Limit test for heavy metals); Ph Eur method 2.4.8	Complies; Not more than 2 ppm as lead
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)	BP (Appendix XI L, Pesticide residues); Ph Eur method 2.8.13	Complies
Microbiology		
While substance manufacturers are encouraged to include limits for objectionable microorganisms, it is the product into which the substance is formulated that is subject to a legally binding set of criteria. The *Therapeutic Goods Order No. 77 'Microbiological Standards for Medicines*' mandates that any finished product which contains the ingredient, alone or in combination, must comply with the microbial acceptance criteria set by Clause 9 of the Order.		

Key to abbreviations:

AS = Australian Standard

BP = British Pharmacopoeia

Ph Eur = European Pharmacopoeia