



**Australian Government**  
**Department of Health and Ageing**  
Therapeutic Goods Administration

## Draft Compositional Guideline for Cellulase

### Name of the ingredient

Cellulase derived from *Trichoderma longibrachiatum* (ABN)

### Definition of the ingredient

Cellulase (endo-1,4-(1,3:1,4)- $\beta$ -D-glucan 4-glucanohydrolase) is an enzyme that is commercially derived from the fungus, *Trichoderma longibrachiatum*, via a fermentation process. During the recovery phase of production, manufacturers destroy *T. longibrachiatum* before removing the non-proteinaceous material away from cellulase. Cellulase recovered from the fermentation broth is usually present in an aqueous solution or processed to a dried state.

CAS No. 9012-54-8

EC No. 3.2.1.4

**Table 1. Ingredient specific requirements**

Test	Method reference	Acceptance criteria
<b>Description</b>		
Appearance	Visual	Liquid or powder
<b>Identification</b>		
Cellulase activity	FCC	Complies
<b>Assay</b>		
Cellulase activity	FCC	No less than 85.0% but no more than 115.0% of the declared activity expressed as CU*
<b>Notes</b>		

Test	Method reference	Acceptance criteria
<b>Notes:</b> *CU = Cellulase unit		

**Table 2. Incidental constituents**

Test	Method reference	Acceptance criteria
<b>Incidental metals and non-metals</b>		
Heavy metals (as lead)	FCC	No more than 30 ppm
Lead	FCC	No more than 5 ppm
<b>Other organic or inorganic impurities or toxins</b>		
Mycotoxins and aflatoxins	FCC, AOAC	Not detected
Antibiotic activity	JECFA	Not detected
<b>Microbiology</b>		
While substance manufacturers are encouraged to include limits for objectionable microorganisms, it is the product into which those substances are formulated that is subject to a legally binding set of criteria. The Therapeutic Goods Order No. 77 <i>'Microbiological Standards for Medicines'</i> mandates that any finished product that contains the ingredient, alone or in combination with other ingredients, must comply with the microbial acceptance criteria set by Clause 9 of the Order.		

**Key to abbreviations: -**

AOAC = Association of Analytical Communities Official Methods of Analysis 16th Ed. AOAC

BP = British Pharmacopoeia

FCC = Food Chemicals Codex IV

JECFA = Joint FAO/ WHO Expert Committee on Food Additives in FAO Food and Nutrition Paper No.52 (Addendum 9)

Ph Eur = European Pharmacopoeia