

CELLULASE

This abbreviated labelling standard (AbLS) is a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It includes generalized claims and is not intended to be a comprehensive review of the medicinal ingredient. Wording of the claim on the PLA and label must therefore be identical to this AbLS.

Date March 30, 2012

Field	Field content	Reference
Proper name(s)	4-(1,3;1,4)-beta-D-glucan 4-glucanohydrolase	IUBMB 2001
Common name(s)	cellulase	IUBMB 2001
Source material(s)	<i>Aspergillus niger</i> van Tieghem 1867 (Trichocomaceae) <i>Trichoderma reesei</i> E.G. Simmons 1977 (Hypocreaceae) <i>Trichoderma longibrachiatum</i> Rifai 1969 (Hypocreaceae)	CABI 2012 FCC 7 Bisby et al. 2010
Route(s) of administration	Oral	
Dosage form(s)	The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets. This AbLS is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.	
Use(s) or Purpose(s)	Digestive enzyme.	
Dose(s)	Dose information must include the quantities of both the enzyme preparation and its enzymatic activity: <ul style="list-style-type: none"> • Enzyme preparation, per dosage unit; and • Enzymatic activity providing up to 112 500 FCC CU¹ per day, in divided doses. 	FCC 7 Glade et al. 2001
Sub-population(s)	Adults	
Duration(s) of use	For prolonged use, consult a health care practitioner.	
Direction(s) of use	Take with food/a meal.	
Risk information	Consult a health care practitioner prior to use if you are pregnant or breastfeeding.	
	Consult a health care practitioner prior to use if you have diabetes.	
	Hypersensitivity/allergy has been known to occur, in which case discontinue use.	

Field	Field content	Reference
Non-medicinal ingredient(s)	Must be chosen from the current NHPD <i>Natural Health Products Ingredients Database</i> and must meet the limitations outlined in the database.	
Specification(s)	<p>A Finished Product Specifications Form must accompany the application.</p> <p>The finished product must comply with the requirements of the current NHPD <i>Evidence for Quality of Finished Natural Health Products</i> guidance document.</p> <p>The specifications must include testing for enzymatic activity of the medicinal ingredient at the finished product stage using the assay outlined in the Food Chemicals Codex (FCC 7): CELLULASE ACTIVITY.</p> <p>Details of the manufacturing of the enzyme at the raw material stage should include fermentation medium, isolation process and the percent purity of the medicinal ingredient.</p> <p>Where published methods are not suitable for use, manufacturers will use due diligence to ensure that the enzymes remain active to the end of their shelf life indicated on the product label.</p>	

¹. FCC 7: one cellulase unit (CU) is defined as the amount of activity that will produce a relative fluidity change of 1 in 5 minutes in a defined carboxymethyl cellulose substrate under the conditions of the assay.

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