

ALPHA-AMYLASE

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-alpha-D-glucan glucanohydrolase	IUBMB 1961
Common name(s)	alpha-amylase/ α -amylase	IUBMB 1961
Source material(s)	<i>Aspergillus niger</i> van Tieghem 1867 (Trichocomaceae)	CABI 2012 FCC 7 Bisby et al. 2010
	<i>Aspergillus flavus</i> var. <i>oryzae</i> (Ahlb.) Kurtzman MJ, Smiley, Robnett & Wicklow 1986 (Trichocomaceae)	CABI 20112 FCC 7 Bisby et al. 2010
	<i>Rhizopus oryzae</i> Went & Prins. Geerl. 1895 (Mucoraceae)	CABI 2012 FCC 7
	Barley (<i>Hordeum vulgare</i> L. (Poaceae)) seed	FCC 7 USDA 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 unit 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 • Enzyme activity providing up to 150 000 FCC DU¹ per day, in divided doses, not to exceed 34 000FCC DU per dose. 	FCC 7 Glade et al. 2001
Sub-	Adults	

Field	Field content	Reference
population(s)		
Duration(s) of use	For prolonged use, consult a health care practitioner.	
Direction(s) of use	Take with food/meal.	
	For enteric-coated products: Swallow whole/do not crush or chew.	CPS 2008
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.	Sweetman 2011
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)	A Finished Product Specifications Form must accompany the application.	
	The finished product must comply with the requirements of the current NHPD <i>Evidence for Quality of Finished Natural Health Products</i> guidance document.	
	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): α -AMYLASE ACTIVITY (NONBACTERIAL).	
	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.	
	Where published methods are not suitable for use, manufacturers will use due diligence to ensure that the enzymes remain active to the end of the shelf life indicated on the product label.	

¹. FCC 7: one α -amylase dextrinizing unit (DU) is defined as the quantity of α -amylase that will dextrinize soluble starch in the presence of an excess of β -amylase at the rate of 1 g/h at 30°.

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FCC 7: Food Chemicals Codex, Seventh edition. Rockville (MD): The United States Pharmacopeial Convention; 2012.

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