

LIPASE

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)	triacylglycerol acylhydrolase/ triacylglycerol lipase	IUBMB 1961
Common name(s)	lipase	IUBMB 1961
Source material(s)	<i>Aspergillus flavus</i> var. <i>oryzae</i> (Ahlb.) Kurtzman MJ, Smiley, Robnett & Wicklow 1986 (Trichocomaceae)	CABI 2012 FCC 7 Bisby et al. 2010
	<i>Aspergillus niger</i> van Tieghem 1867 (Trichocomaceae)	CABI 2012 FCC 7 Bisby et al. 2010
	<i>Rhizopus oryzae</i> Went & Prins. Geerl. 1895 (Mucoraceae)	CABI 2012 FCC 7
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: • Enzyme preparation per dosage unit; and • Enzyme activity providing up to 112 500 FCC LU ¹ per day, in divided doses, not to exceed 29 700 FCC LU per dose.	FCC 7 Glade et al. 2001
Sub-population(s)	Adults	

Field	Field content	Reference
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.	
	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)	<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) : LIPASE 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 the shelf life indicated on the product label.</p>	

¹. FCC 7: one lipase unit (LU) is defined as the quantity of enzyme that will liberate 1 µmol of butyric acid per minute under the conditions of the test.

References cited

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