

## FUNGAL PROTEASE

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
<b>Proper name(s)</b>	fungal protease protease	IUBMB 1992
<b>Common name(s)</b>	fungal protease peptidase protease	IUBMB 1992
	acidic protease/ acid protease/ acid stable protease	
	alkaline protease/ alkaline active protease	
	protease 3.0 protease 4.5 protease 6.0	
<b>Source material(s)</b>	<i>Aspergillus flavus</i> var. <i>oryzae</i> ((Ahlb.) Kurtzman MJ, Smiley, Robnett & Wicklow 1986 (Trichocomaceae))  <i>Aspergillus melleus</i> (Yukawa 1911 (Trichocomaceae)); synonym: <i>Aspergillus quercinus</i> ((Bainier) Thom & Church 1926)  <i>Aspergillus niger</i> (van Tieghem 1867 (Trichocomaceae))	CABI 2011 FCC 7 Bisby et al. 2010
<b>Route(s) of administration</b>	Oral	
<b>Dosage form(s)</b>	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.	
<b>Use(s) or Purpose(s)</b>	Digestive aid.  Helps digest proteins.  Digestive enzyme.	Murray 1996

Field	Field content	Reference
<b>Dose(s)</b>	<p>Dose information must include the quantities of both the enzyme preparation and its enzymatic activity:</p> <ul style="list-style-type: none"> <li>• Enzyme preparation per dosage unit; and</li> <li>• Enzyme activity providing the equivalent 675 000 FCC HUT<sup>1</sup> and/or 6 825 FCC SAP<sup>2</sup> per day<sup>3</sup>.</li> </ul>	FCC 7 Oben et al. 2008 Brown et al. 2004
<b>Sub-population(s)</b>	Adults	
<b>Duration(s) of use</b>	For prolonged use, consult a health care practitioner.	
<b>Direction(s) of use</b>	Take with food/meal.	
	For enteric-coated products: Swallow whole/do not crush or chew.	CPS 2008
<b>Risk information</b>	Consult a health care practitioner prior to use if you are pregnant or breastfeeding.	
	Consult health care practitioner prior to use if you have gastrointestinal lesions/ulcers, are taking anticoagulant agents or anti-inflammatory agents or are having surgery.	
	Hypersensitivity/allergy has been known to occur, in which case discontinue use.	
<b>Non-medicinal ingredient(s)</b>	Must be chosen from the current NHPD <i>Natural Health Products Ingredients Database</i> and must meet the limitations outlined in the database.	
<b>Specification(s)</b>	<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>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>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) : PROTEOLYTIC ACTIVITY, FUNGAL (HUT) PROTEOLYTIC ACTIVITY, FUNGAL (SAP).</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 hemoglobin unit on the tyrosine basis (HUT) of proteolytic (protease) activity is defined as that amount of enzyme that produces, in 1 minute under the conditions of the assay, a hydrolysate whose absorbance at 275 nm is the same as that of a solution containing 1.10 µg/mL of tyrosine in 0.006 N hydrochloric acid.
2. FCC 7: one spectrophotometric acid protease unit (SAP) is that activity that will liberate 1µmol of tyrosine per minute under the conditions of the assay.
3. For multi-ingredient products containing protease from *A. niger* and protease from *A. oryzae*, the maximum proteolytic activity from both sources cannot exceed 300 FCC SAP and/or 125 000 FCC HUT per day (FCC 7).

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