



NATURAL HEALTH PRODUCT

LIPASE

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant’s discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date

April 29, 2019

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)	
		Proper name(s)	Part(s)
<ul style="list-style-type: none"> ▶ Triacylglycerol acylhydrolase ▶ Triacylglycerol lipase 	Lipase	<ul style="list-style-type: none"> ▶ <i>Aspergillus flavus</i> var. <i>oryzae</i> ▶ <i>Aspergillus niger</i> ▶ <i>Rhizopus oryzae</i> 	Whole

References: Proper name: IUBMB 1961; Common name: IUBMB 1961; Source materials: CABI 2012, FCC 8 2012, Bisby et al. 2010.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



Use(s) or Purpose(s)

Digestive enzyme

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Not to exceed 110,000 FCC LU of enzymatic activity, per day; and 30,000 FCC LU per single dose (FCC 8 2012; Glade et al. 2001).

Notes

- ▶ The Quantity per dosage unit must be the enzymatic activity (FCC unit). The quantity of the enzymatic preparation in mg or ml should also be included as additional quantity.
- ▶ One FCC 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 (FCC 8 2012).

Direction(s) for use

All products

Take with food/meal.

Enteric-coated products

Swallow whole/Do not crush or chew (CPS 2008).

Duration(s) of use

Consult a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use.

Risk information

Caution(s) and warning(s)

Consult a health care practitioner/health care provider /health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.



Contraindication(s)

No statement required.

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (Martindale 2011).

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

No statement required.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.
- ▶ Details of the manufacturing of the enzyme at the raw material stage should include fermentation medium and the isolation process of the medicinal ingredient.
- ▶ The specifications must include testing for enzymatic activity of the medicinal ingredient at the appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): LIPASE ACTIVITY
- ▶ 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.

References cited

Bisby F, Roskov Y, Culham A, Orrell T, Nicolson D, Paglinawan L, Bailly N, Appeltans W, Kirk P, Bourgoin T, Baillargeon G, Ouvrard D, editors. Species 2000 & ITIS Catalogue of Life, 15th March 2012 [Internet]. Reading (GB): Species 2000. [Source database: Species Fungorum 9.0, Sep 2010; Accessed 2019 March 14]. Available from: <http://www.catalogueoflife.org>

CABI 2012: Centre for Agriculture and Bioscience International. 2011. Index Fungorum [Internet]. Wallingford (GB): CABI (Centre for Agriculture and Bioscience International); 2012. [Accessed 2019 March 14]. Available from: <http://www.speciesfungorum.org>



CPS 2008: Compendium of Pharmaceuticals and Specialties: The Canadian Drug Reference for Health Professionals. Ottawa (ON): Canadian Pharmacists Association; 2008.

Glade MJ, Kendra D, Kaminski MV. Improvement in protein utilization in nursing-home patients on tube feeding supplemented with an enzyme product derived from *Aspergillus niger* and bromelain. *Nutrition* 2001;17(4):348-350.

FCC 8 2012: Food Chemicals Codex. Eighth edition. Rockville (MD): The United States Pharmacopeial Convention; 2012.

IUBMB 1961: Nomenclature Committee of the International Union of Biochemistry and Molecular Biology [Internet]. London (GB): Queen Mary, University of London [lipase: CAS 9001-62-1, EC 3.1.1.3 created 1961; Accessed 2019 March 14]. Available from: <https://www.qmul.ac.uk/sbcs/iubmb/>

Martindale 2011: Sweetman SC, editor. Martindale: The Complete Drug Reference [Internet]. London (GB): Pharmaceutical Press; 2011. [Pancreatic enzymes latest modification 09-Apr-2011; Accessed 2019 March 14]. Available from: <http://www.medicinescomplete.com>

References reviewed

Cichoke AJ. Pancreatic Enzymes. In: Pizzorno JE, Murray MT, editors. *Textbook of Natural Medicine*, Third edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006. p. 1131-1146.

Evidence for Quality of Finished Natural Health Products, Version 2.0 [Internet]. Ottawa (ON): Natural Health Products Directorate, Health Canada. 2007. [Accessed 2011 August 2]. Available from: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq-eng.php>

Food Standards Australia New Zealand (FSANZ). 7 April 2010 [9-10]. Application A1036 Lipase derived from *Aspergillus niger* as a Processing Aid (Enzyme) Assessment Report [Internet]. [Accessed 2011 August 15] Available from: http://www.foodstandards.gov.au/_srcfiles/A1036%20Lipase%20AR%20FINAL.pdf