



ALPHA-AMYLASE

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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date July 5, 2012

Proper name(s)

4-alpha-D-glucan glucohydrolase (IUBMB 1961)

Common name(s)

alpha-amylase/ α -amylase (IUBMB 1961)

Source material(s)

- ▶ *Aspergillus niger* van Tieghem 1867 (Trichocomaceae) (CABI 2012; Bisby et al. 2010)
- ▶ *Aspergillus flavus* var. *oryzae* (Ahlb.) Kurtzman MJ, Smiley, Robnett & Wicklow 1986 (Trichocomaceae) (CABI 2012; FCC 8; Bisby et al. 2010)
- ▶ *Rhizopus oryzae* Went & Prins. Geerl. 1895 (Mucoraceae) (CABI 2012; FCC 8)
- ▶ Barley (*Hordeum vulgare* L. (Poaceae)) seed (FCC 8; 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 monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s) Statement(s) to the effect of:

Digestive enzyme

Dose(s)

Subpopulation(s)

Adults (≥ 19 years)

Quantity(ies)

Dose unit 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 1.5×10^5 FCC DU per day, in divided doses, not to exceed 3.4×10^4 FCC DU per dose (FCC 8; Glade et al. 2001)

Note

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° (FCC 8).

Directions for use

- ▶ All products:
Take with food/meal.
- ▶ Enteric-coated products:
Swallow whole/ Do not crush or chew (CPS 2008).

Duration of use

For prolonged use, consult a health care practitioner.

Risk information Statement(s) to the effect of:

Caution(s) and warning(s)

- ▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

- ▶ If you have diabetes, consult a health care practitioner prior to use.

Contraindication(s)

No statement required.

Known adverse reaction(s)

Hypersensitivity/allergy has been known to occur, in which case discontinue use (Martindale 2011).

Non-medicinal ingredients

Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

Specifications

- ▶ The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- ▶ 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 appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC):
alpha-AMYLASE ACTIVITY (NONBACTERIAL).
- ▶ 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 2012 March 28]. Available from: <http://www.catalogueoflife.org>

CABI 2012: Centre for Agriculture and Bioscience International. Index Fungorum [Internet]. Wallingford (GB): CABI (Centre for Agriculture and Bioscience International); 2012. [Accessed 2012 March 28]. 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.

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

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.

IUBMB 1961: IUBMB Enzyme Nomenclature [Internet]. London (GB): Queen Mary, University of London. [α -amylase: CAS 9000-90-2, EC 3.2.1.1 created 1961; Accessed 2012 March 28]. Available from: <http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/2/1/1.html>

Martindale 2011: Sweetman SC, editor. Martindale: The Complete Drug Reference [Internet]. London (GB): Pharmaceutical Press; 2012. [Amylase: syn: EC 3.2.1.1 (α -amylase), CAS 9000-85-5 (bacterial α -amylase); 9000-90-2 (porcine α -amylase, pancreatic); latest modification 23 Sep 2011 ; Accessed 2012 March 28]. Available from: <http://www.medicinescomplete.com>

USDA 2010: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [Internet]. Beltsville (MD): National Germplasm Resources Laboratory. [*Hordeum vulgare* L: Last updated 04-Jan-2010; Accessed 2012 March 28]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

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.

Natural Medicines Comprehensive database. AbsorbAid Information. [Accessed 2012 March 28]. Available from: <http://www.naturaldatabase.com>

Nature's Sources. AbsorbAid® A natural Approach... Unlike Antacids and Acid Blockers. Frequently Asked Questions. [Accessed 2012 March 28]. Available from: http://www.naturesources.com/absorbaid_faq.asp