

TRYPSIN

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 and common names	Trypsin	IUBMB 1972
Source material(s)	bovine (<i>Bos taurus</i> (Bovidae)) pancreas porcine (<i>Sus scrofa</i> (Suidae)) pancreas	Bisby et al. 2011 FCC 7 USP 34
Route(s) of administration	Oral	
Dosage form(s)	<p>The acceptable pharmaceutical dosage forms include, but are not limited to, chewables (e.g. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons.</p> <p>This labelling standard is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.</p>	
Use(s) or Purpose(s)	Digestive enzyme	
Dose(s)	<p>Dose information must include the quantities of both the enzyme preparation and its enzymatic activity:</p> <ul style="list-style-type: none"> • Enzyme preparation containing up to 480 mg per day; not to exceed 160 mg per dose; and • Enzyme activity providing up to 1 200 000 USP trypsin units¹ per day; not to exceed 400 000 USP trypsin units per dose. 	<p>Dörr et al. 2007 Martin et al. 2002 Dale et al. 2001</p> <p>USP 34 Dörr et al. 2007 Martin et al. 2002 Dale et al. 2001</p>
Sub-population(s)	Adults	
Duration(s) of use	For prolonged use, consult a health care practitioner.	
Direction(s) for use	Take with food/meal.	
	For enteric-coated products: Swallow whole/do not crush or chew.	CPS 2008

Field	Field content	Reference
Risk information	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, anti-inflammatory agents or other enzyme products or are having surgery.	
	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.	
Storage condition(s)	Store in a tightly closed, light-resistant container in a cool, dry place.	Ph.Eur. 2011 USP 34
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 medicinal ingredient may comply with the specifications outlined in the United States Pharmacopeia (USP 34): Crystallized Trypsin.</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 or the United States Pharmacopeia: FCC 7: TRYPSIN ACTIVITY USP 34: Crystallized Trypsin.</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 USP trypsin unit is the activity causing a change in the absorbance of 0.003/min under the conditions of the assay.

References cited

Bisby FA, Roskov YR, Orrell TM, Nicolson D, Paglinawan LE, Bailly N, Kirk PM, Bourgoin T, Baillargeon G, Ouvrard D, editors. Species 2000 & ITIS Catalogue of Life, 15th March 2012 [Internet]. Reading (GB): Species 2000. [Source database: ITIS: The Integrated Taxonomic Information System, Version Apr 2011; Accessed 2012 March 16]. Available from: <http://www.catalogueoflife.org>

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

Dale PS, Tamhankar CP, George D, Daftary GV. Co-medication with hydrolytic enzymes in radiation therapy of uterine cervix: evidence of the reduction of acute side effects. *Cancer Chemotherapy and Pharmacology* 2001;47(Suppl):S29-S34.

Dörr W, Herrmann T. Efficacy of Wobe-Mugos® E for reduction of oral mucositis after radiotherapy. *Strahlentherapie und Onkologie* 2007;183:121-127.

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

IUBMB 1972: IUBMB Enzyme Nomenclature [Internet]. London (GB): Queen Mary, University of London. [trypsin: CAS 9002-07-7, EC 3.4.21.4 created 1961 as EC 3.4.4.4, transferred 1972 to EC 3.4.21.4; Accessed 2012 March 16]. Available from: <http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/4/21/4.html>

Martin T, Uhder K, Kurek R, Roeddiger S, Schneider L, Vogt HG, Heyd R, Zamboglou N. Does prophylactic treatment with proteolytic enzymes reduce acute toxicity of adjuvant pelvic irradiation? Results of a double-blind randomized trial. *Radiotherapy and Oncology* 2002;65:17-22.

Ph.Eur. 2012: European Pharmacopoeia 2011, 7th edition, Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM).

Sweetman SC, editor. Martindale: The Complete Drug Reference [Internet]. London (GB): Pharmaceutical Press; 2011. [Trypsin: CAS 90002-07-7, latest modification 14-May-2011; Accessed 2012 March 16]. Available from: <http://www.medicinescomplete.com>

USP 34: United States Pharmacopeia and the National Formulary (USP 34 - NF 29). Rockville (MD): The United States Pharmacopeial Convention; 2011.

References reviewed

Cichoke AJ. Pancreatic Enzymes. Chapter 112. In: Pizzorno JE, Murray MT, editors. Textbook of Natural Medicine, Third edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006.

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>