

CHYMOTRYPSIN

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	chymotrypsin	IUBMB 1972
Source material(s)	bovine (<i>Bos taurus</i> L. (Bovidae)) pancreas porcine (<i>Sus scrofa</i> (Suidae)) pancreas	Bisby et al. 2011 FCC 7 USP 34 Bisby et al. 2011 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: <ul style="list-style-type: none"> • Enzyme preparation containing up to 480 mg per day; not to exceed 160 mg per dose; and • Enzymatic activity providing up to 480 000 USP chymotrypsin units¹ per day; not to exceed 160 000 USP chymotrypsin units per dose. 	Dörr and Herrmann 2007; Martin et al. 2002; Dale et al. 2001 USP 34; Dörr and Herrmann 2007; Martin et al. 2002; Dale et al. 2001
Sub-population(s)	Adults	
Duration(s) of	For prolonged use, consult a health care practitioner.	

Field	Field content	Reference
use		
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.	
	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. 2012 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): Chymotrypsin.</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: CHYMOTRYPSIN ACTIVITY USP 34: Chymotrypsin.</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 Chymotrypsin Unit is defined as the activity causing a change in absorbance at the rate of 0.0075/min under the conditions of the assay.

References cited

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