Health Canada Santé Canada

TRYPSIN

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 12, 2012

Proper name(s)

Trypsin (IUBMB 1972)

Common name(s)

Trypsin (IUBMB 1972)

Source material(s)

- Bovine (*Bos taurus* (Bovidae)) pancreas (FCC 8; USP 35; Bisby et al. 2011)
- Porcine (*Sus scrofa* (Suidae)) pancreas (FCC 8; USP 35; Bisby et al. 2011)

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 information must include the quantities of both the enzyme preparation and its enzymatic activity:

- Enzyme preparation containing up to 480 mg per day; not to exceed 160 mg per dose (Dörr et al. 2007; Martin et al. 2002; Dale et al. 2001); and
- Enzyme activity providing up to 1.2 x 10^6 USP trypsin units per day; not to exceed 4.0 x 10^5 USP trypsin units per dose (USP 35; Dörr et al. 2007; Martin et al. 2002; Dale et al. 2001).

Note
One USP trypsin unit is the activity causing a change in the absorbance of 0.003/min under the conditions of the assay (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.
- If you have a gastrointestinal lesion/ulcer, are taking an anticoagulant/ blood thinner oranti-inflammatory, or are having surgery, 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.

Storage conditions

Statement(s) to the effect of:

Store in a tightly closed, light-resistant container in a cool, dry place (Ph.Eur. 2012; USP 35).

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) or the current United States Pharmacopeia (USP):
  FCC: TRYPSIN ACTIVITY
  USP: Crystallized Trypsin.
- The medicinal ingredient may comply with the specifications outlined in the current European (Ph.Eur.) or current United States (USP)pharmacopoeias:
  Ph.Eur: Trypsin
  USP: Crystallized Trypsin.
- 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.

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