Health Canada Santé Canada

CELLULASE

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 11, 2012

Proper name(s)

4-(1,3;1,4)-beta-D-glucan 4-glucanohydrolase (IUBMB 2001)

Common name(s)

Cellulase (IUBMB 2001)

Source material(s)

- *Aspergillus niger* van Tieghem 1867 (Trichocomaceae) (CABI 2012; FCC 8; Martindale 2011; Bisby et al. 2010)
- *Trichoderma longibrachiatum* Rifai 1969 (Hypocreaceae) (CABI 2012; FCC 8; Bisby et al. 2010)
- *Trichoderma reesei* E.G. Simmons 1977 (Hypocreaceae) (CABI 2012; FCC 8; Bisby et al. 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 (Martindale 2011).

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, per dosage unit; and
- Enzymatic activity providing up to 1.1 x 10^5 FCC CU per day, in divided doses (FCC 8; Glade et al. 2001).

Note
One cellulase unit (CU) is defined as the amount of activity that will produce a relative fluidity change of 1 in 5 minutes in a defined carboxymethyl cellulose substrate under the conditions of the assay (FCC 8).

Directions for use

Take with food/ meal.

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.

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):
  CELLULASE 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 their shelf life indicated on the product label.

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