Pancreatic Enzymes

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Pancreatic Enzymes Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 75 KB) 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 The term "pancreatic enzymes" is used as a collective term for various enzyme preparations derived from animal pancreas. For pharmacopoeial grade ingredients, the applicant must use the proper name and common name of the enzyme as provided in the pharmocopoeia. Table 2 in the Specification section indicates the differences in the amounts of the enzyme activities of amylase, lipase and protease for Pancreatic Extract, Pancreatin and Pancrelipase. To ensure consistent representation of enzyme-containing products, pancreatic enzyme activity must be expressed in USP units in the PLA and label. 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 statements are synonymous. Either term or statement may be selected by the applicant. Date April 29, 2019 Proper name(s), Common name(s), Source material(s) Table 1. Proper name(s), Common name(s), Source material(s) Proper name(s) Common name(s) Source material(s) Proper name(s) Part(s) Pancreatic enzymes Pancreatic enzymes Bos taurus Sus scrofa Pancreas Pancreatic extract Pancreatic extract Pancreatin Pancreatin Pancrelipase Pancrelipase References: Proper names: BP 2019, USP 41 2018, Ph.Eur. 2016, WHO 2011, US FDA 2010; Common names: BP 2019, USP 41 2018, Ph.Eur. 2016, WHO 2011, US FDA 2010; Source materials: BP 2019, USP 41 2018, Ph.Eur. 2016, Bisby et al. 2011. Route of Administration Oral Dosage Form(s) This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document. The only acceptable pharmaceutical dosage forms are delayed-release capsules, tablets, or granules (e.g. enteric-coated tablets, capsules containing enteric-coated granules/(mini) microspheres) (Friess et al. 1999; Suarez et al. 1999; Sharpé et al. 1997). The dosage form must be qualified with an additional term to describe the delayed release (e.g. enteric-coated capsules, gastro-resistant tablets, microencapsulated pancreatic enzymes) (WHO 2011). Use(s) or Purpose(s) Digestive enzyme (Cichoke 2006). Digestive aid (Cichoke 2006). Digestive aid to help decrease bloating after high caloric, high fat meals (Suarez et al. 1999). Helps to decrease bloating after high caloric, high fat meals (Suarez et al. 1999). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Enzyme preparation providing all the following enzyme activities (USP 41 2018; Suarez et al. 1999; Domínguez-Muñoz et al. 1997): Amylase: 17,000 to 149,000 USP amylase units per day, not to exceed 37,000 USP units per single dose Lipase: 5,000 to 40,000 USP lipase units per day, not to exceed 20,000 USP units per single dose Protease: 16,000 to 125,000 USP protease units per day, not to exceed 38,000 USP units per single dose Notes Dose information must include the quantities of both the enzyme preparation and its enzymatic activity as potency. Pharmacopoeial units other than USP may be represented on the label as additional information. The following approximate conversion factors can be used to convert the activities of pancreatic enzymes into USP units (Scharpé et al. 1997): Amylase: 1 Ph. Eur. Unit = 1 BP Unit = 1 FIP Unit ~ 4.15 USP Units Lipase: 1 Ph. Eur. Unit = 1 BP Unit = 1 FIP Unit ~ 1 USP Unit Protease: 1 Ph. Eur. Unit = 1 BP Unit = 1 FIP Unit ~ 62.5 USP Units Direction(s) for use All products Take with or immediately before a meal/food (Ferrone et al. 2007; Suarez et al. 1999; Friess et al. 1998; Domínguez-Muñoz et al. 1997). Use the smallest effective dose which controls symptoms (CPS 2008; Sharpé et al. 1997). Enteric-coated products Swallow whole/Do not crush or chew (CPS 2008). Encapsulated products containing granules/(mini)microspheres and delayed-release granules (For individuals who experience difficulties swallowing capsules, the capsules may be opened and) the granules/(mini)microspheres may be mixed with soft food or fluid. Use immediately after mixing (Martindale 2011; CPS 2008). Duration(s) of Use Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4 weeks (Friess et al. 1998). Risk Information Caution(s) and warning(s) All products Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are pregnant, breastfeeding, have diabetes, pancreatitis, pancreatic exocrine insufficiency or cystic fibrosis (Halm et al. 1999; Delhaye et al. 1996; Guarner et al. 1993). Digestive aid/Decrease bloating Consult a health care

practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) All products Do not use this product if you are sensitive to pancreatic enzymes (Martindale 2011; CPS 2008). Products from Sus scrofa pancreas Do not use this product if you are sensitive to pork proteins (Martindale 2011; CPS 2008). Known adverse reaction(s) Stop use and consult a health care practitioner/health care provider/health care professional/ doctor/physician if nausea, vomiting, abdominal pain/epigastric pain and/or heartburn occur (Friess et al. 1998). Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Store in a tightly closed, light-resistant container in a cool, dry place (BP 2019; USP 41 2018; Ph.Eur. 2016). Specifications The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID. The specifications must include testing for enzymatic activity of the medicinal ingredient at the appropriate stages of formulation and manufacturing using the assay outlined in the current United States Pharmacopeia (USP): Pancrelipase - assay for amylase, lipase and protease activity. Overages to compensate for the loss of activity during manufacturing and shelf-life of the finished product are permitted as per the pharmacopoeial standard. 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. In addition, the medicinal ingredient proper name and common name should be determined by the pharmacopoeial amounts of amylolytic, lipolytic and proteolytic activities for Pancreatin, Pancreatic extract and Pancrelipase according to the British, European and U.S. pharmacopoeias (Table 2). Table 2. Amylase, lipase and protease activity units per milligram of pancreas preparation according to the British, European and U.S. pharmacopoeias Pharmacopoeia Enzyme Units of Activity 1 Amylase Lipase Protease BP 2019 Pancreatin 24 FIP 20 FIP 1.4 FIP USP 41 2018 Pancreatin 25 USP 2 USP 25 USP BP 2019 Pancreatic extract 2 12 Ph. Eur. 15 Ph. Eur. 1 Ph. Eur. Ph.Eur. 2016 Pancreatic extract (powder) 2 12 Ph. Eur. 15 Ph. Eur. 1 Ph. Eur. USP 41 2018 Pancrelipase 100 USP 24 USP 100 USP 1. Minimum amounts 2. Cross-referenced within the respective pharmacopoeias. The proper and common name 'Pancreatic extract' should be used for both BP 2019 and Ph.Eur 2016. 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 BP 2019: British Pharmacopoeia 9.6. 2019. 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. CPS 2008: Compendium of Pharmaceuticals and Specialties: The Canadian Drug Reference for Health Professionals. Ottawa (ON): Canadian Pharmacists Association; 2008. Delhaye M, Meuris S, Gohimont AC, Buedts K, Cremer M. Comparative evaluation of a high lipase pancreatic enzyme preparation and a standard pancreatic supplement for treating exocrine pancreatic insufficiency in chronic pancreatitis. European Journal of Gastroenterology and Hepatology 1996;8:699-703. Domínguez-Muñoz JE, Birckelbach U, Glasbrenner B, Sauerbruch T, Malfertheiner P. Effect of oral pancreatic enzyme administration on digestive function in healthy subjects: comparison between two enzyme preparations. Alimentary Pharmacology and Therapeutics 1997;11(2):403- 408. Ferrone M, Raimondo M, Scolapio JS. Pancreatic enzyme pharmacotherapy. Pharmacotherapy 2007;27(6):910-920. Friess H, Kleeff J, Malfertheiner P, Müller MW, Homuth K, Büchler MW. Influence of high- dose pancreatic enzyme treatment on pancreatic function in healthy volunteers. International Journal of Pancreatology 1998;23(2):115-123. Guarner L, Rodríguez R, Guarner F, Malagelada JR. Fate of oral enzymes in pancreatic insufficiency. Gut 1993;34:708-712. Halm U, Löser C, Löhr M, Katschinski M, Mössner J. A double-blind, randomized, multicentre, crossover study to prove equivalence of pancreatin minimicrospheres versus microspheres in exocrine pancreatic insufficiency. Alimentary Pharmacology and Therapeutics 1999;13(7):951- 957. Löhr JM, Hummel FM, Pirilis KT, Steinkamp G, Körner A, Henniges F. Properties of different pancreatin preparations used in pancreatic exocrine insufficiency. European Journal of Gastroenterology & hepatology 2009;21(9):1024-1031. Martindale 2011: Sweetman SC, editor. Martindale: The Complete Drug Reference [Internet]. London (GB): Pharmaceutical Press; 2011. [Pancreatic enzymes : CAS: 8049-47-6, latest modification: 05-Dec-2011; Accessed 2012 July 12]. Available from: http://www.medicinescomplete.com Ph.Eur. 2016: European Pharmacopoeia. 9th edition. 2016. Scharpé S, Uyttenbroeck W, Samyn N. Pancreatic Enzyme Replacement. In: Lauwers A, Scharpé S, editors. Pharmaceutical Enzymes. London (GB): Taylor & Francis, Inc; 1997. p. 187- 221. Suarez F, Levitt MD, Adshead J, Barkin JS. Pancreatic supplements reduce symptomatic response of healthy subjects to a high fat meal. Digestive Diseases and Sciences 1999;44(7):1317-1321. US FDA 2010: Postmarket Drug Safety Information for Patients and Providers. Updated Questions and Answers for Healthcare Professionals and the Public: Use an Approved Pancreatic Enzyme Product (PEP), Page last updated: 05/24/2010. [Internet] [Accessed 2012 March 16]. Available from:

http://www.fda.gov/ Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204745.htm USP 41 2018: United States Pharmacopeia and the National Formulary (USP 41 - NF 36). 2018. WHO 2011: WHO Model List of Essential Medicines. 17th edition. March 2011 [Internet]. [Accessed 2012 March 16]. Available from: http://www.who.int/medicines/publications/essentialmedicines/en/index.html Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Store in a tightly closed, light-resistant container in a cool, dry place (BP 2019; USP 41 2018; Ph.Eur. 2016).

DOSAGE FORM(S)

The only acceptable pharmaceutical dosage forms are delayed-release capsules, tablets, or granules (e.g. enteric-coated tablets, capsules containing enteric-coated granules/(mini) microspheres) (Friess et al. 1999; Suarez et al. 1999; Sharpé et al. 1997). The dosage form must be qualified with an additional term to describe the delayed release (e.g. enteric-coated capsules, gastro-resistant tablets, microencapsulated pancreatic enzymes) (WHO 2011).

RISK INFORMATION

Caution(s) and warning(s) All products Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are pregnant, breastfeeding, have diabetes, pancreatitis, pancreatic exocrine insufficiency or cystic fibrosis (Halm et al. 1999; Delhaye et al. 1996; Guarner et al. 1993). Digestive aid/Decrease bloating Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) All products Do not use this product if you are sensitive to pancreatic enzymes (Martindale 2011; CPS 2008). Products from Sus scrofa pancreas Do not use this product if you are sensitive to pork proteins (Martindale 2011; CPS 2008). Known adverse reaction(s) Stop use and consult a health care practitioner/health care provider/health care professional/ doctor/physician if nausea, vomiting, abdominal pain/epigastric pain and/or heartburn occur (Friess et al. 1998).

NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Store in a tightly closed, light-resistant container in a cool, dry place (BP 2019; USP 41 2018; Ph.Eur. 2016).

STORAGE CONDITION(S)

Store in a tightly closed, light-resistant container in a cool, dry place (BP 2019; USP 41 2018; Ph.Eur. 2016).

SPECIFICATIONS

The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.The medicinal ingredient must comply with the requirements outlined in the NHPID.The specifications must include testing for enzymatic activity of the medicinal ingredient at the appropriate stages of formulation and manufacturing using the assay outlined in the current United States Pharmacopeia (USP): Pancrelipase - assay for amylase, lipase and protease activity.Overages to compensate for the loss of activity during manufacturing and shelf-life of the finished product are permitted as per the pharmacopoeial standard.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.In addition, the medicinal ingredient proper name and common name should be determined by the pharmacopoeial amounts of amylolytic, lipolytic and proteolytic activities for Pancreatin, Pancreatic extract and Pancrelipase according to the British, European and U.S. pharmacopoeias (Table 2). Table 2. Amylase, lipase and protease activity units per milligram of pancreas preparation according to the British, European and U.S. pharmacopoeiasPharmacopoeiaEnzymeUnits of Activity1AmylaseLipaseProteaseBP 2019Pancreatin24 FIP20 FIP1.4 FIPUSP 41 2018Pancreatin25 USP2 USP25 USPBP 2019Pancreatic extract212 Ph. Eur.15 Ph. Eur.1 Ph. Eur.Ph.Eur. 2016Pancreatic extract (powder)212 Ph. Eur.15 Ph. Eur.1 Ph. Eur.USP 41 2018Pancrelipase100 USP24 USP100 USP 1.Minimum amounts 2.Cross-referenced within the respective pharmacopoeias. The proper and common name 'Pancreatic extract' should be used for both BP 2019 and Ph.Eur 2016.

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source material(s)	
Proper name(s)	Part(s)		
Pancreatic enzymes	Pancreatic enzymes	Bos taurusSus scrofa	Pancreas
Pancreatic extract	Pancreatic extract		
Pancreatin	Pancreatin		
Pancrelipase	Pancrelipase		

Pharmacopoeia	Enzyme	Units of Activity1		
Amylase	Lipase	Protease		
BP 2019	Pancreatin	24 FIP	20 FIP	1.4 FIP
USP 41 2018	Pancreatin	25 USP	2 USP	25 USP
BP 2019	Pancreatic extract2	12 Ph. Eur.	15 Ph. Eur.	1 Ph. Eur.
Ph.Eur. 2016	Pancreatic extract (powder)2	12 Ph. Eur.	15 Ph. Eur.	1 Ph. Eur.
USP 41 2018	Pancrelipase	100 USP	24 USP	100 USP