

NATURAL HEALTH PRODUCT

DIGESTIVE ENZYMES

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 ingredients.

Notes

- Any ingredient in Tables 1 to 3 may be formulated as single ingredient products, or two or more ingredients may be combined to form multi-ingredient products.
- The enzyme nomenclature identification number (IUBMB No.) is not required but may be provided as additional information on the cover letter.
- The text in parentheses is additional optional information which can be included on the label at the applicant's discretion.
- The solidus (/) indicates that either term and/or statement may be selected on the label.

Rules when this monograph is combined with other monographs (Class II and III applications):

- Liquid and liquid-containing dosage forms (e.g., capsule, soft; spray) are not acceptable as Class II applications when an enzyme is combined with non-enzymatic ingredients as this may impact the enzyme activity. These products may be submitted as a Class III application.
- However, this restriction does not apply if the enzymes are microencapsulated (i.e., Capsule, enteric-coated pellets and Tablet, enteric-coated granules).

Date

December 19, 2025

Proper name(s), Common name(s), Source information

Table 1. **Carbohydrases:** Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
4-alpha-D-Glucan glucanohydrolase	alpha-Amylase	• <i>Aspergillus flavus</i> var. <i>oryzae</i>	Whole
		• <i>Aspergillus niger</i>	
		<i>Hordeum vulgare</i>	Seed
		<i>Rhizopus oryzae</i>	Whole
alpha-D-Galactoside galactohydrolase	alpha-Galactosidase	<i>Aspergillus niger</i>	Whole



Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
1,3-(1,3;1,4)-beta-D-Glucan 3(4)-glucanohydrolase	beta-Glucanase	<ul style="list-style-type: none"> • <i>Aspergillus niger</i> • <i>Trichoderma longibrachiatum</i> • <i>Trichoderma reesei</i> 	Whole
<ul style="list-style-type: none"> • 1,4-alpha-D-Glucan glucohydrolase • 4-alpha-D-Glucan glucohydrolase 	<ul style="list-style-type: none"> • Acid maltase • Amyloglucosidase • Glucoamylase 	<ul style="list-style-type: none"> • <i>Aspergillus flavus</i> var. <i>oryzae</i> • <i>Aspergillus niger</i> • <i>Rhizopus niveus</i> • <i>Rhizopus oryzae</i> 	Whole
4-(1,3;1,4)-beta-D-Glucan 4-glucohydrolase	Cellulase	<ul style="list-style-type: none"> • <i>Aspergillus flavus</i> var. <i>oryzae</i> • <i>Aspergillus niger</i> • <i>Trichoderma longibrachiatum</i> • <i>Trichoderma reesei</i> 	Whole
<ul style="list-style-type: none"> • 1,3-beta-D-Xylan xylanohydrolase • 1,4-beta-D-Mannan mannanohydrolase • 1,5-alpha-L-Arabinan arabinanohydrolase • alpha-L-Arabinofuranoside arabinofuranohydrolase 	Hemicellulase	<ul style="list-style-type: none"> • <i>Aspergillus flavus</i> var. <i>oryzae</i> • <i>Aspergillus niger</i> • <i>Trichoderma longibrachiatum</i> • <i>Trichoderma reesei</i> 	Whole
<ul style="list-style-type: none"> • beta-D-Fructofuranoside fructohydrolase • beta-Fructofuranosidase 	<ul style="list-style-type: none"> • Invertase • Sucrase 	<ul style="list-style-type: none"> • <i>Aspergillus niger</i> • <i>Saccharomyces cerevisiae</i> 	Whole
Malt diastase	Malt diastase	<i>Hordeum vulgare</i>	Seed
<ul style="list-style-type: none"> • Pectin pectylhydrolase • Poly(1,4-alpha-D-galacturonide) glycanohydrolase • Poly(1,4-alpha-D-galacturonide)lyase • Poly(methoxyl-L-galacturonide)lyase 	<ul style="list-style-type: none"> • Pectinase • Polygalacturonase 	<ul style="list-style-type: none"> • <i>Aspergillus flavus</i> var. <i>oryzae</i> • <i>Aspergillus niger</i> • <i>Trichoderma longibrachiatum</i> • <i>Trichoderma reesei</i> 	Whole
<ul style="list-style-type: none"> • 1,3-beta-D-Xylan xylanohydrolase • 1,4-beta-D-Xylan xylanohydrolase 	<ul style="list-style-type: none"> • beta-1,3-Xylanase • beta-1,4-Xylanase • Xylanase 	<ul style="list-style-type: none"> • <i>Trichoderma longibrachiatum</i> • <i>Trichoderma reesei</i> 	Whole



Table 2. **Proteases:** Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
Bromelain	Bromelain	<ul style="list-style-type: none"> <i>Ananas comosus</i> var. <i>bracteatus</i> <i>Ananas comosus</i> var. <i>comosus</i> 	<ul style="list-style-type: none"> Fruit Stem
Bacterial protease	Bacterial protease	<i>Bacillus subtilis</i>	Whole
Chymotrypsin	Chymotrypsin	<ul style="list-style-type: none"> <i>Bos taurus</i> <i>Sus scrofa</i> 	Pancreas
Fungal protease	<ul style="list-style-type: none"> Fungal protease Protease 	<ul style="list-style-type: none"> <i>Aspergillus flavus</i> var. <i>oryza</i> <i>Aspergillus niger</i> 	Whole
Pancreatic enzymes	Pancreatic enzymes	<ul style="list-style-type: none"> <i>Bos taurus</i> <i>Sus scrofa</i> 	Pancreas
Pancreatic extract	Pancreatic extract		
Pancreatin	Pancreatin		
Pancrelipase	Pancrelipase		
Papain	Papain	<i>Carica papaya</i>	<ul style="list-style-type: none"> Fruit Leaf
<ul style="list-style-type: none"> Pepsin A Pepsin B 	Pepsin	<i>Sus scrofa</i>	Stomach
Trypsin	Trypsin	<ul style="list-style-type: none"> <i>Bos taurus</i> <i>Sus scrofa</i> 	Pancreas

Table 3. **Other enzymes:** Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
Hydrogen-peroxide:hydrogen-peroxide oxidoreductase	Catalase	<ul style="list-style-type: none"> <i>Aspergillus niger</i> <i>Saccharomyces cerevisiae</i> 	Whole
beta-D-Galactoside galactohydrolase	<ul style="list-style-type: none"> beta-Galactosidase Lactase 	<i>Aspergillus flavus</i> var. <i>oryzae</i>	Whole
<ul style="list-style-type: none"> Triacylglycerol acylhydrolase Triacylglycerol lipase 	Lipase	<ul style="list-style-type: none"> <i>Aspergillus flavus</i> var. <i>oryzae</i> <i>Aspergillus niger</i> <i>Rhizopus oryzae</i> 	Whole



Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
<ul style="list-style-type: none"> • myo-Inositol-hexakisphosphate 3-phosphohydrolase • myo-Inositol-hexakisphosphate 4-phosphohydrolase • Orthophosphoric-mono ester phosphohydrolase 	<ul style="list-style-type: none"> • 1-Phytase • 3-Phytase • 4-Phytase • 6-Phytase • Phytase 	<i>Aspergillus niger</i>	Whole

References Tables 1 to 3: Proper names: BP 2025; IUBMB 2025; Ph.Eu 2025; FCC 2024; USP-NF 2024; WHO 2011; Common names: BP 2025; IUBMB 2025; Ph.Eu 2025; FCC 2024; USP-NF 2024; WHO 2011; Source information: BP 2025; CABI 2025; COL 2025; Ph.Eu 2025; USDA 2025; Brayfield and Cadart 2024; FCC 2024; Kirk 2024; ITIS 2024; RSC 2024; USP-NF 2024; Bisby et al. 2010; Morton 1987.

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.

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. It includes the dosage forms listed below for pancreatic enzymes.

Pancreatic enzymes; pancreatic extract; pancreatin; pancrelipase:

The only acceptable dosage forms are: Capsule, enteric-coated; Capsule, soft, enteric-coated; Capsule, enteric-coated pellets; Granule enteric-coated; Tablet, enteric-coated; Tablets, enteric-coated granules.

Use(s) or Purpose(s)

All products

- Digestive enzyme(s).
- Digestive aid.

Products containing proteases (Table 2)

- Helps digest proteins (Murray 1996).

Products containing pancreatic enzymes; pancreatic extract; pancreatin; pancrelipase

- 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).

Products containing alpha-galactosidase

- Helps prevent gastrointestinal intolerance of oligosaccharides/fermentable carbohydrates (Di Stefano et al. 2007; Pray 2006; Ganiats et al. 1994).
- Helps reduce gas production/flatulence following a meal rich in oligosaccharides/fermentable carbohydrates (such as vegetables, pulses/legumes/beans and whole grains) (Di Stefano et al. 2007; Pray 2006; Lettieri and Dain 1998; Ganiats et al. 1994).

Products containing bromelain

- Used in Herbal Medicine to help relieve minor pain, swelling and inflammation (Walker et al. 2002; Blumenthal 1998).

Products containing lactase

- Assist in the digestion of foods containing lactose (e.g., dairy foods, milk, etc.) (Ramirez et al. 1994; Lin et al. 1993; Biller et al. 1987; Moskovitz et al. 1987).
- Helps prevent symptoms of lactose intolerance (including gas, bloating, cramping, and diarrhea) (Ramirez et al. 1994; Lin et al. 1993; Biller et al. 1987; Moskovitz et al. 1987).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Table 4. Daily maximum of enzymatic activity unit (refer to Appendix I for the definitions of the activity units)

Medicinal ingredients	Quantities (enzymatic activity per day; and per single dose, when applicable) ^{1,2}
alpha-Amylase	No to exceed 150,000 FCC DU per day; and 34,000 FCC DU per single dose
alpha-Galactosidase	<i>Digestive enzyme/Digestive aid</i> Not to exceed 3,000 FCC GalU per day
	<i>Prevention of gastrointestinal intolerance/</i>



Medicinal ingredients	Quantities (enzymatic activity per day; and per single dose, when applicable) ^{1,2}
	<i>Reduction of flatulence</i> 260 - 3,000 FCC GaU per day.
Bacterial protease	Not to exceed 490,000 FCC PC per day
beta-Glucanase	Not to exceed 210 FCC BGU per day
Bromelain	<i>Digestive enzyme/Digestive aid/Digest proteins</i> Not to exceed 130,000,000 FCC PU per day; and 45,000,000 FCC PU per single dose <i>Minor pain, swelling, and inflammation relief</i> 480,000 - 130,000,000 FCC PU per day; Not to exceed 45,000,000 FCC PU per single dose
Catalase	Not to exceed 3,200 FCC BU per day
Cellulase	Not to exceed 110,000 FCC CU per day
Chymotrypsin	Not to exceed 480,000 USP ChyU units per day; and 160,000 USP ChyU per single dose
Fungal protease	Not to exceed 680,000 FCC HUT and/or 6,800 FCC SAP per day
Glucoamylase (Amyloglucosidase)	Not to exceed 300 FCC GU per day
Hemicellulase	Not to exceed 45,000 FCC HCU per day
Invertase/sucrase	Not to exceed 3,000 FCC INVU and/or 4,200 FCC SU per day
Lactase	<i>Digestive enzyme/Digestive aid</i> Not to exceed 54,000 FCC ALU per day; and 18,000 FCC ALU per single dose <i>Lactose digestion/Symptoms of lactose intolerance</i> 3,000 - 54,000 FCC ALU per day; and not to exceed 18,000 FCC ALU per single dose
Lipase	Not to exceed 110,000 FCC LU per day; and 30,000 FCC LU per single dose
Malt diastase	Not to exceed 6,000 FCC DP per day
Pancreatic enzymes; pancreatic extract; pancreatin; pancrelipase ³	<ul style="list-style-type: none"> • Amylase: 17,000 to 149,000 USP amylase units per day; and not to exceed 37,000 USP units per single dose • Lipase: 5,000 to 40,000 USP lipase units per day; and not to exceed 20,000 USP units per single dose • Protease: 16,000 to 125,000 USP protease units per day; and not to exceed 38,000 USP units per single dose
Papain	Not to exceed 7,200,000 FCC PU per day; and 2,400,000 FCC PU per single dose
Pectinase	Not to exceed 180 endo-PG per day
Pepsin	Not to exceed 1,900,000 FCC PepU per day
Phytase	Not to exceed 75 FCC FTU per day
Trypsin	Not to exceed 1,200,000 USP TrypU per day; and 400,000 USP TrypU per single dose
Xylanase	Not to exceed 3,300 XU per day



References: alpha-Amylase: FCC 2024; Glade et al. 2001; alpha-Galactosidase: FCC 2024; Di Stefano et al. 2007; Pray 2006; Lettieri and Dain 1998; Ganiats et al. 1994; Cellulase: FCC 2024; Glade et al. 2001; Chymotrypsin: USP-NF 2024; Dörr and Herrmann 2007; Martin et al. 2002; Dale et al. 2001; Bromelain: Kerkhoffs et al. 2004; Walker et al. 2002; Glade et al. 2001; Singer et al. 2001; Klein and Kullich 2000; Gutfreund et al. 1978; Lactase: FCC 2024; Ramirez et al. 1994; Lin et al. 1993; Lipase: FCC 2024; Glade et al. 2001; Papain: Martin et al. 2002; Dale et al. 2001; Trypsin: USP-NF 2024; Dörr and Herrmann 2007; Martin et al. 2002; Dale et al. 2001; Fungal protease: FCC 2024; Oben et al. 2008; Brown et al. 2004; Pancreatic enzymes: USP-NF 2024; Suarez et al. 1999; Domínguez-Muñoz et al. 1997; Other enzymes: NNHPD 2012.

¹When multiple enzymes are combined, the total activity of each enzyme in the finished product must not exceed the maximum single and daily activities listed in Table 4.

²Other recognized enzymatic activity units may be listed on the product label as long as equivalent to the ones indicated on this monograph and PLA form.

³Pharmacopoeial 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 (including pancreatic extract, pancreatin, pancrelipase) 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

Note: The quantity per dosage unit must be the enzymatic activity. The quantity of the enzymatic preparation in mg or ml may also be included as additional quantity.

Direction(s) for use

All products; Optional for bromelain used for minor pain, swelling, and inflammation relief

Take with (or immediately before) a meal/food.

Products containing pancreatic enzymes; pancreatic extract; pancreatin; pancrelipase

Use the smallest effective dose which controls symptoms (CPS 2008; Sharpé et al. 1997).

Capsule, enteric-coated; Capsule, soft, enteric-coated; Capsule, enteric-coated pellets; Granule enteric-coated; Tablet, enteric-coated; Tablets, enteric-coated granules

Swallow whole. Do not crush or chew (CPS 2008).

Capsule, enteric-coated pellets; Tablets, enteric-coated granules

(For individuals who experience difficulties swallowing) Capsules/Tablets may be opened and the content may be mixed with soft food or fluid. Use immediately after mixing (CPS 2008).

Combination rules

- For multi-ingredient products containing bromelain and papain, the maximum enzymatic



activity from both enzymes combined cannot exceed the maximum proteolytic activity of 130,000,000 FCC PU per day and 45,000,000 FCC PU per single dose.

Duration(s) of use

Products providing 60,000,000 FCC PU or less bromelain, per day

Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 16 weeks (Kasemsuk et al. 2016; Gutfreund et al. 1978).

Products providing more than 60,000,000 FCC PU bromelain, per day and products containing pancreatic enzymes; pancreatic extract; pancreatin; pancrelipase

Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4 weeks.

Products containing any other enzyme from Tables 1, 2 and 3

Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4 to 8 weeks¹.

¹**Note:** The term ‘prolonged use’ used in previous version of the monograph has been further defined to avoid confusion.

Risk information

Caution(s) and warning(s)

All products

Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding.

Products containing one or more carbohydrases (Table 1); cellulase; lactase; pancreatic enzymes; pancreatic extract; pancreatin; pancrelipase

Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes.

Products containing one or more proteases (Table 2); chymotrypsin; bromelain; papain; trypsin

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have gastrointestinal lesions/ulcers or are having surgery.**
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners or anti-inflammatory medications.**



Products containing papain

Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have an allergy to latex or fruits (such as avocado, banana, chestnut, passion fruit, fig, melon, mango, kiwi, pineapple, peach, and tomato) (US FDA 2008; APhA 2006; Brehler et al. 1997).

Products containing pancreatic enzymes; pancreatic extract; pancreatin; pancrelipase

Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have pancreatitis, pancreatic exocrine insufficiency or cystic fibrosis (Halm et al. 1999; Delhaye et al. 1996; Guarner et al. 1993).

Prevention of gastrointestinal intolerance/Reduction of flatulence/Minor pain, swelling, and inflammation relief/Lactose digestion/Symptoms of lactose intolerance/Digestive aid/Decrease bloating

Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

Contraindication(s)

Products containing pancreatic enzymes; pancreatic extract; pancreatin; pancrelipase

Do not use if you are sensitive to pancreatic enzymes (Brayfield and Cadart 2025; CPS 2008).

*Products sourced from *Sus scrofa* pancreas*

Do not use if you are sensitive to pork proteins (Brayfield and Cadart 2025; CPS 2008).

Known adverse reaction(s)

All products

Stop use if hypersensitivity/allergy occurs (Brayfield and Cadart 2025; Pray 2006; CPS 2005; Ganiats et al. 1994).

Products containing lactase

Stop use if gastrointestinal discomfort/disturbances occur (HC 2011).

Products containing pancreatic enzymes; pancreatic extract; pancreatin; pancrelipase

Stop use and ask 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).

Products containing bromelain

When using this product you may experience gastrointestinal discomfort/disturbances (Brayfield and Cadart 2025; Brinker 2010; Brien et al. 2006; Murray and Pizzorno 2006; Blumenthal et al. 2000; Baur and Fruhmam 1979).

Non-medicinal ingredients

Must be chosen from and meet the limitations outlined in the Natural Health Products Ingredients Database (NHPID).

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

Specifications

- The finished product specifications must be established in accordance with the requirements described in the Quality of Natural Health Products Guide.
- The medicinal ingredient(s) must comply with the requirements outlined in the NHPID.
- Details of the manufacturing of the enzyme(s) at the raw material stage should include fermentation medium and the isolation process.
- The specifications must include testing for enzymatic activity of the medicinal ingredient(s) at appropriate stages of formulation and manufacturing using the assay outlined in the Food Chemicals Codex (FCC).
- Testing for endo-polygalacturonase activity must be done at the appropriate stages of formulation and manufacturing as outlined in Blandino et al. 2002.
- Testing for xylanase activity must be done at the appropriate stages of formulation and manufacturing as outlined in Ghose and Bisaria 1987.
- Manufacturers are responsible for ensuring that activity assays that are used outside the conditions specified in the FCC have been sufficiently validated for their intended use in accordance with the requirements of good manufacturing practices.
- 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 assays are not suitable for use, manufacturers should use due diligence to ensure that the enzymes remain active to the end of the shelf-life indicated on the product label.
- **Pancreatic enzymes:** The medicinal ingredient proper name and common name should be determined by the amounts of amylolytic, lipolytic, and proteolytic activities for pancreatin, pancreatic extract, and pancrelipase according to the British, European and United States pharmacopoeias (Appendix II).



EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document: [Labelling of Natural Health Products](#) for more details.

Product Facts
Medicinal ingredients in each capsule alpha-Amylase (<i>Aspergillus niger</i> – Whole) XX FCC DU (YY mg) Cellulase (<i>Aspergillus niger</i> – Whole) XX FCC CU (YY mg)
Uses Digestive enzymes
Warnings If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame
Ask a health care practitioner before use if • you are pregnant or breastfeeding • you have diabetes.
Stop use if allergy occurs.
Directions Adults 18 years and older: • Take X capsule(s), X time(s) per day • Take with a meal • Swallow whole. Do not crush or chew ² • Capsules may be opened and the content may be mixed with soft food or fluid. Use immediately after mixing ³ • Ask a health care practitioner for use beyond 4 to 8 weeks.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

¹This section can be removed from the table if the product contains no allergen or aspartame.

²Enteric-coated products.

³Capsule, enteric-coated pellets.

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Appendix I

Definitions of the activity units listed in Table 4:

- **ALU:** One lactase unit (ALU) is defined as that quantity of enzyme that will liberate *o*-nitrophenol at a rate of 1 $\mu\text{mol}/\text{minute}$ under the conditions of the assay.
- **BGU:** One β -glucanase unit (BGU) is defined as that quantity of enzyme that will liberate reducing sugar (as glucose equivalence) at a rate of 1 $\mu\text{mol}/\text{minute}$ under the conditions of the assay.
- **BU:** One Baker unit is defined as the amount of catalase that will decompose 264 mg of hydrogen peroxide under the conditions of the assay.
- **ChyU:** One USP chymotrypsin unit (ChyU) is defined as the activity causing a change in absorbance at the rate of 0.0075/minute under the conditions of the assay.
- **CU:** 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.
- **DP:** One unit of diastase activity, expressed as degrees diastatic power (DP°), is defined as that amount of enzyme contained in 0.1 mL of a 5% solution of the sample enzyme preparation that will produce sufficient reducing sugars to reduce 5 mL of Fehling's solution when the sample is incubated with 100 mL of the substrate for 1 hour at 20°C.
- **DU:** One α -amylase dextrinizing unit (DU) is defined as the quantity of α -amylase that will dextrinize soluble starch in the presence of an excess of β -amylase at the rate of 1 g/hour at 30°C.
- **endo-PG:** One endo-polygalacturonase unit (endo-PG) is the amount of enzyme required to release 1 $\mu\text{mol}/\text{minute}$ of galacturonic acid from polygalacturonic acid under the conditions of the assay.
- **FTU:** One phytase unit (FTU) is the amount of enzyme that liberates inorganic phosphate at 1 $\mu\text{mol}/\text{minute}$ from 0.0051 mol/L of sodium phytate at 37°C and pH 5.50 under the conditions of the test.
- **GalU:** One galactosidase activity unit (GalU) is defined as the quantity of the enzyme that will liberate *p*-nitrophenol at the rate of 1 $\mu\text{mol}/\text{minute}$ under the conditions of the assay.

- **GU:** One glucoamylase unit (GU) is defined as the amount of glucoamylase that will liberate 0.1 μmol /minute of *p*-nitrophenol from the *p*-nitrophenyl- α -D-glucopyranoside solution under the conditions of the assay.
- **HCU:** One hemicellulase unit (HCU) is defined as that activity that will produce a relative fluidity change of 1 over a period of 5 minutes in a locust bean gum substrate under the conditions specified.
- **HUT:** One hemoglobin units on the tyrosine basis (HUT) is defined as that amount of enzyme that produces, in 1 minute under the specified conditions, a hydrolysate whose absorbance at 275 nm is the same as that of a solution containing 1.10 $\mu\text{g}/\text{mL}$ of tyrosine in 0.006 N hydrochloric acid.
- **SAP:** One spectrophotometric acid protease unit (SAP) is that activity that will liberate 1 μmol of tyrosine per minute under the conditions specified.
- **INVU:** One invertase unit (INVU) is defined as the amount of enzyme that hydrolyzes 1.0 micro μmol of sucrose to invert sugar per minute at 55°C and pH 4.5.
- **LU:** One lipase unit (LU) is defined as the quantity of enzyme that will liberate 1 μmol of butyric acid per minute under the conditions of the test.
- **PC:** One bacterial protease unit (PC) is defined as that quantity of enzyme that produces the equivalent of 1.5 $\mu\text{g}/\text{mL}$ of l-tyrosine per minute under the conditions of the assay.
- **PepU:** One pepsin unit (PepU) is defined as that quantity of enzyme that produces the equivalent of 1 μmol of tyrosine per minute under the conditions of the assay.
- **PU:** One papain unit (PU) is defined as that quantity of enzyme that liberates the equivalent of 1 μg of tyrosine per hour under the conditions of the assay. One gelatin digestion unit (GDU) is approximately equivalent to 15,000 FCC papain units (1 GDU \approx 15,000 FCC PU).
- **SU:** One Sumner unit (SU) is the quantity of enzyme which, under the conditions of the assay, will convert 1 mg of sucrose to glucose and fructose in 5 minutes.
- **TrypU:** One USP trypsin unit (TrypU) is the activity causing a change in the absorbance of 0.003 per minute under the conditions of the assay.
- **XU:** One xylanase unit (XU) is defined as the amount of enzyme that releases 1 μmol of reducing sugar, equivalent to xylose, per minute under specific conditions. These standard conditions include a pH of 5.3 and a temperature of 50°C.

Appendix II

Amylase, lipase and protease activity units per milligram of pancreas preparation according to the British, European and United States pharmacopoeias

Pharmacopoeia	Enzyme	Units of activity ¹		
		Amylase	Lipase	Protease
BP 2025	Pancreatin	24 FIP	20 FIP	1.4 FIP
USP 2024	Pancreatin	25 USP	2 USP	25 USP
BP 2025	Pancreatic extract ²	12 Ph. Eur.	15 Ph. Eur.	1 Ph. Eur.
Ph.Eur. 2025	Pancreatic extract (powder) ²	12 Ph. Eur.	15 Ph. Eur.	1 Ph. Eur.
USP 2024	Pancrelipase	100 USP	24 USP	100 USP

¹Minimum amounts.

²Cross-referenced within the respective pharmacopoeias. The proper and common name 'Pancreatic extract' should be used for both BP 2025 and Ph.Eur 2025.