Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Jun-2023
Document Type: USP Monographs
DocId: GUID-2989BE69-82EE-4E79-875F-55586E02D938_6_en-US
DOI: https://doi.org/10.31003/USPNF_M44050_06_01
DOI Ref: qdq98

Lactase

DEFINITION

Lactase (β-D-galactoside galactohydrolase) is a hydrolytic enzyme derived from the mold *Aspergillus oryzae*. It contains NLT 30,000 USP Lactase Units/g.

[NOTE—1 USP Lactase Unit is the lactase activity contained in the amount of enzyme that hydrolyzes 1 microequivalent of galactosidic linkage/min at a pH of 4.5 and at 37°, as directed in the *Assay* for *Lactase Activity*.]

ASSAY

• **LACTASE ACTIVITY**

Solution A: Dilute 57.5 mL of glacial acetic acid with sufficient water to make a 500-mL solution. Transfer 50 mL of the glacial acetic acid solution into a 1000-mL volumetric flask, add 11.3 mL of 4 N sodium hydroxide, and dilute with water to volume. If necessary, adjust with glacial acetic acid solution or 4 N sodium hydroxide to a pH of 4.50 ± 0.05.

Substrate solution: On the day of use, weigh 370.0 mg of *o*-nitrophenyl-β-D-galactopyranoside, and place in a 100-mL volumetric flask. Add about 50 mL of *Solution A*, swirl to dissolve, and then dilute with *Solution A* to volume.

Standard solution: Prepare a 0.4 mg/mL solution of USP Lactase RS in water by allowing the material to stand for 15 min in a small volume of water; swirl gently, and dilute with water to the final concentration. Pipet 3.0 mL of this solution into a 200-mL volumetric flask, and dilute with water to volume.

Sample solution: Prepare 0.4 mg/mL solution of Lactase in water by allowing the material to stand for 15 min in a small volume of water; swirl gently, and dilute with water to the final concentration. Pipet 3.0 mL of this solution into a 200-mL volumetric flask, and dilute with water to volume.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: Vis

Analytical wavelength: 420 nm

Cell: 1 cm

Analysis

Samples: *Standard solution* and *Sample solution*

Pipet 2.0 mL of *Substrate solution* into 3 separate test tubes labeled "S", "U", and "B". Transfer the tubes to a thermostated water bath maintained at 37.0 ± 0.1°, and incubate for 10 min. Following the incubation, rapidly add 0.5 mL of the *Standard solution* to tube S, 0.5 mL of the *Sample solution* to tube U, and 0.5 mL of water to tube B (the reagent blank). Mix each tube on a vortex mixer for 1 s, and immediately return the tubes to the water bath, which has been maintained at 37.0 ± 0.1°. After 15 min of incubation, rapidly add 2.5 mL of a 10% sodium carbonate solution to each test tube to stop the enzyme reaction. Add 20.0 mL of water to each test tube, and mix. Concomitantly determine the absorbances of the 3 solutions.

Calculate the number of USP Lactase Units in the portion of Lactase taken:

$$\text{Result} = [(A_U - A_B)/(A_S - A_B)] \times P \times (W_S/W_U)$$

A_U = absorbance of the *Sample solution* (tube U)

A_B = absorbance of the reagent blank (tube B)

A_S = absorbance of the *Standard solution* (tube S)

P = potency of USP Lactase RS (USP Lactase Units/g)

W_S = weight of USP Lactase RS in the *Standard solution* (g)

W_U = weight of Lactase in the *Sample solution* (g)

Acceptance criteria: NLT 30,000 USP Lactase Units/g

IMPURITIES

Change to read:

• ▲*Arsenic* ⟨211⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023) : NMT 3 µg/g

Change to read:

• ▲Lead ⟨251⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023) : NMT 5 µg/g

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed 10^3 cfu/g, and the total molds and yeasts count does not exceed 10^2 cfu/g. It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

• **Loss on Drying ⟨731⟩**

Analysis: Dry under vacuum at 60° for 4 h.

Acceptance criteria: NMT 6.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers at room temperature.

• **Labeling:** Label it to indicate lactase activity in USP Lactase Units.

• **USP Reference Standards ⟨11⟩**

USP Lactase RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
LACTASE	Maria Monagas Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 45(2)

Current DocID: GUID-2989BE69-82EE-4E79-875F-55586E02D938_6_en-US

DOI: https://doi.org/10.31003/USPNF_M44050_06_01

DOI ref: qdq98