BD Difco™ Penase
Difco™ Penase Concentrate

S1078(01)
2012-12

INTENDED USE

Penase and Penase Concentrate are beta-lactamases which hydrolyze the beta-lactam ring in penicillins, thereby, inactivating the antimicrobial properties of penicillin.

Both products are used in media for sterility testing of penicillins and for determining microbial counts of materials containing penicillin.

Precautions:

For Laboratory Use.

FORMULA

Penase and Penase Concentrate are highly purified, non-toxic, waterclear preparations of penicillinase having the potency and ability to inactivate penicillin listed below:

	Potency[1]	Inactivation of Penicillin G[2]
Penase	2000 LU/mL/min	1,000,000 IU/mL
Penase Concentrate	20,000 LU/mL/min	10,000,000 IU/mL

1. Levy unit (LU) – amount of penicillinase that inactivates 59.3 IU (international units) of sodium penicillin G per hour at pH 7.0 and 25 ºC.
2. Not all penicillins are comparable to penicillin G in regard to their inactivation by penicillinase. Some may require as much as 20 times more penicillinase than does penicillin G.

PRODUCT EXAMINATION BEFORE USE

Penase and Penase Concentrate have been processed to render them free of microorganisms that would interfere with their intended use. The process has not been validated to the level required for an injectable drug or an implantable device. The products have, however, passed a performance test for their intended use as well as a sterility test. Before preparation, observe the product for contamination or other signs of deterioration. After preparation, the recommendation of CFR 436 Subpart B, “Sterility Test Methods,” should be followed, i.e., “Prior to use, or at the time of the test, a representative number of the tubes containing added penicillinase are incubated at 30 – 32 ºC for 24 hours to 48 hours, and are examined for sterility.”

METHOD OF PREPARATION

1. Prepare the desired culture medium (Brain Heart Infusion, Tryptic Soy Broth, Fluid Thioglycollate Medium, etc.), dispense into 100 mL amounts, autoclave and cool to 50 ºC.
2. Aseptically add 1 mL Penase or 0.1 mL Penase Concentrate, or more as dictated by the situation.

Storage: On receipt store at 2 – 8 ºC.

AVAILABILITY

Cat. No.	Description
215331	**Difco™** Penase, 10 x 20 mL.
215332	**Difco™** Penase Concentrate, 10 x 20 mL.

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 USA
800-638-8663
www.bd.com/ds

Becton Dickinson France S.A.S.
11 rue Aristide Bergès
38800 Le Pont de Claix, France

Difco is a trademark of Difco Laboratories, a subsidiary of Becton, Dickinson and Company.
BD and BD Logo are trademarks of Becton, Dickinson and Company. © 2012 BD.