

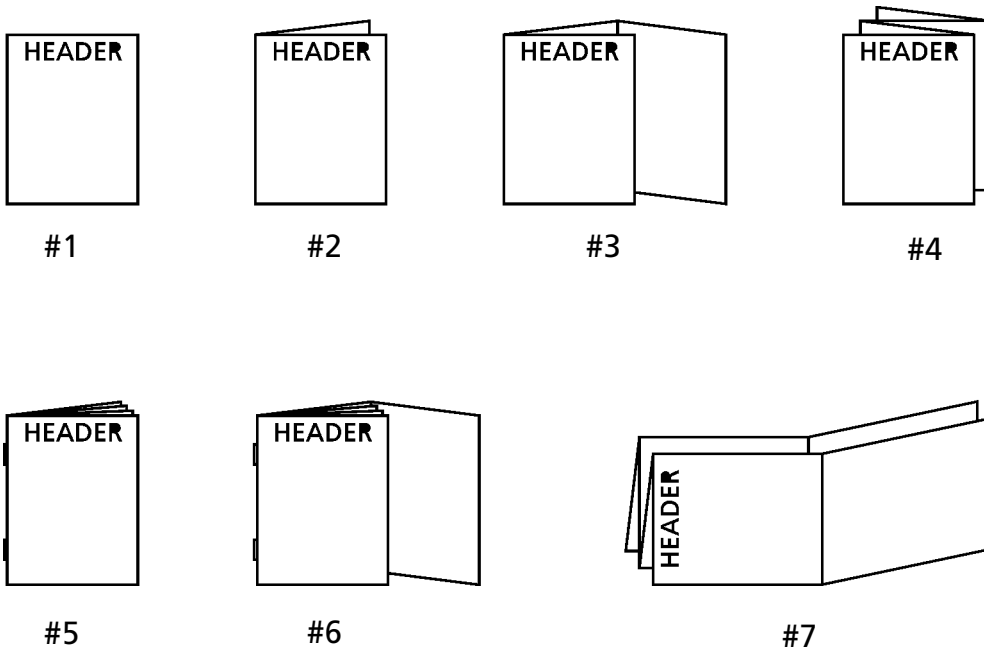
Revisions

SO 0191-5

Rev from	Rev to	ECO #
0803	2010/09	5491-10

Notes:

1. BD Cat. Number 234510, 234610, 234620, 234630
2. Blank (Sheet) Size: Length: 3" Width: 3"
 Number of Pages: 2 Number of Sheets: 1
 Page Size: Length 2.625" Width 3" Final Folded Size: 2.625" x 3"
3. Style (see illustrations below): # 1



4. See Specification Control Number N/A for Material Information
5. Ink Colors: Printed two sides Yes No
 No. of Colors: 1 PMS# 2755 Blue
6. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level

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Proofer	Date			
Checked By	Date			
Part Number: S1078JAA		Category and Description Package Insert, BD Penase, Penase Concentrate	Sheet: 1 of 3 <hr/> Scale: N/A	A

 **BD Difco™ Penase**
Difco™ Penase ConcentrateS1078JAA
2010/09**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:

	Potency¹	Inactivation of Penicillin G²
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°C.
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 test, a representative number of the tubes containing added penicillinase are incubated at 30 – 32°C for 24 to 48, 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°C.
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°C.

AVAILABILITY

Cat. No.	Description
234510	Difco™ Penase, 6 x 20 mL.
234610	Difco™ Penase Concentrate, 6 x 20 mL.
234620	Difco™ Penase Concentrate, 100 mL.
234630	Difco™ Penase Concentrate, 6 x 100 mL.

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