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:

<table>
<thead>
<tr>
<th>Product</th>
<th>Potency 1</th>
<th>Inactivation of Penicillin 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penase</td>
<td>2000 LU/mL/min</td>
<td>1,000,000 IU/mL</td>
</tr>
<tr>
<td>Penase Concentrate</td>
<td>20,000 LU/mL/min</td>
<td>10,000,000 IU/mL</td>
</tr>
</tbody>
</table>

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 the test, a representative number of the tubes containing added
penicillinase are incubated at 30 – 32 °C 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 °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
215331 Difco™ Penase, 10 x 20 mL.
215332 Difco™ Penase Concentrate, 10 x 20 mL.