

**SUGGESTED FORMULA****PZI U-100 Injectable**

Version number: 1.0

Volume: 100 mL

Insulin-Pork 500units/mL Injectable	20mL
PZI Buffer solution #1 injectable	30mL
PZI Buffer solution #2 injectable	50mL

This compound should be prepared in an ISO Class 5 environment by a licensed pharmacist or supervised pharmacy technician trained in proper aseptic technique. Review USP <797> and check with your state board(s) of pharmacy to ensure proper compliance with regulations on the preparation of CSPs. Personnel assessments, sterility, potency and endotoxin levels testing should be outlined in the pharmacy SOPs.

SUGGESTED COMPOUNDING PROCEDURES

1. Weigh and mix Buffer #1 and Buffer #2 in depyrogenated, calibrated beaker.
2. pH of combined buffer solutions must be 7, before insulin is added
3. After combining buffers allow resulting suspension to sit in hood (covered) for 15mins
4. After 15min add Insulin and stir well.
5. Allow to sit for at least 15 minutes stirring occasionally
5. Suggested Quality Assessments – follow pharmacy SOPs:
 - a. Bubble point filter integrity
 - b. Particulate
 - c. Sterility
 - d. Endotoxins
 - e. Label - auxiliary labels, storage, BUD, compounded medication

Protect from Light

Store Room Temperature

Note: According to USP Chapter <797>, in the absence of passing a sterility test the storage periods for compounded sterile preparations (high risk) cannot exceed the following time periods:

Controlled Room Temperature: not more than 24 hours

Cold Temperature: not more than 3 days

Refer to USP chapter <797>.

No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date. It is recommended that you follow USP <795> recommendations for potency testing.

Beyond-Use Date is estimated to be 90 days

Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. Wear appropriate

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