

Table 1: Pharmacy Bulk Package Sterility Assurance

<p>Does the proposed product labeling indicate a time to complete the dispensing/aliquoting operations of greater than 4 hours?</p>	<p><input type="checkbox"/> No</p>	<p><input type="checkbox"/> Yes</p> <p>Is a microbiological study(ies) provided to support dispensing/aliquoting operations for greater than 4 hours? (provide hyperlink to study(ies) location)</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>If the product is reconstituted, does the product labeling indicate a single penetration/breach of the closure after PBP reconstitution?</p>	<p><input type="checkbox"/> Yes</p>	<p><input type="checkbox"/> No</p> <p>If No, is justification provided for not including this statement in package labeling?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>If the PBP container is a bag with a port, is there only 1 functioning port on the container system?</p>	<p><input type="checkbox"/> Yes</p>	<p><input type="checkbox"/> No</p> <p>If No:</p> <p>Is justification provided for a second port provided?</p> <p>Is the drug product OR a powder that requires reconstitution?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Does the product labeling indicate dispensing/aliquoting aseptically in a laminar flow work area?</p>	<p><input type="checkbox"/> Yes</p>	<p><input type="checkbox"/> No</p>