VALITEQ®
ASEPTIC TECHNIQUE VERIFICATION SYSTEM

Guidelines for Determining Immediate Use or Risk Level of CSPs

Adapted from The United States Pharmacepeial Convention, Proposed revisions to Chapter <797>, Pharmaceutical Compounding – Sterile Preparation, copyright 2006.

IMMEDIATE USE— CSPs must meet ALL of the following conditions

1. a) Only simple measuring and transfer manipulations
   b) Only sterile, non-hazardous commercial drug and diagnostic components
   c) Not more than three components, including an infusion or diluent solution
2. Unless required for preparation, the prep procedure occurs continuously AND does not exceed one hour.
3. At no point during preparation and prior to administration are critical surfaces or ingredients directly exposed to contact contamination.
4. Administration begins NO MORE than one hour following the START of preparation of the CSP.
5. Administration is either by the preparer, witnessed by the preparer, or the label contains the following information:
   a) patient identification
   b) names and amounts of ingredients
   c) name or initials of preparer
   d) the exact one hour beyond use date
6. If administration does not begin within one hour from the start of preparation, the CSP is immediately, completely, and safely discarded and shall not be stored for later use.

LOW-RISK USE— CSPs must meet ALL of the following conditions

1. Compounded in an ISO Class Five environment and three or less sterile products and entries into any container.
2. Sterility tested OR:
   a) Stored not more than 48 hours at controlled room temperature
   b) Stored not more than 14 days at cold temperature
   c) Stored not more than 45 days at -20 degrees Celsius or colder
3. Media-fill test at least annually by compounding personnel

MEDIUM-RISK USE — CSPs must meet ALL of the following conditions

1. Compounded in an ISO Class Five environment and prolonged and complex mixing or transfer or more than three sterile products and entries into any container OR pooling ingredients from multiple sterile products to prepare multiple CSPs
2. Sterility tested OR:
   a) Stored not more than 30 hours at controlled room temperature
   b) Stored not more than nine days at cold temperature or
   c) Stored not more than 45 days at -20 degrees Celsius or colder
3. Media-fill test at least annually by compounding personnel

HIGH-RISK USE — CSPs may meet ANY of the following conditions

1. Confirmed presence of nonsterile ingredients and/or devices.
2. Confirmed or suspected exposure of sterile ingredients for more than one hour to air quality greater than ISO Class Five before final sterilization.

HIGH-RISK USE— CPSs must meet ALL of the following conditions

1. Sterilization method verified to achieve sterility for the quantity and type of containers
2. Meet endotoxin limit requirements
3. Maintain strength and purity of ingredients within allowable limits and maintain container integrity to preserve sterility
4. Sterility test OR:
   a) Stored not more than 24 hours at controlled room temperature
   b) Stored not more than three days at cold temperature
   c) Stored not more than 45 days at -20 degrees Celsius or colder
5. Media-fill test at least semi-annually by compounding personnel.