

## STANDARD OPERATING PROCEDURE

**Title: Validation of Aseptic Filling Processes**

Effective Date: \_\_\_\_\_

**Approvals** (Signature and Date):

\_\_\_\_\_  
Responsible Department Head

\_\_\_\_\_  
Technical Authority

\_\_\_\_\_  
QA/QC

### 1. PURPOSE

- 1.1 To define procedures for validating and maintaining the validation of all aseptic filling processes (AFPs).
- 1.2 To describe the general content requirements for sterile media AFP MBRs and PNSs.

### 2. SCOPE

- 2.1 This procedure applies to all aseptically filled sterile products intended for human use. Hereinafter, "products intended for human use" are referred to as "products."
- 2.2 This procedure does not apply to any product that is terminally sterilized after filling.

### 3. RESPONSIBILITY

- 3.1 The Validation Engineer coordinates the aseptic filling validation program and writes the sterile media AFP QVD reports.
- 3.2 Manufacturing generates the sterile media AFP PNSs and MBRs and performs the sterile media fills.
- 3.3 QA/QC and Manufacturing perform the testing and assist with the monitoring required for each sterile media fill.

### 4. REFERENCES AND APPLICABLE DOCUMENTS

- 4.1 The following references were used to develop this procedure:

- FDA *Guideline on Sterile Drug Products Produced By Aseptic Processing*. June, (b) (4)
- Parenteral Drug Association. *Validation of Aseptic Filling for Solution Drug Products*, PDA Technical Monograph No. 2, 1980.
- FDA. *Guideline on General Principles of Process Validation*. May (b) (4)
- Agalloco, James P. and Frederick J. Carlton, eds. (b) (4) *Validation of Aseptic Pharmaceutical Processes*, 1st edition, New York: Marcell Dekker.
- *Process Simulation Testing for Aseptically Filled Products*, PDA Draft Technical Report, July 3, (b) (4)
- Korczynski, Michael S. (b) (4) The ISO Draft International Standard - *Aseptic Processing of Health Care Products*. *PDA Journal of Pharmaceutical Science and Technology*, 50, 189-195.

- 4.2 The following documents are referenced elsewhere in this SOP:

- MBR 800024-01, *Bulk Tryptic Soy Broth, Sterile*
- PNS 800024-01, *Bulk Tryptic Soy Broth, Sterile*
- SOP 09-0042, *Performance Testing & Growth Promotion of Media*

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