

## SOP-0007 – Batch Release

### Section: Purpose

Defines responsibilities and criteria for batch release.

### Section: Sampling

Samples must be collected per WI-014. Minimum N=3 containers per lot.

### Section: Acceptance Criteria

- Assay 98–102%
- Dissolution  $\geq 80\%$  in 30 min
- Microbial: per Ph. Eur. 5.1.4

### Section: Authority

Final release decision: QA Manager or designee.