



SOP: LFA 00075
Analysis and Release of Finished Product
Samples

Alastair Sanderson

31/08/16

1 Objective

To provide a guideline for Analysis and Release of Finished Product Samples

2 Scope

Applicable for all Analysis and Release of Finished Product Samples

3 Responsibility

By QC Officer/Executive

4 Accountability

QC Manager

5 Procedure

- 5.1. All finished samples from injectable/beta lactam manufacturing should be analysed as per the guideline outlined under the Standard Test Procedure or Pharmacopoeia policy.
- 5.2. For other products, analysis should be performed by the production department personnel. Fill out the sample intimation request and forward to the IPQA sampling. Sample must be provided to the Quality Control along with the request.
- 5.3. Once sampling is done, enter it in the Annexure -I
- 5.4. QC head should delegate the work to the supervisor and the results forwarded to the concerned department after completion of the analysis through the QA head.
- 5.5. Record the result of the completed test as per the annexure number II and III, which should be included in the sample report.

6 Abbreviations

SOP Standard Operating Procedure

QA Quality Assurance

IPQA In-process Quality Assurance

QC Quality Control

Annexure -II

Product		A.R. No.	
Batch No.		Samples On	
Mfg, \. Date		Analyzed On	
Exp. Date		Released On	
Batch Size		Spec. No.	

Test	Specification	Observation

Remark: The sample compiles / does not comply as per IP/BP/USP and in-house specification.

Analysed by: _____
(Officer QC)

Approved by: _____
(Manager QA)

Date: _____

Date: _____

Checked by: _____

Date: _____