1 Purpose

The purpose of this International Procedure is to describe the process for the manufacture, packing and/or shipping material ahead of clearance.

2 Scope and Applicability

This Procedure can be applicable to any manufacturing Operations sites that is using, packing and/or shipping materials ahead of clearance.

3 Definitions

3.1 Manufacture Ahead of Clearance

Manufacturing using the following materials Ahead of Clearance:

- Raw materials for the synthesis of Active Pharmaceutical Ingredients (API).
- Excipients and APIs for the formulation of Bulk Pharmaceutical Products.
- Packaging components for the packaging of finished products.

3.2 Pack Ahead of Clearance

Packing of Bulk Pharmaceutical Products Ahead of Clearance into Finished Product Packs for sale.

3.3 Ship Ahead of Clearance

Shipment of APIs, Crude Bulk Drugs, Intermediates, Bulk Pharmaceutical Products and Finished Products Ahead of Clearance to:

- Another location within the same Operations site
- Another Operations site.

3.4 “Ahead of Clearance”

In this Procedure the term óAhead of Clearanceô means that before the material is used, packed or shipped ahead of clearance the following activities have been completed:

- Batch manufacturing and/or packaging documentation have been reviewed by the QA function.
- Deviations have been fully investigated and closed.

The only outstanding release activity remaining to be completed is the analytical testing, and subsequent review of the analytical report.

3.5 Material

In this Procedure óMaterialô means APIs, Intermediates, Crude Bulk Drugs, Excipients, Raw Materials, Packaging Components, Bulk Pharmaceutical Products

- Case by case approval by the QA Manager, or delegates to use a material ahead of clearance.
- Resultant products cannot be released for further handling without the final material clearance being obtained.

5.3 Pack & Ship or Ship & Pack Ahead of Clearance Between Sites

5.3.1 Control of Material

Packing &/or Shipping, or Shipping & Packing ahead of clearance shall only be practiced if the QA Managers at the supplying and receiving sites/departments are satisfied that the material and resultant materials can be strictly controlled. Procedures shall ensure that resultant materials cannot be released to market until the material final clearance has been received.

5.3.2 QA Agreements

Where it is intended to adopt Pack & Ship, or Ship & Pack ahead of clearance as a routine practice between operations sites, the QA Agreement between the supplying and receiving sites shall be amended to reflect these practices and to state which products this involves.

5.3.3 Release of Material

When the material has been given a final full clearance at the supplying site, the QA Manager or deputy at the receiving site shall be informed without delay. This shall be done by a Certificate of Analysis, Analytical Report or an Electronic Clearance. The material shall be released upon receipt of this clearance providing all other routine controls are satisfactory. In the event that the material is rejected, it shall usually be returned to the supplying site. If it has been agreed that the material remains at the receiving site there must be:

- Appropriate controls in place for the rework or destruction at the receiving site.
- An agreement in place regarding allocation of the rework or disposal cost.
- No contraventions of fiscal controls emanating from ownership of the product e.g. under toll arrangements.

5.4 Contractors

It is acceptable to pack, or ship & pack ahead of clearance at contractors, who are managed and supply to an agreed Operations site. The requirements for strict controls and QA Agreements described in section 5.3 apply.

Finished product must not be shipped ahead of clearance to a contractor, but the contractor may ship finished product to an operations site ahead of clearance.

