

Standard Operating Procedure

Title: Criteria for sourcing of Raw Materials, Critical Packaging Components and Imported Finished Goods

3. Selection Procedure

3.1. General Requirements Vendor

Vendors are selected using the following parameters:

- a) Ability to consistently supply material to the specification (laboratory records).
- b) Ability to deliver the required material in the quantities ordered in the required timeframe (Procurement records).
- c) Previous experience with the vendor (raw material records, laboratory records, reject material/component forms).

3.2. General Requirements Manufacturer

The selection procedure for a manufacturer of a raw material is dependent upon the classification of the material, i.e. active, excipient or critical packaging component, however there are a number of parameters, which are common:

- 3.2.1. Ability to consistently comply with the agreed material specification requirements.
- 3.2.2. Previous experience with the manufacturer.
- 3.2.3. Perceived reputation of the manufacturer within the industry and with regulatory authorities (communication, newsletters).
- 3.2.4. Level of technical support where required, which encompasses availability of product Master file, related substances (where applicable) and access to Head Office Technical/Research departments. Pilot production runs with the material demonstrating satisfactory conformance, where required.
- 3.2.5. Corporate Supply Chain recommendation/requirement based on quality, audits and commercial evaluation.
- 3.2.6. The ability to demonstrate continuous improvement in products and processes.

3.3. Active Material

In addition to the general requirements described above, material supplied from a particular manufacturer must undergo extensive evaluation both as the bulk raw material and with studies of product formulated using the material. The studies encompass chemical and physico-chemical evaluations of finished products, production processing studies (where applicable) and stability trials covering long-term studies under various conditions and accelerated studies under stressed conditions.

A multi-stage approach is employed in selecting an active material as detailed below.

3.3.1. Stage 1

A sample of the active is analysed using the test methods specified in the current standard methods (i.e. BP/USP) provided by the manufacturer and any additional requirements where applicable. Compliance with the requisite specifications is mandatory prior to continuation of the evaluation to the next stage of the process. Particular attention is given to the purity and content of degradation products in the material.

In the case where a manufacturer is being evaluated to replace a current manufacturer or to augment the supply situation by having dual manufacturers then the new material is also analysed against the current material with emphasis given