

Standard Operating Procedure

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

Related Documents

QMS-030	A.8.2 Preparation, Maintenance and Change Control of Master Documents
QMS-045	D.8.24 Vendor Selection and Evaluation

EHS Statement

There are no EHS issues with documentation.

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Procedure

1. Aim

The aim is of this SOP to define a manufacturer and vendor; detail selection criteria and selection procedures; provide details for the assessment of manufacturers and processes for approval of the manufacturers.

Active materials can only be obtained from approved manufacturers and in accordance with the registered details of the products with regulatory agencies.

Excipients and critical packaging materials are obtained from manufacturers capable of supplying material of the required grade and complying with the specified standard and/or specifications.

Bulk products for packing and imported finished goods from contract manufacturers. These products are obtained from the contract manufacturers in accordance with the registered details of the regulatory authorities.

Mention is also made for approved vendors in ISO 9000 and the relevant Code of GMP.

2. Definitions

2.1. Vendor Actives, Excipients and Critical Packaging Components

A vendor is a company from whom we directly obtain the material. (The 'vendor' may also be called the 'Agent', 'Distributor', or 'Supplier'.) The vendor may also be the manufacturer and may be local or overseas based. The decision as to which vendor is used to supply the material is one of consultation with Supply Chain, Technical, and Laboratory departments. The non-manufacturing vendor can only purchase material from the approved manufacturer as directed by Site.

2.2. Manufacturer

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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

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time, adherence to packaging requirements and products received free of damage. The quality of the materials is also monitored as part of the post production stability surveillance program of finished products which utilise these materials. Vendors/manufacturers are evaluated based upon the following criteria:

- 4.3. An annual vendor review is performed and documented by the procurement team using quarterly Service Level Agreements and KPIs, review data and additional information provided from QC test results, stability analyses from post production stability monitoring, production records, and Deviation Reports
- 4.4. If an adverse trend is detected by routine testing of the materials then the Laboratory Manager, in conjunction with the Procurement Manager, will review, discuss and take appropriate action.
- 4.5. Audits of the Manufacturing site for active materials and finished products are mandatory and are carried out by accredited Auditors. Audits of manufacturers producing excipients and critical packaging components, while not mandatory, are recommended in order to verify that the company operates under acceptable manufacturing procedures and systems.

5. Documentation Process for Approved Manufacturers

5.1. General

The status of manufacturers (that is whether they are approved, non-approved or discontinued) is disseminated to the QA, Procurement and Technical departments via memo by Technical Service Manager. This initiates the following steps:

- 5.1.1. The preparation of a material specification or modification of an existing specification in accordance with SOP **QMS-030**. The Technical Service Associate prepares specifications for critical packaging materials.
- 5.1.2. The Procurement Department negotiates and formalises a supply and service level agreement which is signed by both parties.
- 5.1.3. This SOP need to be updated accordingly.

5.2. Approved Manufacturers Raw Materials

The range of all raw materials (including actives) and associated manufacturers/ vendors are listed in details in Technical Service documentation area.

5.3. Approved Manufacturers Imported Products

This is maintained in Product Register in Technical Service documentation area.

6. Summary of Changes

Version #	Revision History
QMS-115	New