

Standard Operating Procedure

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

Department	Quality Management	Document no	QMS-115
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Document Owner

Supply Chain Manager

Affected Parties

Colleagues working in sourcing of raw materials, packaging components, bulk actives and imported finished goods in Technical Service, Supply Chain, Procurement and Laboratory Departments.

Purpose

The purpose of this SOP is to describe the process for approval of an external vendor/manufacturer supplying products into Sydco. It covers active raw materials (including bulk products for subsidiaries and contract manufacturers), excipients, critical packaging components in contact with product and imported finished goods. The SOP also references affiliated documentation detailing the scope of active materials used and the approved manufacturers of these materials.

Scope

Procurement Manager	Choice of vendor for active ingredients, excipients and critical packaging materials
Technical Service Manager/Laboratory Manager/Procurement Manager	Choice of manufacturer of actives and excipients
Procurement Manager / Technical Service Manager	Choice of manufacturer of critical packaging components
Supply Chain Manager	Choice of manufacturer imported finished goods
Technical Service Manager/Laboratory Manager	Stability/processing trials for actives
Technical Service Manager/Laboratory Manager	Stability/processing trials for excipients
Technical Service Manager/Laboratory Manager	Stability/processing trials for critical packaging components
Technical Service Manager	Preparation of registration documents for submission to regulatory authorities
Laboratory Manager/Technical Service Manager	Review of trend cards, laboratory records, reject material/component forms

Definition

DR	Deviation Report System
KPI	Key Performance Indicator

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A manufacturer is the company that synthesises or produces the material. The manufacturer is normally responsible for all aspects of manufacture and quality control of the material. Technical support is often provided with respect to product knowledge, stability data, impurity profile of the material and technical expertise relating to the material. In the case of active manufacturers the manufacturer is responsible for the provision and maintenance of a Product Master File.

2.2.1. **Approved Manufacturer Active materials**

A manufacturer is designated as approved under the following conditions:

- a) Via the legislation of regulatory authority.
- b) Following submission of data as part of a product registration process.

The manufacturer may be local or overseas based. The approval of a manufacturer includes compliance with GMP as authorised by a recognised regulatory authority.

2.2.2. **Approved Manufacturer Excipient Materials**

There is no requirement to specify the manufacturer of an excipient material for the registration of a product. It is mandatory that the material supplied must comply with the grade and material specification registered as part of the registration process. The specification to which the material must comply may have been registered under the following conditions:

- a) Via the legislation of local regulatory authority.
- b) Following submission of data as part of a product registration process.

The manufacturer may be local or overseas based. It is preferred that a manufacturer of excipient materials be recognised as complying with GMP principles, yet this is not a legal requirement for these type of manufacturers.

2.3. **Approved Manufacturer Critical Packaging Components**

In most instances the manufacturers of critical packaging components are identified as part of the registration process, yet this is dependent upon the class of material. This may be via the legislation of local regulatory authority or submission of actual data for the more recent registrations.

The manufacturer may be local or overseas based. It is preferred that a manufacturer of critical packaging components be recognised as complying with GMP principles, yet this is not a legal requirement for these type of manufacturers.

2.4. **Approved Manufacturer Bulk Products and Imported Finished Goods**

A manufacturer is designated as approved under the following conditions:

- a) Via the legislation of local regulatory authority.
- b) Following submission of data as part of a product registration process.

The approval of a manufacturer includes compliance with GMP as authorised by a recognised regulatory authority.

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to the purity profile between the two materials. The test procedures used are those for the current material. It is a prerequisite that the new material be of equal quality to that of the current material. In particular, the impurity profile of the new material must be the same or preferably purer than the current material.

3.3.2. Stage 2 (where applicable)

Development formulations filled into the proposed container systems are prepared and subjected to conditions to simulate a rapid stability study to ascertain the appropriateness of the material. The conditions to be laid down for the rapid stability trials are determined by a project team and are dependent upon the type of formulation, chemistry of the active, physico-chemical properties of the container and container material.

The stability profile is reviewed in accordance with pharmacopoeial and/or other requirements. The stability studies may be augmented by additional degradation studies where the raw material and formulations are subjected to oxidation, heat, light and acid/base conditions. Any degradation products arising from the study are examined and the implication of these evaluated.

3.3.3. Stage 3 (where applicable)

A minimum of two batches of each formulation are prepared, filled into the proposed container using production equipment and subjected to routine stability studies. The batch size of these development batches must be greater than 10% of the expected production batch. Documentation for the manufacture and filling of the stability trial batches are written and authorised by the Technical Service Department and the Laboratory

Both accelerated and real time studies are carried out. This process is designed to simulate the final production process in order to determine the final shelf life of the product as it would be supplied to the market. The storage conditions for these trials are determined as described under Stage 2. Where rapid stability studies had been performed the results from these studies are also taken into consideration when setting the storage conditions for the studies under Stage 3.

3.3.4. Stage 4

At the completion of the stability studies, technical documentation is prepared for the registration file. This documentation includes, stability reports, expert reports, all specifications, formulations, methods of manufacture and component details. The documentation is prepared in accordance with SOP **QMS-030**.

3.4. Excipient Materials

The choice of manufacturer is primarily dependent upon the capability of the manufacturer to provide material, which complies with the specified grade and registered specification. The requirements under 3.2 must also be fulfilled.

Contact with excipient material vendors/manufacturers is limited. Since the material quality is governed in the majority of cases to pharmacopoeial grade materials, the choice of vendors is limited to those companies who can comply with the stringent material specifications needed for pharmaceutical use. Appropriate audits of the company are to be carried out in order to evaluation of the material.

3.4.1. A Pre-Procurement sample of the material is analysed using the test methods specified in the current pharmacopoeial monograph and any additional requirements where applicable.

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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