

Wersja obowiązująca	Wersja po ew. zmianach
<p>(...) <b>Starting materials</b> 5.25 The purchase of starting materials is an important operation which should involve staff who have a particular and thorough knowledge of the suppliers.</p> <p>5.26 Starting materials should only be purchased from approved suppliers named in the relevant specification and, where possible, directly from the producer. It is recommended that the specifications established by the manufacturer for the starting materials be discussed with the suppliers. It is of benefit that all aspects of the production and control of the starting material in question, including handling, labelling and packaging requirements, as well as complaints and rejection procedures are discussed with the manufacturer and the supplier.</p>	<p>(...) <b>Starting materials</b> 5.25 Starting materials should only be purchased from manufacturers, importers or distributors of active substances approved by the manufacturers of medicinal products, named in the relevant specification and, where possible, directly from the manufacturer of the starting material. Purchase of starting materials should be controlled by written procedures. The supply chain of each starting materials should be known and be documented. It is recommended that the specifications established by the manufacturer for the starting materials be discussed with the suppliers. It is of benefit that all aspects of the production and control of the starting material in question, including handling, labelling, packaging and distribution requirements, as well as complaints and rejection procedures are discussed with the manufacturer and supplier, and that the outcome of these discussions are documented.</p> <p>5.26 The selection, including qualification and approval of suppliers, and the purchase of starting materials is an important operation which should involve staff who have a particular and thorough knowledge of the suppliers and the associated risks involved in that starting material's supply chain. Procedures for the assessment and purchase and acceptance of starting materials, including critical packaging materials should be documented as part of the quality management system. The approval of suppliers of starting materials should be controlled by QC and production. Suppliers of active substances and, certain excipients considered to be high risk materials used as starting materials, should be periodically audited to confirm that they comply with current GMP requirements and that supply chain traceability[1] of the starting material is being maintained. The findings from each audit should be documented, and audit reports should be available for review by Inspectors.</p> <p><i>[1] A record of where each active substance (including its critical starting materials) is manufactured, propagated, processed and handled prior to its use in the manufacture of a medicinal product. The record should include the names and addresses (including reference to the DUNS number) of each manufacturer, distributor, trader/broker and shipper involved in this part of the supply chain.</i></p>

5.27 For each delivery, the containers should be checked for integrity of package and seal and for correspondence between the delivery note and the supplier's labels.

(...)

5.31 Only starting materials which have been released by the Quality Control Department and which are within their shelf life should be used.

5.27 For each delivery, the containers should be checked for integrity of package and seal and for correspondence between the delivery note and the supplier's labels. Verification of the supply chain traceability should also be established and documented.

(...)

5.31 Manufacturers of the medicinal product are responsible for any testing of starting materials as described in the marketing authorisation dossier. Manufacturers of finished product can subcontract the testing of starting materials described in the marketing authorisation dossier to the approved starting material manufacturer but must, as a minimum, perform a confirmation of identity themselves. The following requirements should be fulfilled when introducing subcontracting of partial or full testing:

- A formal agreement should be signed between the finished product manufacturer and the starting material manufacturer. Among the respective responsibilities described in the formal agreement, special attention should be paid to those related to the distribution conditions (transport, wholesaling, storage and delivery) in order to maintain the quality characteristics of the starting materials and to ensure that test results remain applicable to the delivered material.
- The finished product manufacturer should perform audits at appropriate intervals at the site(s) carrying out the testing (including sampling) of the starting materials in order to assure compliance with GMP and the specifications and testing methods described in the Marketing Authorisation.
- The certificate of analysis provided by the starting material manufacturer should be signed by a designated person with appropriate qualifications and experience. This person should ensure that each batch has been manufactured and checked for compliance with the requirements of the formal agreement,
- Full analyses should be conducted on at least three different batches before reducing in-house testing. As a minimum, the finished product manufacturer should also perform a full analysis at appropriate intervals and compare the results with the supplier's Certificate of Analysis in order to check its

<p>5.32 Starting materials should only be dispensed by designated persons, following a written procedure, to ensure that the correct materials are accurately weighed or measured into clean and properly labelled containers.</p> <p>5.33 Each dispensed material and its weight or volume should be independently checked and the check recorded.</p> <p>5.34 Materials dispensed for each batch should be kept together and conspicuously labelled as such.</p> <p>(...)</p>	<p>reliability. Should this testing identify discrepancies then the acceptance of certificates of analysis from the supplier should be discontinued until investigations are completed.</p> <p><b>Notes:</b></p> <ol style="list-style-type: none"><li>1. The same requirements apply to packaging materials as stated in GMP part I, 5.40.</li><li>2. Identity testing of starting materials should be performed according to the methods and the specifications of the relevant Marketing Authorisation dossier.</li></ol> <p>5.32 Only starting materials which have been released by the Quality Control Department and which are within their shelf life should be used.</p> <p>5.33 Starting materials should only be dispensed by designated persons, following a written procedure, to ensure that the correct materials are accurately weighed or measured into clean and properly labelled containers.</p> <p>5.34 Each dispensed material and its weight or volume should be independently checked and the check recorded.</p> <p>5.35 Materials dispensed for each batch should be kept together and conspicuously labelled as such.</p> <p>(...)</p>
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------