

SAMPLING OF STARTING AND PACKAGING MATERIALS

Principle

Sampling is an important operation in which only a small fraction of a batch is taken. Valid conclusions on the whole cannot be based on tests which have been carried out on non-representative samples. Correct sampling is thus an essential part of a system of Quality Assurance.

Note

Sampling is dealt with in Chapter 6 of the Guide, items 6.11. to 6.14. This annex gives additional guidance on the sampling of starting and packaging materials.

Personnel

1. Personnel who take samples should receive initial and on-going regular training in the disciplines relevant to correct sampling. This training should include:
 - sampling plans,
 - written sampling procedures,
 - the techniques and equipment for sampling,
 - the risks of cross-contamination,
 - the precautions to be taken with regard to unstable and/or sterile substances,
 - the importance of considering the visual appearance of materials, containers and labels,
 - the importance of recording any unexpected or unusual circumstances.

Starting materials

2. The identity of a complete batch of starting materials can normally only be ensured if individual samples are taken from all the containers and an identity test performed on each sample. It is permissible to sample only a proportion of the containers where a validated procedure has been established to ensure that no single container of starting material has been incorrectly labelled.
3. This validation should take account of at least the following aspects:
 - the nature and status of the manufacturer and of the supplier and their understanding of the GMP requirements of the Pharmaceutical Industry;
 - the Quality Assurance system of the manufacturer of the starting material;

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- the manufacturing conditions under which the starting material is produced and controlled;
- the nature of the starting material and the medicinal products in which it will be used.

Under such a system, it is possible that a validated procedure exempting identity testing of each incoming container of starting material could be accepted for:

- starting materials coming from a single product manufacturer or plant;
- starting materials coming directly from a manufacturer or in the manufacturer's sealed container where there is a history of reliability and regular audits of the manufacturer's Quality Assurance system are conducted by the purchaser (the manufacturer of the medicinal product) or by an officially accredited body.

It is improbable that a procedure could be satisfactorily validated for:

- starting materials supplied by intermediaries such as brokers where the source of manufacture is unknown or not audited;
 - starting materials for use in parenteral products.
4. The quality of a batch of starting materials may be assessed by taking and testing a representative sample. The samples taken for identity testing could be used for this purpose. The number of samples taken for the preparation of a representative sample should be determined statistically and specified in a sampling plan. The number of individual samples which may be blended to form a composite sample should also be defined, taking into account the nature of the material, knowledge of the supplier and the homogeneity of the composite sample.

Packaging material

5. The sampling plan for packaging materials should take account of at least the following: the quantity received, the quality required, the nature of the material (e.g. primary packaging materials and/or printed packaging materials), the production methods, and what is known of the Quality Assurance system of the packaging materials manufacturer based on audits. The number of samples taken should be determined statistically and specified in a sampling plan.