

ANNEX D GLOSSARY

Concurrent Validation

Validation carried out during routine production of products intended for sale.

Finished Product

A product that has undergone all stages of production and quality control, including packaging in its final container and labelling.

Pilot Batches

These may be used in the development or optimization stage. Pilot batch size should correspond to at least 10% of the future industrial-scale batch. For oral solid dosage forms this size should be at least 10% or 100,000 units whichever is greater unless otherwise justified.

Production Batch

A batch of a drug substance or drug product manufactured at production scale by using production equipment in a production facility as specified in the application.

Prospective Validation

Establishing documented evidence that a process, procedure, system, equipment or mechanism used in manufacture does what it purports to do based on a pre-planned validation protocol.

Retrospective Validation

Validation of a process for a product that has been marketed based upon accumulated manufacturing, testing and control batch data.