Health Canada Santé Canada

Glossary of Quality Terms

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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. Health Canada	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. Health Products and Food Branch

Également disponible en français sous le titre : *Glossaire des termes associés à la qualité*

Document Change Log

Version	Glossary of Quality Terms	**Replaces**	Draft Guidance
Date	2017/10/30	**Date**	2016/08/31
Change	August 31, 2016		
Nature of and/or Reason for Change	Guidance finalized 1. Addition of definitions for executed batches and executed production records, non-isolated intermediate and Normal Operating range. 2. Editorial changes		

This glossary only includes terms used in the Guidance Document*:* Quality (Chemistry and Manufacturing): New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs) which are not defined in International Council for Harmonisation (ICH) guidance documents or other Health Canada Documents

For additional definitions of terms used in quality documents, refer to the following documents:

***Food and Drug Regulations*:**
http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html

Individual ICH Quality Guidance Documents
http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html

Health Canada GMP guidance documents
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/index-eng.php

Good Manufacturing Practices (GMP) Guidelines - 2009 Edition, Version 2 (GUI-0001)
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0001-eng.php#references

Interim Policy on Health Canada's Interpretation of Medicinal Ingredient
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/notice_im_pol_mi_avis-eng.php

Guidance Document: Biopharmaceutics Classification System Based Biowaiver
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/bcs_guide_ld_scb-eng.php

Definitions

Bridging study: A bridging study is defined as a supplemental study performed to provide bioequivalence, pharmacodynamic or clinical data to support that significant changes in the formulation or manufacturing of a drug product result in an equivalent product to the product used for pivotal clinical trials. Such studies usually involve bioequivalence studies.

Drug product intermediate: A material that is the result of a drug substance having undergone at least one processing step in the presence of any other substance(s) (used in the manufacture of the drug product whether it appears in the finished dosage form or not) which must undergo further processing step(s) to become the finished dosage form.

That-first processing step of the drug substance in the presence of any other substance(s) would be considered a drug product manufacturing (fabrication) activity, subject to Part C, Division 2

of the Food and Drug Regulations, and would define the date from which the expiry date for the drug product would be established.

Executed Batch: A batch which has been manufactured and for which complete documentation is available recording the conditions and in-process controls followed during manufacturing (for details of documentation see the guidance document ***Quality (Chemistry and Manufacturing): New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)***- Master Production Document R.1.2).

Executed Production Records: Production (manufacturing) documents (i.e. batch records) for a batch for which manufacturing has been completed.

Fabrication: This is a term defined in GUI-001, but is considered synonymous with the ICH Q7 term "manufacture" in the guidance document*: **Quality (Chemistry and Manufacturing): New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)***.

Key Intermediate: an intermediate in which an essential molecular characteristic(s), usually involving the proper stereochemical configuration required for structure/activity (pharmacological and/or physiological activity of the drug substance), is first introduced into the structure (for example [e.g.], introduction of a chiral centre or the production of one geometric isomer in preference to another).

Mass Balance: The process of adding together the assay value and levels of degradation products to see how closely these add up to 100% of the initial value, with due consideration of the margin of analytical error.

Non-isolated intermediate: A compound which is synthesised or formed by fermentation during the production of an active pharmaceutical ingredient, but which is not purified or extracted prior to executing the next synthetic step.

Normal Operating Range (NOR): The range in which *unintentional* variation is reasonably anticipated to occur during operation for a process parameter when it is set at its target value.

Semi-synthetic drug product: A drug product containing one or more semi-synthetic drug substance(s), or a drug product containing both synthetic (or semi-synthetic) and non-synthetic/non-semi-synthetic drug substances (e.g. a drug product containing both a synthetic drug substance and a biological drug substance).

Semi-synthetic drug substance: A semi-synthetic drug substance is one in which the structural constituents have been introduced by a combination of chemical synthesis and elements of biological origin (e.g. obtained from fermentation or by extraction from botanical material). A synthesis step involves cleavage and formation of covalent bonds.

Small Scale Batch: A small scale batch is considered less than 100 000 units for solid oral dosage forms or less than 10% of commercial scale batch size. The batch is manufactured in a manner that is considered representative of the proposed commercial scale process.