



Press Release

Brussels (Belgium), 10 February 2021

The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of the revised and updated IPEC General Glossary of Terms and Acronyms for Pharmaceutical Excipients (Version 2, 2021). The glossary was originally published in 2014 and has been used to define excipient terms and acronyms commonly found in IPEC guides.

While updating the IPEC General Glossary of Terms and Acronyms for Pharmaceutical Excipients, the team developed a strategy with the following rationale for determining when a term/definition should be included in the IPEC Glossary:

Rationale for what terms/definitions should be included in the IPEC Glossary.

Term/definition should be one of the following:

- specific to excipients
- used/referenced in multiple IPEC guides
- provide a better understanding of manufacture or application of an excipient
- describe and/or differentiate regulatory requirements for an excipient

Terms/definitions not included in the IPEC Glossary

- commonly used dictionary terms
- terms generally used by other industries (e.g. SOP, SPC, API)
- terms specific to one IPEC guide (better to describe and/or include reference in guide vs adding to glossary)
- terms defined in other official publicly available guidances/resources (reference the guidance and/or resource for the term directly in the guide). This would not include terms only referenced in documents that must be purchased (e.g. ANSI Standard, USP)

Terms not meeting the above criteria, which are currently **bolded** in at least one IPEC guide (indicating definition found in the IPEC Glossary), were **highlighted** (along with [reference to the guide(s)]). As the current versions of these guides are updated, **highlighted terms** will be unbolded and eventually removed from the IPEC General Glossary.

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Another new feature to this Glossary is a column that includes reference to a list of external sources where the term has been defined. Several of the sources include ICH Guidelines and WHO Technical Reports where the definitions are often more applicable to API than excipient; therefore, the defined definition in this Glossary may have been modified to be more appropriate for an excipient.

In addition to the updated IPEC General Glossary of Terms and Acronyms for Pharmaceutical Excipients, an excel workbook containing mapping for terms and acronyms found in each of the current IPEC guides was developed and will be available to IPEC members. The Excel workbook also contains a list of ~700 pharmaceutical terms and definitions currently found and defined in external glossaries (e.g. ICH Guidelines, WHO Technical Reports, FDA Guidances and webpages).

The guide will be available on the IPEC Federation and national/regional members' websites.

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