IPEC FEDERATION

The International Pharmaceutical Excipients Council

General GLOSSARY of Terms and Acronyms

For Pharmaceutical Excipients

Version 2
2021

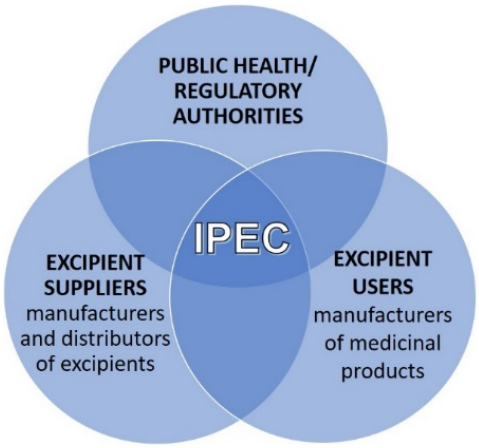
This document represents voluntary guidance for the excipient industry and the contents should not be interpreted as regulatory requirements. Alternatives to the approaches in this Guide may be used to achieve an equivalent level of assurance for excipient quality.

FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient manufacturers, distributors and users. At the current writing there are regional pharmaceutical excipient industry associations located in the Americas, Europe, Japan, China, and India. IPEC's objective is to contribute to the international excipient standards development and harmonization, provide information useful for new excipient development and introduction, and offer best practice and guidance concerning excipient development.

IPEC has three major stakeholder groups:

1. excipient manufacturers and distributors, defined as suppliers in this document,
2. pharmaceutical manufacturers, defined as users in this document, and
3. public health and regulatory authorities.



This Guide is intended to be voluntary, to indicate best practice, and to be globally applicable. However, it should be recognized that the rules and regulations applying to excipients will vary from region to region and country to country. In addition, the rules and regulations are continually evolving. It is the responsibility of users of the Guide to determine whether there are any additional legal or regulatory requirements, in addition to the recommendation given in this Guide, applicable to a particular region or country in which they are doing business.

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ACKNOWLEDGEMENTS

This glossary was updated from the 2014 International Pharmaceutical Excipient Council General Glossary of Terms and Acronyms by representatives from several member companies of the International Pharmaceutical Excipients Council, an industry association whose principal members consist of excipient manufacturers and their pharmaceutical users. Company representatives who worked on updating this version of the glossary are listed below:

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1 INTRODUCTION

While updating the glossary, 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 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 un-bolded and eventually removed from the IPEC General Glossary.

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.

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2 IPEC GENERAL GLOSSARY OF TERMS

Term	Definition	Other sources
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances, intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or any function of the body of humans or animals.	1, 8, 13, 15, 16, 19
Additive	A substance added to the excipient to improve or maintain a characteristic such as a preservative, flow agent, antimicrobial, etc.	
Aflatoxins	Aflatoxins are a group of structurally related toxic compounds produced by certain strains of the fungi Aspergillus flavus and A. parasiticus. Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins. The most pronounced contamination has been encountered in tree nuts, peanuts, and other oilseeds, including corn and cottonseed.	24
Allergens	A substance that causes an abnormal response by the immune system (e.g. gastrointestinal disturbances and skin irritations, to anaphylaxis, anaphylactic shock and death) to certain proteins found in the substance.	25
Animal Sourced	Contains and/or manufactured with starting materials of animal origin.	26
Atypical Active	Excipient, food additive or personal care ingredient that is being used as an "active ingredient" in a formulation.	
Barrier Packaging Materials	Either primary or secondary packaging materials which also have the function of preventing the permeation of gases, moisture or volatile concomitant components into or from the excipient. NOTE: Shipping pallets are not considered secondary packaging. [Significant Change]	
Batch (Lot)	A specific quantity of material produced in a process or a series of processes so that it may be expected to be uniform in character and quality, within specified limits. In the case of a continuous process, a batch may correspond to a defined fraction of the production. The batch size may be defined by a fixed quantity or by the amount produced in a fixed time interval.	1, 8, 13, 16, 17
Batch Manufacture	A method of manufacturing where the products are made as specified groups or amounts, within a time frame. The batch size may be defined by a fixed quantity or by the amount produced in a fixed time interval.	
Batch Number (Lot Number)	A unique combination of numbers, letters and/or symbols that identifies a batch and from which the production and distribution history can be determined.	1, 8, 13, 15, 16
Batch Processing	(refer to batch manufacture)	1

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Term	Definition	Other sources
Bioburden	The level and type (e.g. objectionable or not) of micro-organisms that can be present in raw materials, starting materials, excipients, intermediates or APIs. Bioburden should not be considered contamination unless the levels have been exceeded or defined objectionable organisms have been detected. [EIP]	8
Biological Origin	Any substance produced from animal or vegetable materials including starting materials and processing materials where the latter can come into contact with the excipient.	
Bioterrorism Act	The US Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) which directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take additional steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.	27
Blending	The sufficient mixing of materials to produce a homogeneous mixture.	
Bovine Spongiform Encephalopathy (BSE)	A slowly progressive, degenerative, fatal disease affecting the central nervous system of adult cattle.	28
Certificate of Analysis (COA)	A legal document that certifies the quality of the excipient and demonstrates that the batch conforms to the defined specifications, has been manufactured under excipient GMP, and is suitable for use in pharmaceuticals.	1, 16
Certificate of Suitability to the European Pharmacopoeia (CEP)	Certificate granted by the European Directorate for the Quality of Medicines (EDQM) to manufacturers of active ingredients or excipients confirming that the applicable Ph Eur monographs and general chapters are adequate to control the chemical purity of the material. Also, a CEP can also be granted to confirm a material conforms to the Ph. Eur. general chapter 5.2.8 'Minimizing the risk of transmitting animal spongiform encephalopathy agents via medicinal products', even if the material itself does not have a Ph. Eur. monograph.	
Change Control	A process used for management review of proposed changes that may impact the quality or regulatory conformance of the excipient.	1
Commissioning	A systematic approach to the start-up and turnover of facilities, systems, and equipment to end-users and ensuring that user requirements and design specifications are met (International Society of Pharmaceutical Engineering [ISPE], 2007). Activities within this phase may include design reviews, factory acceptance testing, installation verification, and functional testing. Summary reports are generated at the conclusion of commissioning activities and include an overview of the results and any deviations encountered during testing.	18
Component	Any material present in the excipient that arises as a consequence of the raw materials and/or manufacturing process.	1

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Term	Definition	Other sources
Composition Profile	A description of all of the components present in the excipient.	
Concomitant Component	A substance found in an excipient that is not the nominal chemical entity, may be necessary for assuring the proper performance of the excipient in its intended use, and is not undesirable, an impurity or a foreign substance. Sometimes referred to as minor component.	
Contamination	The undesired introduction of impurities of a chemical or microbiological nature or foreign matter into or onto a raw material, intermediate or excipient during production, sampling, packaging or repackaging, storage or transport.	1, 8, 13, 15
Continuous Process or Processing	A process that continually produces material from a continuing supply of raw material.	1
Control Strategy	A planned set of controls, derived from current product and process understanding, that assures process performance and product quality. The controls can include parameters and attributes related to excipient materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control.	1, 6, 11, 12, 22, 23
Co-processed Excipients	A co-processed excipient is a combination of two or more compendial or non-compendial excipients designed to physically modify their properties in a manner not achievable by simple physical mixing, and without significant chemical change. However, in some instances, formation of necessary components may occur, such as in situ salt formation.	
Co-processing	The act of manufacturing a co-processed excipient. Several methods may be used, including standard unit operations such as granulation, spray drying, melt extrusion, milling, etc.	
Country of Origin	Regulators typically consider the country of origin of an excipient to be the place in which the final chemical step was completed. [EIP]	
Critical Material Attribute (CMA)	An excipient physical, chemical, or microbiological attribute (defined by an excipient User), not necessarily reflected in supplier specifications or monographs that must be within appropriate limits, ranges, or distributions, to ensure that critical quality attributes (CQAs) for a particular drug product are maintained throughout the product life cycle.	
Critical Process Parameter	A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality.	9
Critical Quality Attributes (CQA)	A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality.	2, 23
Cross-contamination	Contamination of a material or product with another material or product. [EIP]	1, 8, 13,15

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Term	Definition	Other sources
Date of Manufacture	A date indicating the completion of the final manufacturing process (as defined by the supplier for the particular excipient and process).	
Date Retested (retest date)	See retest date	1, 3, 8,15, 16
Decision Tree	A visual presentation of the sequence of events that can occur, including decision points.	
Degradation product	A molecule resulting from a chemical change in the drug molecule brought about over time and/or by the action of e.g., light, temperature, pH, water, or by reaction with an excipient and/or the immediate container/closure system. Also called decomposition product.	7
Design of Experiments (DoE)	A structured, organized method for determining the relationship between factors affecting a process and the output of that process. Also known as "formal experimental design"	9
Design Space	The multidimensional combination and interaction of input variables (e.g., material attributes) and process parameters that have been demonstrated to provide assurance of quality.	9, 11, 23
Distribution	The division and movement of excipients from the premises of the manufacturer via distributor(s) to the excipient user.	1, 2
Distributor	A company procuring, importing, holding, supplying or exporting excipients. A distributor takes possession and ownership of the excipient(s), including e.g. repackaging, warehousing and transportation, but does not alter the excipients' physical and/or chemical characteristics e.g. processing / reprocessing.	1, 2
DMF Holder	The company or individual who has filed a Drug Master File with a Drug Regulatory Authority (e.g. US FDA, EU EMA, etc.).	29
Document Management System	The system that controls the life cycle of documents; their creation, reviewed, publication, and use, as well as how they are disposed of or retained.	
Dosage Form	A pharmaceutical product type (e.g., tablet, capsule, solution, cream) that contains a drug substance generally, but not necessarily, in association with excipients.	3, 20
Drug Master File (DMF)	Submissions to a drug regulatory authority (such as the United States Food and Drug Administration, Health Canada, and the Japanese Pharmaceutical and Medical Devices Agency) that may be used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products. Intended for incorporation by reference into a new drug application, supplemental new drug application, abbreviated new drug application, investigational new drug application, or biological license application.	21, 29
Drug Product	A finished dosage form, for example, tablet, capsule, or solution, that contains an active ingredient, generally with excipients, that has been prepared for consumer use and that has undergone all stages of	1, 2

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Term	Definition	Other sources
	production including packaging and labeling. In Europe aka "medicinal product."	
Elemental Impurity	Trace metals, catalysts and environmental contaminants which may occur naturally, added intentionally or introduced inadvertently. [EIP]	
Endotoxin	Lipopolysaccharides (LPS), also known as lipoglycans and endotoxin, are large molecules consisting of a lipid and a polysaccharide found in the outer membrane of Gram-negative bacteria, and elicit strong immune responses in animals. Lipopolysaccharides may be released on destruction of the bacteria, and that the immunogenic response leads to an increase in body temperature. [EIP]	
Equipment	The implements used in the manufacture of an excipient. [EIP]	
Excipient	Substances other than the API which have been appropriately evaluated for safety and are intentionally included in a drug delivery system.	1, 3, 15, 16
Excipient Information Package (EIP)	An IPEC initiative to provide standards for the exchange of data between excipient suppliers and excipient users. The EIP is comprised of the Site Quality Overview, Product Regulatory Datasheet, and Site and Supply Chain Security Overview. IPEC's Standardized Excipient Information Protocol User Guide provides information on the preparation of the EIP documents. [EIP]	36
Expiry (Expiration) Date	The date designating the time during which the excipient is expected to remain within specifications and after which it should not be used.	1, 8, 15, 16
Exotoxin	A toxin released by a living bacterial cell into its surroundings. [EIP]	
Feedstock	An alternative name for a raw material used in certain sectors of the chemical industry. [Composition]	
Forced Degradation/Stress Testing	Forced degradation studies are used to determine the intrinsic chemical stability of the excipient by investigating and confirming chemical degradation pathways, and to confirm the stability-indicating potential of analytical procedures. ICH Q1A(R2); Stability Testing of New Drug Substances and Products uses the term „stress testing". Such studies are also known as „forced degradation" studies. [Composition]	
Functionality	A desirable property of an excipient that aids and/or improves the manufacture, quality, or performance of the product.	1
Genetically Modified Organism (GMO)	An organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.	30
Genotoxic Impurities	Impurities present in the finished dosage form that may cause changes to the genome.	12

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Term	Definition	Other sources
Good Distribution Practices (GDP)	General principles of appropriate practices to maintain the quality and traceability of pharmaceutical starting materials throughout the entire supply chain from the manufacturer to the end-user.	1
Good Manufacturing Practices (GMP)	Minimum requirements for the quality management system, methods to be used in, and the facilities or controls to be used for the manufacture, processing, testing, packing, or holding of an excipient and its ingredients. Conformance to these minimum requirements, in part, assures that a drug (i.e., excipient, API, and drug products) will consistently meet quality standards and assure patient safety.	1, 16, 19
Grade	A version of an excipient which is recognized to have the same chemical composition and is covered by the same general monograph, but which differ in one or more attributes that may qualify its performance and use.	
Guidance	Guidance is a term commonly used by the FDA to represent the Agency's current thinking on a particular subject.	
Guide	Guide is a term commonly used by IPEC to differentiate between documents that are issued by regulatory Agencies. An IPEC guide is intended to be used as a support tool to further expand and/or clarify on guidance or guidelines, or lack thereof.	
Guideline	Guideline is a term used by regulatory agencies and other organizations (e.g. ICH) providing guidance on the scientific or regulatory aspects of the development of medicines and applications for marketing authorization. Although guidelines are not legally binding, applicants need to provide justification for any deviations.	
Halal	The term indicates that an item is permitted and fit for consumption by Muslims. [EIP]	
Harm	Damage to health, including the damage that can occur from loss of product quality or availability.	10
Hazard	The potential source of harm.	10, 14
Historical Norms	The totality of the data set for the excipient and expected range values that have been obtained over time. This includes but is not limited to comparison of chemical & physical properties, microbiological properties, composition profile, stability and/or performance.	
Hypersensitivity	A violent reaction by the immune system to a substance that is normally considered harmless.	
Impurity	An undesirable material found in an excipient as a consequence of the raw materials, excipient manufacturing process, or excipient degradation.	1, 4, 7, 8, 12
Intended Range	The range set based on the desired target.	
Interchangeability	Equivalent in the qualitative composition profile and the manufacturing, stability and post-administration performance in the given application.	19

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Term	Definition	Other sources
Kosher	Kosher refers to a set of intricate biblical laws that detail the types of food that a Jewish person may eat and the ways in which it may be prepared. To be certified kosher, all ingredients in every product—and the process of preparing the product—must be certified for orthodox kosher-compliance too.	32
Label	The display of written, printed or graphic matter on the immediate container of the excipient (inactive ingredient) product.	1
Labeling (material)	All written, printed or graphic matter accompanying an excipient at any time while it is in-transit to the customer or being held for sale after shipment or delivery to the customer.	
Labeling (process of)	The action involving the selection of the correct label, with the required information, followed by line-clearance and application of the label.	1, 15, 16
Lot	A batch or a specific identified portion of a batch. (see “batch”)	1, 8
Manufacture	Various operations, such as processing, packaging, labeling, and testing.	1, 8, 13, 15, 16
Manufacturer	Manufacturer means party (raw material, excipient, drug product) who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging or repackaging of a product.	13, 19
Melamine	A chemical that has many industrial uses which became a concern in 2008 due to incidents of product being adulterated with melamine to falsify analytical test results, resulting in contaminated pharmaceutical supply chains. It is therefore a contamination concern. [EIP]	
Mineral Based	Contains starting materials of mineral origin.	
Mixed Excipient	A mixed excipient is defined as a simple physical mixture of two or more compendial or non-compendial excipients produced by means of a low- to medium-shear process where the individual components are mixed but remain as discrete chemical entities, i.e., the nature of the components is not chemically changed.	
Mixtures	Products resulting from the physical combination of multiple excipients, often through a mixing operation and the nature of the processing is such that the materials are not co-processed together.	
Monograph (compendial)	Standard that specifies the quality attributes of an excipient, drug substance or drug product. Typically includes the name, description, packaging/storage/labeling requirements and specifications.	
Mycotoxin	A toxic secondary metabolite produced by organisms of the fungus kingdom. A contamination concern which is often tested in final drug product. [EIP]	
Nanotechnology	Nanotechnology is an emerging technology that can be used in a broad array of regulated products. The nanoscale range differs by region. Nanoscale materials can exhibit different chemical or physical properties, or biological effects compared to larger-scale counterparts. [EIP]	

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Term	Definition	Other sources
Nitrosamines and related compounds	A functional group classified as a probable human carcinogen. It is therefore a contamination concern for pharmaceuticals, for which a risk assessment is often performed on the API or excipient. [EIP]	
Nominal Component	The main component for which the excipient is named. For an excipient mixture, the main component may not be present at greater than 50%.	
Normal Variability	The variability expected to be obtained for the excipient during typical processing and evaluation when the process operates in a state of control with no special causes of variation. [Significant Change]	
Novel Excipient	An excipient used for the first time in a drug product or a new route of administration or a higher level of use in a drug product. When a novel excipient chemistry is used for the first time in a drug product it is referred to as a new chemical entity (NCE).	
Nutritional Information	The declaration of specific nutritional components such as total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, iron.	31
Official Distributor(s)	Distributor(s) with which the manufacturer has a business relationship; usually a formal distribution agreement.	
Original Manufacturer	Person or company manufacturing a material to the stage at which it is designated as a pharmaceutical starting material. (GDP Guide/WHO Good Trade and Distribution Practices) [CoA]	1, 2, 16
Other Components	Materials present in an excipient that arise as a consequence of the raw materials and/or manufacturing process and are not concomitant component.	
Pedigree	Documentation that provides traceability of the material throughout the supply chain.	33
Precedence of Use	Previously used in an approved drug product. [EIP]	
Primary Packaging Materials	Packaging materials which have direct contact with the excipient.	
Process (Processing) Aid	Materials, excluding solvents, used as an aid in the manufacture of an intermediate, excipient or API that do not themselves participate in a chemical or biological reaction (e.g. filter aid, activated carbon, etc.).	
Process Analytical Technology (PAT)	A system for designing, analyzing, and controlling manufacturing through timely measurements (i.e., during processing) of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality. [EIP]	
Process Capability Index (Cp)	A statistical measurement that can be used to assess whether or not the process is adequate to meet specifications. A “State of Statistical Control” can be said to exist if the random variation in test results for a process	

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Term	Definition	Other sources
	parameter is such that the calculated process capability is greater than 1.33. [CoA]	
Process Parameter	A measurable operating condition. [Significant Change]	
Process Step	A documented instruction to the **pharmaceutical** excipient manufacturing personnel directing that an operation be done.	
Product of Biotechnology	A product derived from any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. [Significant Change]	
Proposition 65 (California)	The California Safe Drinking Water and Toxic Enforcement Act of 1986, better known by its original name of Proposition 65, is "right to know" legislation regarding substances known to the State of California to cause cancer or birth defects or other reproductive harm. [EIP]	
Quality Agreement	A formal agreement between the excipient manufacturer and their pharmaceutical customer that stipulates the responsibilities of each party in meeting the regulatory requirements for sale and use of the excipient in a dosage form.	
Quality by Design (QbD)	A systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management.	9
Quality Critical	Describes a material, process step or process condition, test requirement or any other relevant parameter that directly influences the quality attributes of the excipient and which must be controlled within predetermined criteria.	1
Quality Management System (QMS)	A management system that directs and controls how the organization implements quality policies and achieves quality objectives. NOTE — Requirements for quality management systems can be found in ISO 9001 and ICH Q10.	1
Quality Target Product Profile (QTPP)	A prospective summary of the quality characteristics of a drug product that ideally will be achieved to ensure the desired quality, taking into account safety and efficacy of the drug product. [QbD Sample]	2, 9
Raw Material	In the context of excipient manufacturing, a general term used to denote materials, reagents and solvents intended for use in the production of intermediates or excipients.	1

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Term	Definition	Other sources
Recall (USA: see Retrieval)	A process for withdrawing or removing product from the distribution chain because of defects in the materials or complaints of a serious nature. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency. Note: In the USA, the term recall has specific regulatory implications that do not directly apply to excipients. Therefore, the term retrieval is typically used in the USA. In this document "recall" has the same meaning as retrieval.	1
Re-evaluation Date/(Retest Date)	The date beyond which the excipient should not be used without further appropriate re-examination to ensure that it is still in conformance with the specification.	1
Relabeling	Process of putting a new label on the excipient. Traceability to the original manufacturer is only assured if the relabeler provides access to its quality systems. [EIP]	16
Reliability	An expression of the degree to which a measurement performed by different people at different times and under different circumstances produces the same results (see also validity).	19
Repackaging	The action of changing the packaging of the material. [EIP, CoA]	2, 16
Replacement in Kind	Manufacturing equipment that uses the same operating principle and is of similar construction or packaging components made with the same materials of construction and sealed in a similar manner.	
Reprocess	Repetition of an activity that is a normal part of the manufacturing process and that has been documented previously.	13
Residual Solvents	Residual solvents are defined as organic chemicals that are used or produced in the manufacture of active substances or excipients, or in the preparation of medicinal products. ICH Q3C Impurities: Residual Solvents. [EIP, Composition]	5
Responsible Care	A voluntary program to achieve improvements in environmental, health and safety performance. Adopted by most Chemical Industry associations worldwide.	34
Retained Sample	Representative sample of a batch/delivery that is sufficient quantity to perform at least **2** full quality control analyses and will be kept for a defined period of time.	
Retest Date	(refer to Re-evaluation Date)	1, 3, 8, 15, 16

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Term	Definition	Other sources
Retest Period	The period of time during which the excipient is expected to remain within its specification and, therefore, can be used in the manufacture of a given drug product, provided that the excipient has been stored under the defined conditions. After this period, a batch of excipient destined for use in the manufacture of a drug product should be re-tested for compliance with the specification and then used immediately. A batch of excipient can be re-tested multiple times and a different portion of the batch used after each re-test, as long as it continues to comply with the specification.	3
Reworking	Subjecting previously processed material that did not conform to standards or specifications to processing steps that differ from the normal process.	1, 13
Risk Acceptance	The decision to accept risk (ISO Guide 73). [Risk Assessment Part 1]	6, 10
Risk Analysis	The estimation of the risk associated with the identified hazards. [Risk Assessment Part 1]	2, 6, 10, 23
Risk Assessment	A systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards. [Significant Change, IE Risk Assessment]	1, 2, 6, 10, 23
Risk Communication	The sharing of information about risk and risk management between the decision maker and other stakeholders. [Risk Assessment Part 1]	10
Risk Control	Actions implementing risk management decisions.	10
Risk Evaluation	The comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk. [Risk Assessment Part 1]	10, 23
Risk Identification	The systematic use of information to identify potential sources of harm (hazards) referring to the risk question or problem description.	6, 10, 23
Risk Management	The systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating and reviewing risk.	6, 10
Risk Reduction	Actions taken to lessen the probability of occurrence of harm and the severity of that harm. [Risk Assessment Part 1]	10
Risk Review	Review or monitoring of output/results of the risk management process considering (if appropriate) new knowledge and experience about the risk.	10, 23
Secondary Packaging Materials	Packaging materials which do not have direct contact with the excipient.	

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Term	Definition	Other sources
Shelf Life	The duration, normally expressed in months or years from the date of manufacture, throughout which the excipient should continue to conform to the specification.	
Significant Change	Any change that has the potential to alters an excipient's physical, chemical, or microbiological property from the norm, and/or that may alter the excipient's performance in the dosage form.	1
Site	A defined location of the equipment in which the excipient is manufactured. It may be within a larger facility. A change in site may be to a different part of the existing facility, but in a different operational area, or to a remote facility including a contract manufacturer.	
Skip-Lot (periodic) Testing	The performance of specified tests at release on pre-selected batches and/or at predetermined intervals, rather than on a batch-to-batch basis, with the understanding that those batches not tested must still meet all the acceptance criteria established for that product. This represents a less than full schedule of testing.	16
Skip-Lot Testing Program	Periodic or intermittent testing performed for a particular test parameter, which is justified by historical data demonstrating a state of statistical process control.	
Specification	A list of tests, references to analytical procedures and pre-established numerical limits, ranges or other criteria for the tests described, that the material is required to meet.	1, 3, 7, 13
Specified impurity	An identified or unidentified impurity that is selected for inclusion in excipient product specification and is individually listed and limited in order to assure the quality of the excipient.	4, 7
Stakeholder	Any individual, group or organization that can affect, be affected by, or perceive to be affected by any action. Primary stakeholders often include excipient manufactures, distributors, users, regulators and pharmacopeial organizations.	10, 23
State of Control	A condition in which the set of controls consistently provides assurance of continued process performance and product quality.	1
Statistical Process Control	A statistical technique involving ongoing evaluation of measurements to monitor and analyze the variation in processes. [EIP]	
Supplier	Person or company providing excipients on request. Suppliers may be distributors or traders, etc.	1, 2, 16
Supply Chain	Supply chain is defined as all steps in the entire chain of distribution starting from the point at which an excipient is transferred outside the control of the original manufacturer's material a management system downstream to the final user of the excipient.	1, 2
Synthetic	Products which are not derived from starting materials sourced from plants, animals or minerals and that are not products of fermentation. Note: Also see specific regional or national organic food legislation for additional information on the use of the term synthetic.	

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Term	Definition	Other sources
Tamper Evident	Describes a means to reveal any interference with the integrity of the finished packaged excipient and designed to make improper opening of an excipient's packaging evident to the purchaser.	
Technically Unavoidable Particle Profile (TUPP)	Document in which an excipient manufacturer describes the type(s) of technically unavoidable particle(s) found in the excipient, along with its(their) origin from a particular manufacturing process or product. A TUPP includes results of prior investigations of various particles, results of risk assessments, raw material characterization, unavoidable particles from product packaging, etc.	37
Technically Unavoidable Particles (TUPs)	Particles that are visibly different from the bulk of the material when viewed with the naked eye within the container or against a suitable background (examples are size, shape, color, number, texture), AND: 1. Are inherent to the excipient manufacturer's process, product or raw materials. 2. Are technically unavoidable	37
Traceability	Ability to determine the history, application or location that is under consideration, for example, origin of materials and parts, processing history or distribution of the product after delivery.	1
Transmissible Spongiform Encephalopathy (TSE)	TSEs are fatal, subacute degenerative diseases of humans and animals with characteristic neuropathology (spongiform change and deposition of an abnormal form of a prion protein present in all mammalian brains).	35
Unidentified Impurity	An impurity for which a structural characterization has not been achieved and that is defined solely by qualitative analytical properties (e.g., chromatographic retention time).	
Unspecified Impurity	An impurity that is limited by a general acceptance criterion, but not individually listed with its own specific acceptance criterion.	
User	A party who utilizes an excipient in the manufacture of a drug product or another excipient.	
Validated State	Status of a GMP relevant system or process that is achieved after having provided documented evidence that the system or process is capable for the intended use in the manufacturing of pharmaceutical excipients.	
Validation	A documented program that provides a high degree of assurance that a specific product, method, procedure (e.g., cleaning), or system will consistently produce a result meeting predetermined acceptance criteria.	1, 8, 13, 16, 19, 20, 23
Vegetable Sourced	Contains starting materials of plant origin.	
Verification	The application of methods, procedures, tests and other evaluations to provide objective evidence that the output of a particular operation meets the specified requirements for that operation.	1, 14, 20, 23

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3 IPEC GENERAL GLOSSARY OF ACRONYMS

Acronym	Definition
21 CFR	Title 21 of the United States Code of Federal Regulations
ACC	The American Chemistry Council
ADI	Acceptable Daily Intake
ADME	Absorption, distribution, metabolism and excretion
AEO	Authorised Economic Operator
AIB	The American Institute of Baking
AIFA	Agenzia italiana del Farmaco (Italy)
ANSI	American National Standards Institute
ANSM	National Agency for Medicines and Health Products Safety (France)
ANVISA	Agência Nacional de Vigilância Sanitária (Brazil)
API	Active Pharmaceutical Ingredient
BfArm	Bundesinstitut für Arzneimittel und Medizinprodukte (Germany)
BP	British Pharmacopoeia
BPE	Bulk Pharmaceutical Excipient
BRC	British Retail Consortium
BSE	Bovine Spongiform Encephalopathy
CAPA	Corrective and Preventative Actions
CAS Number	Chemical Abstracts Service Registry Number
Cefic	The European Chemical Industry Council
CEP	Certificate of Suitability to the European Pharmacopoeia
CFATS	Chemical Facility Anti-Terrorism Standards
cGMP	Current Good Manufacturing Practice
ChP	Chines Pharmacopoeia
CMC	Chemistry, Manufacturing and Controls
CMO	Contract Manufacturing Organization
COA	Certificate of Analysis
COC	Certificate of Conformity
Cp	Process Capability Index
CPP	Critical Process Parameter
CQA	Critical Quality Attribute
CTD	Common Technical Document
C-TPAT	Customs - Trade Partnership Against Terrorism
DMF	Drug Master File

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Acronym	Definition
DoE	Design of Experiments
DQ	Design Qualification
EC	European Commission
EDI	Estimated Daily Intake
EDQM	European Directorate for the Quality of Medicines
EEFO	Earliest Expiry/First Out Principle Concept
EFPIA	European Federation of Pharmaceutical Industries and Associations
EIP	Excipient Information Package
EMA	European Medicines Agency (Europe)
FCC	Food Chemicals Codex
FDA	Food and Drug Administration
FECC	European Federation of Chemical Distributors
FEMA	Flavor and Extract Manufacturers Association of the United States
FIFO	First in/First out Principle Concept
FMD	Falsified Medicines Directive (Europe)
FMEA	Failure Mode and Effects Analysis
FMECA	Failure Mode, Effects and Criticality Analysis
FPA	Food Products Association
FSSC 22000	Foundation Food Safety System Certification 22000
FTA	Fault Tree Analysis
GAMP	Good Automated Manufacturing Practices
GDP	Good Distribution Practice
GEP	Good Engineering Practices
GMA	Grocery Manufacturers Association
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practices
GRAS	Generally Recognized as Safe
GSP	Good Storage Practices
GTDP	Good Trade and Distribution Practices
HACCP	Hazard Analysis Critical Control Point
HARPC	Hazard Analysis and Risk-Based Preventive Controls
HAZOP	Hazard Operability Analysis
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.
IID	Inactive Ingredient Database
INCI	International Nomenclature of Cosmetic Ingredients and Handbook.

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Acronym	Definition
IPEA	International Pharmaceutical Excipients Auditing, Inc.
IPEC	International Pharmaceutical Excipients Council
IPEC PQG	International Pharmaceutical Excipients Council and the Pharmaceutical Quality Group
IQ	Installation Qualification
ISO	International Organization for Standardization.
ISO 14000	The International Organization for Standardization's family of standards on environmental management Site and Supply Chain Security Overview – Section 4
ISO 9001	International Standards Organization guidelines for a Quality Management System
JP	Japanese Pharmacopoeia
JPE	Japanese Pharmaceutical Excipients
JSFA	Japanese Standards for Food Additives
LOEL	Lowest-Observed Effect Level
MAH	Manufacturing Authorisation Holders
MHLW	Ministry of Health, Labour and Welfare (Japan)
NACD	National Association of Chemical Distributors (NEW)
NMPA	National Medical Products Administration (China)
NOAEL	No-Observed-Adverse-Effect Level
NOEL	No-Observed-Effect Level
NSF	National Sanitation Foundation
OC	Operating Characteristic
OHSAS 18001	International occupational health and safety management system specification.
OOT	Out of Trend
OQ	Operational Qualification
OVI	Organic Volatile Impurities, USP/NF General Chapter <467> [6]
PAT	Process Analytical Technology
PDE	Permissible Daily Exposure
PDG	Pharmacopoeial Discussion Group
Ph. Eur.	European Pharmacopoeia
PHA	Preliminary Hazard Analysis
PhRMA	Pharmaceutical Research and Manufacturers of America
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PQ	Performance Qualification
PQG	Product Quality Group

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Acronym	Definition
PQS	Pharmaceutical Quality Practices
PRDS	Harmonised IPEC-PQG Excipient Manufacturer Product Regulatory Data Sheet
QA	Quality Assurance
QbD	Quality by Design
QC	Quality Control
QIP	Quality Improvement Plan
QMS	Quality Management System
QRM	Quality Risk Management Data Sheet
QTPP	Quality Target Product Profile
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RPN	Risk Priority Number
Rx-360	An International Pharmaceutical Supply Chain Consortium
SDS	Safety Data Sheet
SOP	Standard Operating Procedure
SQC	Statistical Quality Control
TGA	Therapeutic Goods Administration
TSCA	Toxic Substances Control Act
TSE	Transmissible Spongiform Encephalopathy
TUPP	Technically Unavoidable Particle Profile
USP/NF	United States Pharmacopeia/National Formulary [6]
VMP	Validation Master Plan
VP	Validation Protocol
VR	Validation Report
WHO	World Health Organization

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4 IPEC GENERAL GLOSSARY REFERENCES

No.	Reference Title	Reference Webpage
1	EXCiPACT® Certification Standards for Pharmaceutical Excipients, 2017	https://www.excipact.org/files/EXCiPACT/Downloads/20180123%20EXC%20Standard_Final-webversion.pdf
2	PDA Technical Report No. 54-6 (TR 54-6) Formalized Risk Assessment for Excipients	https://www.pda.org/bookstore/product-detail/5413-tr-54-6-formalized-risk-assessment
3	ICH Q1A(R2): Stability Testing of New Drug Substances and Products (Second Revision) (2003)	https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.pdf
4	ICH Q3A(R2): Impurities in New Drug Substances (2006)	https://database.ich.org/sites/default/files/Q3A%28R2%29%20Guideline.pdf
5	ICH Q3C(R6): Impurities: Guideline for Residual Solvents (2016)	https://database.ich.org/sites/default/files/Q3C-R6_Guideline_ErrorCorrection_2019_0410_0.pdf
6	ICH Q3D(R1): Guideline for Elemental Impurities (2019)	https://database.ich.org/sites/default/files/Q3D-R1EWG_Document_Step4_Guideline_2019_0322.pdf
7	ICH Q6A: Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances (1999)	https://database.ich.org/sites/default/files/Q6A%20Guideline.pdf
8	ICH Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (20000	https://database.ich.org/sites/default/files/Q7%20Guideline.pdf
9	ICH Q8: (R2) Pharmaceutical Development (2009)	https://database.ich.org/sites/default/files/Q8%28R2%29%20Guideline.pdf
10	ICH Q9: Quality Risk Management (2005)	https://database.ich.org/sites/default/files/Q9%20Guideline.pdf
11	ICH Q10: Pharmaceutical Quality System (2008)	https://database.ich.org/sites/default/files/Q10%20Guideline.pdf
12	ICH M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential (2017)	https://database.ich.org/sites/default/files/M7_R1_Guideline.pdf
13	WHO TR Series, No. 908, 2003, Annex 4, Good Manufacturing Practices for pharmaceutical products: main principles	https://gmpua.com/World/WHO/Annex4/trs908-4.pdf
14	WHO TR Series, No. 908, 2003, Annex 7, Application of Hazard Analysis and Critical Control Point (HACCP) methodology to pharmaceuticals	https://www.who.int/medicines/areas/quality_safety/quality_assurance/ApplicationHACCPMethodologyPharmaceuticalsTRS908Annex7.pdf?ua=1
15	WHO TR Series, No. 908, 2003, Annex 9, Guide to good storage practices for pharmaceuticals	https://www.who.int/medicines/areas/quality_safety/quality_assurance/GuideGoodStoragePracticesTRS908Annex9.pdf

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16	WHO TR Series No. 917, 2003, Annex 2, Good trade and distribution practices for pharmaceutical starting materials	https://www.who.int/medicines/areas/quality_safety/quality_assurance/Annex2_TRS917_2003Goodtrade_distribution.pdf
17	WHO TR Series No. 929, 2005, WHO Guidelines for sampling of pharmaceutical products and related materials	https://www.who.int/medicines/areas/quality_safety/quality_assurance/GuidelinesSamplingPharmProductsTRS929Annex4.pdf?ua=1
18	WHO TR Series No. 937, 2006, Annex 4, Supplementary guidelines on good manufacturing practices: validation	https://www.who.int/medicines/areas/quality_safety/quality_assurance/SupplementaryGMPValidationTRS937Annex4.pdf
19	WHO TR Series No. 937, 2006, Annex 6, A model quality assurance system for procurement agencies	https://www.who.int/medicines/publications/ModelQualityAssurance.pdf
20	WHO TR Series No. 937, 2006, Annex 7, Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability	https://www.who.int/medicines/areas/quality_safety/quality_assurance/Annex7-TRS992.pdf
21	WHO TR Series No. 885, 1999, Annex 5, Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients	https://www.who.int/medicines/areas/quality_safety/quality_assurance/SupplementaryGMPPharmaceuticalExcipientsTRS885Annex5.pdf?ua=1
22	WHO TR Series No. 966, 2016, Annex 5, Guidance on good data and record management practices	https://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf
23	WHO TR Series No. 981, 2013, Annex 2, WHO guidelines on quality risk management	http://digicollection.org/whoqapharm/documents/s20093en/s20093en.pdf
24	Aflatoxins - US FDA Miscellaneous Term	https://wayback.archive-it.org/7993/20170406190301/https://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071020.htm
25	Allergens - US FDA Miscellaneous Term	https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/food-allergensgluten-free-guidance-documents-regulatory-information
26	Animal Sourced - US FDA Miscellaneous Term	https://www.fda.gov/media/102126/download
27	Bioterrorism Act - US FDA Miscellaneous Term	https://www.fda.gov/food/importing-food-products-united-states/prior-notice-imported-foods
28	Bovine Spongiform Encephalopathy - US FDA Miscellaneous Term	https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-final-rule-bovine-spongiform-encephalopathy
29	DMF US FDA DMF Guidance - US FDA Miscellaneous Term	https://www.fda.gov/media/131861/download
30	Genetically Modified Organism (GMO) - US FDA Miscellaneous Term	https://www.fda.gov/food/food-new-plant-varieties/understanding-new-plant-varieties

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No.	Reference Title	Reference Webpage
31	Nutritional Information US FDA DMF Guidance	https://www.fda.gov/food/food-labeling-nutrition/nutrition-information-raw-vegetables
32	KOSHER	https://www.ok.org/companies/what-is-kosher/
33	Pedigree	https://ipecamericas.org/sites/default/files/Excipient_Pedigree.pdf
34	Responsible Care	https://responsiblecare.americanchemistry.com/
35	Transmissible Spongiform Encephalopathy (TSE)	https://www.fda.gov/media/102126/download
36	IPEC EIP	
37	IPEC TUPP Guide	

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