The International Pharmaceutical Excipients Council

Good Distribution Practices Audit Guide

For Pharmaceutical Excipients

Third Version
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.

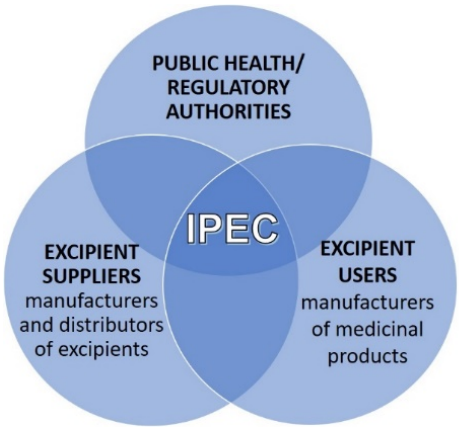
This guide was created to help companies understand current expectations on this topic and is not intended for use by third party certification bodies to conduct audits or to certify compliance with the guide.

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 IPEC documents,
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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This document has been written to provide a tool for those companies auditing the supply chain of pharmaceutical excipients.

This Audit Guide should be used in conjunction with the IPEC Good Distribution Practices Guide. This guide is a tool to help the auditor conduct a complete audit of all relevant GDP principles for pharmaceutical excipients.

This document is a consolidation and revision of the IPEC Europe Good Distribution Practices Audit Guideline for Pharmaceutical Excipients 2011 [1] and the IPEC-Americas Good Distribution Practices Audit Guide for North American Distribution of Pharmaceutical Excipients 2011 [2]

NOTE: Refer to the "International Pharmaceutical Excipients Council Glossary: General Glossary of Terms and Acronyms" [6] for definitions. The first use of a term found in the glossary will be in **BOLD**.

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Table of Contents

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I. Introductory Note

The International Pharmaceutical Excipients Council Europe (IPEC Europe) published the IPEC Europe Good Distribution Practices Audit Guideline for Pharmaceutical Excipients in 2011 [1]. This guide was based on the assessment questionnaire SQAS ESAD Section F&G [11]. The SQAS ESAD assessment system is widely used by European distributors to demonstrate their quality, safety and environmental performance. Sections F&G of this assessment questionnaire cover specifically GDP aspects for food, cosmetic and pharma ingredients. Not to just duplicate this questionnaire, IPEC Europe aligned it's IPEC Europe GDP Audit Guideline for Distributors of Bulk Pharmaceutical Excipients 2011 [1] to Sections F&G of the SQAS ESAD questionnaire ensuring its consistency with the IPEC GDP Guidelines for pharmaceutical excipients 2006. In parallel, IPEC Americas developed a GDP audit guide in 2011 which was aligned to the IPEC GDP guidelines for pharmaceutical excipients 2006 and to the specific needs in North America.

This document was developed as a consolidation of both aforementioned GDP audit guides. It harmonises both guides and is a revision to align the guide with the *IPEC GDP Guide for Pharmaceutical Excipients revised in 2017* [3].

The purpose of the document is to assist the users in evaluating the practices and quality systems of distributors who sell, store or repackage pharmaceutical excipients or any combination thereof.

For the purpose of this guideline "distributors" includes those parties involved in trade and distribution, repackaging, relabelling, sampling, testing, retesting, transportation and warehousing operations, as well as forwarding agents, brokers, traders, and suppliers other than the original manufacturer.

For definition of technical terms, please refer to the current *IPEC General Glossary of Terms and Acronyms* [6].

For auditing of manufacturing activities such as repackaging, reprocessing, blending, mixing, milling, micronisation or any other physical manipulation of pharmaceutical excipients, please refer also to the current *IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients* [4] and the current *IPEC GMP Audit Guide for Pharmaceutical Excipients* [5].

II. Scope

This Questionnaire is linked to the *IPEC GDP Guide for Pharmaceutical Excipients revised in 2017* [3] which is based on the *WHO Good Trade and Distribution Practices for Pharmaceutical Starting Materials* [7], and therefore it follows the same structure.

It applies to all steps in the distribution/supply chain starting from the point at which an excipient is transferred outside the control of the original manufacturer's material management system. Some sections and/or sub-sections in this document may not apply to all involved parties.

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This document is intended to provide a framework for the auditor who must always decide to what level of detail and focus the audit must follow. It can therefore be used either as a self-assessment questionnaire to be completed by a distributor/supplier, or as an audit check-list.

III. Pharmaceutical Grade Excipients

Parties involved in the supply chain should be aware that an excipient can only be designated pharmaceutical grade when it is in compliance with pharmacopeial specifications and/or appropriate regulatory requirements (if existing for the specific excipient) and is manufactured, repackaged, and handled in accordance with excipient GMP principles (e.g., IPEC PQG GMP [4], WHO Excipient GMP [8], EXCiPACT GMP/GDP Standard [9] and/or NSF/IPEC/ANSI 363 GMP [10]).

Upgrading any other grade, e.g., food, technical, or industrial grade material to pharmaceutical grade quality based only on analytical results found in conformance with the requirements of a pharmacopeial monograph, is not an acceptable practice.

IV. Acknowledgements

IPEC would like to acknowledge the World Health Organisation (WHO) for their extensive efforts in developing the guidelines “Good Trade and Distribution Practices for Pharmaceutical Starting Materials” [6] in the revised version of 2016, which is valued by the IPEC Federation as a significant step forward in the development of tools for the improvement of safety and quality of starting materials and finished pharmaceuticals.

This Guide was developed by representatives from International Pharmaceutical Excipients Council (IPEC) member companies. IPEC is an industry association whose members consist of excipient manufacturers, distributors, and users. The company representatives who worked on this Guide are listed below:

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IPEC GDP Guide	Question	Comments/Notes
1 Quality Management		

1.1	• Which type of quality management system (QMS) has been implemented?
	• According to which standard has the QMS been designed against? (e.g., ISO 9001, GDP/GMP by a competent authority, EXCiPACT®, ANSI/NSF/IPEC 363, safety standards or another recognized standard)?
	• How is the QMS documented?
	• How does it address the following elements?
	  ○ scope of the QMS
	  ○ organizational structure
	  ○ written procedures, processes and resources or reference to them; and
	  ○ a description of the sequence and interaction between the procedures and departmental functions
	• Does the Quality Policy contain commitment and adherence to GDP/GMP signed off by top management?	

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IPEC GDP Guide	Question	Comments/Notes
1.2	• Which elements comprise the infrastructure of the QMS taking into account the size, structure and complexity of the distributor and its activities? • Describe the principles and tools of Quality Risk Management within the QMS enabling a systematic process for the assessment, control, communication and review of quality risks to the product? • How is it demonstrated that there is an independent quality unit (or designee), which is responsible for all quality-related matters • How are suppliers of pharmaceutical excipients and services selected, approved, disqualified and re-approved? • How are deviations managed? • How are changes controlled? • Under what conditions are customers notified about changes? • How is traceability of the excipient and associated documentation ensured throughout the supply chain? • How are the principles and scope for validation and qualification defined depending upon the operations to be performed?	

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IPEC GDP Guide	Question	Comments/Notes
1.3	• The system should cover for example, but not limited to the quality assurance principles in the GDP Guide	
1.4	• What is the evidence for shared responsibility assuring that the excipient conforms to the mutually agreed specification and is suitable for its intended use by the pharmaceutical industry? • How is it ensured that materials are purchased against agreed specifications and only from approved suppliers? • What proven evidence is in place to assure that the distributor and the customer have mutually agreed upon the specifications and other requirements?	
1.5	• How is it ensured that there is an adequate number of qualified personnel available to perform all operations in compliance with this guide (refer to 2.2)? • Who in the organisation is responsible to ensure compliance with the applicable provisions of the GDP guide? • Demonstrate who is responsible for final batch release in the QMS, if applicable? • What controls are in place for the responsibilities of the quality unit that have been delegated to other personnel and/or contractors?	

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IPEC GDP Guide	Question	Comments/Notes
1.5	• If contractors are used to perform responsibilities, how have they been trained and qualified for this purpose?	
1.6	• How is it ensured that E-Commerce procedures are documented and comply with the requirements for excipient quality and traceability according to GDP?	
1.7	• How does the release procedure ensure that when material is released for its intended purpose, it is of an appropriate quality, meets its specifications and is sourced from approved suppliers? • What do you inspect on excipient provided only in originally sealed containers from the manufacturer? • How is the GMP status of the excipient verified and documented?	
1.8	• Which QRM principles are applied to demonstrate compliance with GDP? • How do those applied principles demonstrate compliance with GDP?	
1.9	• How does the organization manage the internal quality audit program? • How does the internal quality audit program direct continuous improvement?	

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IPEC GDP Guide	Question	Comments/Notes
1.9	• Which principles are applied to determine the internal audit plan and schedule? • How are internal audits documented and related activities (e.g., investigations, corrective and preventive actions) tracked? • How are the responsible management personnel made aware of the audit findings and the corrective and preventive actions to be taken? • How is it ensured that corrective and preventive actions are completed and checked for effectiveness?	
2 Organisation and Personnel		
2.1	• How are adequate personnel resources provided in terms of number and qualification to perform and supervise the operations performed in compliance with applicable GDP requirements? • How is the organizational structure documented? • How is independency of the quality unit or function from operational functions ensured?	

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2.1	• How is demonstrated that the quality unit is able to perform the relevant tasks, e.g., handling of non-conformities, documentation and traceability of the excipient distribution activities?	
2.2	• How are required qualifications assigned for GDP related tasks? • How are qualifications and training documented for each employee? • How is it demonstrated that the qualification and training program for individual personnel is suitable for the operations performed? • How are levels of authorization and decision-making workflow defined, communicated and documented? • What information is contained in the list of providers of GDP related services?	
2.3	• How is it ensured that all relevant personnel are aware of the principles of the appropriate guidelines, including but not limited to GDP?	
2.4	• Describe the system for planning, delivery, frequency and follow up of initial and continuing training?	

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IPEC GDP Guide	Question	Comments/Notes
2.4	• How is it ensured that trainers are appropriately qualified for the trainings to be given? • How are trainings documented? • How is it ensured that trainings are conducted in accordance with the training plans for all employees including consultants and contractors? • How is training effectiveness and employee competency assessed? • How are job-specific training requirements clearly defined? • How is it demonstrated that GDP principles are included in training and qualification for all relevant personnel?	
2.5	• What training is provided to personnel for safe hazardous material handling (such as highly active, toxic, infectious, flammable, sensitizing or corrosive materials) including Personal Protective equipment (PPE) requirements? • What are the procedures in place to ensure appropriate protection of the personnel from hazardous materials? • How is it demonstrated that the necessary PPE is provided for handling hazardous materials? How is this communicated to employees?	

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2.5	• How is it ensured that protection procedures are not in conflict with the hygiene program or a risk assessment to ensure the quality and the hygiene for the product is maintained?	
2.6	• What personnel hygiene requirements and PPE are specified and how is it communicated to employees? Ensure that requirements indicate cleanliness of apparel and PPE. • How are personnel informed of the requirement to report any health conditions that may have an adverse effect on the product? • How are personnel with illness or open skin lesions prevented from potential contaminate or otherwise adversely affect the safety or quality of the product are allowed to work in any operation that could cause the product to become contaminated? • What is the policy on loose and/or unsecured jewellery or other items in operations where they can fall into the product? How are personnel observed to be in compliance? • Where can personnel store and consume food, beverage, tobacco products or personal medication? How are these areas designated?	

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IPEC GDP Guide	Question	Comments/Notes
3 Premises		
3.1	• Describe how the space and environmental controls ensure excipient integrity and avoid mix-ups or cross-contamination during handling, packaging, testing and storage operations. • Describe how facilities and buildings appear. Are they in a good state of repair? • Describe how the preventive maintenance program ensures the integrity of operations that are being performed. • Are the facilities clean appropriate to the operations being performed? • How is cleaning of the facilities facilitated? • What risk assessment was performed concerning other materials packaged or stored in close proximity to the excipient where it is exposed to the environment? • In case highly sensitizing, toxic or volatile products are handled, how are they separated and are there risk based controlled to avoid cross-contamination or mix-ups? What evidence is there that these measures are effective?	

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IPEC GDP Guide	Question	Comments/Notes
3.1	• How is it demonstrated that there are adequate facilities to perform sampling and testing of raw materials, packaging components, intermediates and finished excipients, if required?	
3.2	• What measures have been taken to prevent unauthorized access to the premises? • What measures are in place to prevent unauthorized access to packaging, warehouse and laboratory areas?	
3.3	• What measures are taken to protect the excipient from contamination due to insects, rodents, birds, and other animals, especially in case premises and equipment are located outside? • What kind of pest control program is in place and how is it managed? • How is it controlled and how is its effectiveness monitored?	
3.4	• How is contamination, cross-contamination and degradation of excipient avoided in supporting facilities, such as air control, ventilation and lighting?	

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3.4	• Are the utilities that could affect excipient quality identified and how are they determined to be appropriately monitored? • What kind of risk assessment has been conducted to determine the necessary controls for utilities (e.g., nitrogen, compressed air, steam, water) that could affect excipient quality?	
3.5	• If sampling is performed, which measures are in place to avoid deterioration, contamination and cross-contamination (e.g., separation, controls of environment)? • What cleaning procedures are in place for the sampling area?	
4 Procurement, warehousing and storage		
4.1	• How are excipient specifications agreed?	
4.2	• What procedures are in place to minimize the risk of receiving or forwarding falsified and/or non-conforming excipients?	
4.3	• How is receipt, storage and distribution of excipients performed and is this described in a written procedure?	

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IPEC GDP Guide	Question	Comments/Notes
4.3	• How does the written procedure cover visual inspection of the container (packaged or bulk) including its security features (e. g. seals), confirmation of excipient identity from the label against documentation and recording of these data? • What assurances are in place that all receipts are from approved suppliers? • What checks are performed prior to loading of excipients and do they include a check for cleanliness of the vehicle used?	
4.4	• How is it ensured that the storage area has sufficient capacity to ensure orderly storage, appropriate segregation and correct selection of designated excipients? • How is segregated storage of different batches of excipients and of excipients from other grade materials ensured to avoid contamination and mix-ups? • How is it ensured that containers are stored protected from adverse environmental conditions, and stored in compliance with safety requirements (e. g. in case of dangerous goods)? • Where are computerized system utilised to support segregation during storage?	

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IPEC GDP Guide	Question	Comments/Notes
4.4		
4.5	• How are reception/ dispatch areas set up? Do they allow for the cleaning of incoming containers if necessary? • How are received excipients segregated until release?	
4.6	• How are received, quarantined, rejected, recalled, returned, non-conforming and commissioned excipients segregated? • How is it ensured that any quarantined, rejected, recalled or otherwise blocked excipient cannot be selected for production or distribution purposes? • If no physical segregation is implemented, how is it ensured, that the electronic system used for segregation is properly and consistently working? • How is access to blocked material controlled?	
4.7	• In what condition is the storage area?	
4.8	• How are segregated areas and excipients identified?	
4.9	• How are any required storage and/or shipping conditions controlled during possession of the excipient by the auditee?	

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IPEC GDP Guide	Question	Comments/Notes
4.10	• How are required storage conditions for excipients applied, monitored and documented? • What are the actions to be taken in case of deviations from required conditions?	
4.11	• How is it ensured that highly active materials, narcotics, other dangerous drugs and substances presenting special risks of abuse, fire or explosion are stored in a safe, dedicated and secure areas apart from excipients?	
4.12	• How is it ensured that equipment used for bulk handling and storage is suitable for the excipient, regularly cleaned and maintained? • What additional controls for bulk excipients are used to assure material purity, freedom from contamination and mix-up (e.g., dedicated tankers/storage tanks, certificates of cleaning and identification/restriction of prior content)?	
4.13	• How is packaging of excipients performed and does this include appropriate protection of the excipient quality and authenticity? • In which way are excipient containers sealed to identify any evidence of tampering?	

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IPEC GDP Guide	Question	Comments/Notes
	• Where special shipping conditions are required show how they are defined, provided and controlled.	
4.14	• What evidence is there that spills are to be cleaned up promptly (equipment, procedures)?	
4.15	• How are waste materials stored, identified and disposed of?	
4.16	• How is stock rotation managed in the warehouse (e. g. EEFO, FIFO)?	
4.17	• How is it ensured that excipients that reached their expiry or retest date are withdrawn from saleable stock unless the shelf life has been extended in case of retest dates?	
4.18	• How is stock inventory regularly checked for quantities and expiry/retest dates and what is done in case of discrepancies?	
4.19	• What controls are in place to ensure that the correct excipient is picked, packed and distributed with appropriate remaining shelf life (if applicable) and are these documented including batch numbers?	

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IPEC GDP Guide	Question	Comments/Notes
4.20	• Describe how the sanitation program is documented? • How is cleaning of the warehouse performed and documented? • How do you document findings following formal inspections of the warehouse including for waste, vermin and pest control?	
5 Equipment		
5.1	• How is equipment commissioned, designed, installed and qualified prior to initial use? • Is equipment maintained in a good state of repair? • What material of construction is used to not adversely affect the excipient? • How is preventive maintenance and equipment cleaning scheduled? • What system is in place for cleaning, inspecting and approving equipment for use after maintenance and repairs have been performed and how is this process documented and managed? • How have the personnel been trained to perform and record these activities?	

IPEC GDP Guide	Question	Comments/Notes
5.2	• How do you ensure that defective equipment is not used?	
5.3	• How is it ensured that the status of equipment can readily be identified?	
5.4	• What is the method to identify content (and direction of flow if applicable) of pipework?	
5.5	• How do you avoid mix-up of connections for services, piping and devices? How are services, devices and pipework identified? • Describe provisions of non-interchangeable connections or adaptors for dangerous gases, liquids and other materials if applicable.	
5.6	• Are balances and other measuring devices of suitable range and precision? • How is calibration of critical measuring devices ensured, traceable to applicable standards, documented and recorded? • What actions does the calibration procedure describe to be taken regarding measurements using a balance or device that is subsequently found to have been beyond the due date or out of calibration limits?	

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5.6	• How is the current calibration status and range known to users and is it readily available?	
5.7	• If equipment is not dedicated, what controls are used to prevent cross-contamination (e.g., cleaning)? • How is the record of use of the equipment documented? • What data shows that cleaning procedures are adequate to remove the previous materials? • How are hoses and additional connection parts adequately stored to avoid contamination and damage, when not in use?	
5.8	• What measures are in place to prevent contamination in case of open equipment, if used?	
5.9	• Describe the procedures in place for the operation and maintenance of equipment. • How is it ensured that lubricants or other materials with potential direct contact with the excipient are of appropriate grade e.g., suitable in food applications?	
5.10	• How do you ensure that washing and cleaning equipment does not contaminate the excipient?	

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IPEC GDP Guide	Question	Comments/Notes
6 Documentation		
6.1	• What procedure describes the writing, handling and updating of documents? • Who is authorized to complete, approve, sign and date documents? • What is the procedure for making changes to documents? • How is version control managed? • How are specifications for materials and packaging handled including reviews, revisions and availability?	
6.2	• Do documents contain a title and describe their nature and purpose? • Are documents written in a clear, easy to check format? • How is the revision history of documents displayed?	
6.3	• What kind of CoA is provided to the customer? • How does the CoA allow traceability to the original manufacturer and organization issuing the CoA?	

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IPEC GDP Guide	Question	Comments/Notes
6.3	• How are the results determined for each test reported on the CoA? If skip lot testing is performed, how is it indicated? • If batch (lot) mixing is performed, does the distributor test and issue its own CoA?	
6.4	• How does the distributor verify the manufacturer's CoA and test results support conformance to the excipient specification? • How is it ensured that a CoA is made available for each shipment to the customer?	
6.5	• How is information about original manufacturer and intermediaries handling the excipient being made available to authorities and end-users?	
6.6	• What are the criteria used to determine the need for quality agreements? • How do the quality agreements ensure, that mechanisms are in place to allow transfer of information, e.g., quality or regulatory information and change control?	
6.7	• Are labels applied by the distributor clear and unambiguous?	

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IPEC GDP Guide	Question	Comments/Notes
6.7	• How do you ensure that labels are permanently fixed to containers? • What material of construction makes labels indelible?	
6.8	• Does the excipient label contain adequate information to identify the contents, quantity, batch number, manufacturer (where applicable), retest or expiry date and name and contact details of the supplier? • Is information on storage conditions and handling precautions on the label? • If labels are printed as needed, what system is used to verify and document the accuracy of the label content?	
6.9	• How are relevant storage and handling information as well as safety data sheets made available?	
6.10	• How is it ensured that all records relating to the requirements of Good Distribution Practices are kept and readily available? • Does the record retention policy cover the required record retention period of one year after expiry or re-evaluation date or 5 years from date of manufacture?	

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IPEC GDP Guide	Question	Comments/Notes
7 Repackaging and relabeling		
7.1	• How are operations, such as combining into a homogeneous batch, repackaging and/or relabeling performed? • Which quality management principles do you apply?	
7.2	• How is the prevention of contamination, cross-contamination and mix-ups managed and assured? • What environmental conditions are required to be in place and when repackaging is performed how is contamination prevented during those operations? • How is the risk assessment designed to minimize the risk of contamination and cross contamination? • How are personnel hygiene and any special hygiene requirements ensured? How is training recorded? • What protective clothing are operators to wear in the packaging area? • How are labels (including labels for relabeling) controlled (see detailed questions in 7.12)?	

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IPEC GDP Guide	Question	Comments/Notes
7.2	• How is ensured that there is traceability to the batch number, manufacturing date and expiry date of the original manufacturer? • How is product integrity maintained throughout the repackaging/relabeling process? • How is the original product label controlled? • How is each step for repackaging and relabeling recorded?	
7.3	• How is packaging material received, quarantined, inspected and released or rejected?	
7.4	• How is conformity of each batch confirmed prior to blending into a homogeneous batch? • How is it ensured that blending processes are performed in conformance with IPEC PQG GMP Guidelines? • How is homogeneity of blended batches ensured, demonstrated, and documented?	
7.5	• How is it ensured that only batches from the same manufacturing site are mixed? • How are mixed batches sampled, tested and released? • How are CoAs for mixed batches generated?	

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IPEC GDP Guide	Question	Comments/Notes
7.5	• Which data are provided on CoAs for mixed batches?	
7.6	• How is traceability back to the original manufacturer and manufacturing site documented and communicated to the customer?	
7.7	• How are expiry or retest dates defined for mixed batches?	
7.8	• What analytical data are provided on the CoAs? • Which analytical methods are applied in case of re-testing?	
7.9	• How are quality and suitability of packaging materials established? • How are packaging materials approved?	
7.10.	• In cases where containers are re-used, how are processes defined and risk evaluated? • How are cleaning processes of re-usable containers validated?	
7.11	• How are the required environmental conditions ensured during repackaging?	

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IPEC GDP Guide	Question	Comments/Notes
7.12	• How is it ensured that all information is correct on the labels? • How are crosschecks made that the correct information is contained on the labels? • How is it ensured that the correct quantity of labels are printed and issued? • How and where are labels stored? • What is the process to avoid mislabeling? • How are labelling and label reconciliation processes documented? • What is the procedure and who is responsible to remove and destroy any excess labels that are not required for (re-) packaging? • Where are copies/samples of labels kept for each batch?	
7.13	• How is information about the original manufacturing site provided to the customer?	
7.14	• How is identity and quality of the excipient maintained before and after repackaging? • How is traceability of the excipient documented before and after repackaging?	

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IPEC GDP Guide	Question	Comments/Notes
7.15	• How is it ensured, that each repackaged batch conforms to the specification taking into account those properties that might be affected by the repackaging?	
7.16	• Describe the procedure to ensure that appropriate repackaging documentation is evaluated together with the test results prior to release of the repacked material.	
7.17	• How is it ensured that sampling, analytical testing and batch release procedures comply with GMP?	
7.18	• Which analytical methods o are pharmacopoeia methods? o are alternative methods? o are original manufacturer's methods? • How do you ensure that alternative methods are validated? • Show the validation results, if applicable. • How are the methods identified on the CoA? • How are test results of contract laboratory identified on the CoA?	

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IPEC GDP Guide	Question	Comments/Notes
7.18	• How is skip batch (lot) testing or reduced testing identified on the CoA? • How is it ensured the methods used are current and valid?	
7.19	• How are out-of-specification test results investigated and documented?	
7.20	• How long are retain samples kept? • How is the retention period of retain samples justified? • Which quantity of retain sample is kept? • How are the storage conditions of the retain samples justified?	
7.21	• How is it ensured that stability and shelf life of repackaged material is not adversely affected? • How are stability studies of the excipient within the used packaging material conducted? • How are primary packaging materials and storage conditions taken into account? • How long is the shelf life (retest or expiry period) compared to recommended shelf life provided by the original manufacturer?	

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IPEC GDP Guide	Question	Comments/Notes
7.21	• How are shelf lives justified which are different from the manufacturer's recommendation? • How are special storage conditions indicated on the label?	
8 Complaints		
8.1	• What is your procedure for handling of complaints? • What are the actions to be taken and the criteria on which recall decisions should be based? • Who has responsibility for investigation of complaints? • How and where are the complaint records retained? • How are complaint records periodically reviewed for trends, frequency, and criticality in order to identify preventive actions and how is this documented?	
8.1 and 8.2	• What is the investigation process? • How do you determine root cause, definition of CAPAs, and related documentation? • How is the customer informed of investigatory findings?	

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8.3	• Where complaints are justified, has consideration been given whether the reported defect is limited to a single batch? How is this documented? • How are (potentially) impacted batches identified, labelled and/or segregated and subsequently managed?	
8.4	• Where a complaint is justified, how do you define follow-up actions and evaluation of the complaint?	
8.5	• Where a complaint is justified, how is the excipient manufacturer as well as the customer notified?	
9 Recalls		
9.1	• What is your process for conducting a product recall (retrieval) or market withdrawal? How does it cover the following? o managing the risk involved? o defining responsibilities and functions to be involved? Including approval o communication and documentation? o determining the steps needed to retrieve the excipient?	

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IPEC GDP Guide	Question	Comments/Notes
9.1	○ ensuring that recalls (retrievals) are managed promptly and effectively?	
9.2	• How do you notify the excipient manufacturer about recalls (retrievals)?	
9.3	• How and when was the recall (retrieval) procedure last verified?	
9.4	• How is recalled excipient controlled to prevent its inadvertent release while pending investigation and disposition?	
9.5	• In the event of serious or potentially life-threatening situations: How is it ensured that all customers and competent authorities are promptly notified of the decision to recall the excipient in all countries that have received the excipient?	
9.6	• How are pertinent records made available to the person responsible for the recall activities? • How is it ensured that the records contain sufficient information to facilitate the recall activities?	

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9.7	• How is the effectiveness of the arrangements (procedure and process) for recalls evaluated? • At what frequency are mock recalls conducted?	
10 Returned Goods		
10.1	• How do you ensure identification, quarantine and traceability of returned excipients? • What information do records on returns contain? • How are storage and transportation conditions when not under control of the distributor taken into account when evaluating the quality of returned excipient? ○ Are they evaluated by the Quality Unit prior to disposition? • How are these processes documented?	

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IPEC GDP Guide	Question	Comments/Notes
10.2	• Who is responsible for deciding about the disposition of returned excipients? • What is your procedure and what are the criteria to decide upon the disposition of returned excipients? • How does your process address the following risks? o evidence of tampering o inappropriate storage conditions o remaining shelf-life period o approval of the excipient disposition by an unauthorized and/or unqualified person o loss of information/traceability	
11 Handling of Non-conforming Materials		
11.1	• How do you ensure that non-conforming excipients are not (re-) introduced into the market including those provided to external organizations for destruction? • What do records of non-conforming excipients contain?	
11.2	• What is your investigation procedure for non-conforming excipients?	

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11.2	• How do you determine root cause, consideration of other batches and materials that might be affected, definition of CAPAs, measures to establish the effectiveness of the actions taken and related documentation?	
11.3	• How do you document the disposition of non-conforming excipients including its downgrading?	
11.4	• How do you ensure that non-conforming excipients are not blended with excipients that comply with their specifications?	Note: Mixing is not stated in the GDP guide.
12 Dispatch and Transport		
12.1	• How is it ensured that loading, unloading and transport activities do not adversely affect excipient quality? • What is the process for qualifying and approving carriers? • How are special transport conditions such as temperature, humidity and/or absence to sunlight exposure, or special equipment, if required by the excipient characteristics, communicated, agreed between supplier, carrier and customer, monitored, controlled and recorded in transit? • How are deviations from special conditions managed?	

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IPEC GDP Guide	Question	Comments/Notes
12.2	• How is it ensured that information such as product quality/grade, special transport/storage conditions, as existing, and/or legal requirements are provided to customers for each shipment? • How is it ensured that special storage and/or transportation conditions (if applicable) are referenced on the container label?	
12.3	• How is the ability of the carrier assessed and documented to meet special transport conditions and/or requirements for special transport equipment?	
12.4	• How are the requirements for bulk vehicles and equipment communicated and documented to the carrier? • How are specific conditions for cleaning of transport equipment, handling, sealing, application of prior cargo product restriction or acceptance policy, and/or segregated cargoes been agreed and documented between excipient supplier and carrier? • How is the cleanliness of the vehicle assessed and documented for bulk shipments? • Which records are kept for cleaning activities?	

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IPEC GDP Guide	Question	Comments/Notes
12.5	• If applicable describe the handling process for bulk shipments. • Is dedicated equipment used for bulk shipments? If not, what precautions are taken to prevent contamination and cross-contamination of the excipient? • How is it ensured that the type of transport and auxiliary equipment such as seals, fittings, hoses, pumps and contact materials are compatible with the excipient product? • Describe the control process for changes to transport equipment and supplies handled by the carrier?	
12.6	• How is it ensured that packaging materials and transportation containers are suitable to protect the excipient during transport?	
12.7	• How have cleaning procedures and schedules been demonstrated and validated to adequately remove the prior contents to an acceptable level? • How are cleaning procedures and schedules agreed between supplier and carrier, maintained and records of previous cargoes provided by the carrier? • How is the list of restricted or acceptable prior cargo in the vehicle maintained?	

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IPEC GDP Guide	Question	Comments/Notes
12.8	• How are shipments secured based on risk to prevent unauthorized access to the excipient during transport? • Describe which security aspects, such as appropriate tamper-evident seals are applied for transport equipment and packaging?	
12.9	• For shipment, how is it ensured that applicable requirements including local requirements for transportation are fulfilled with regards to safety aspects (e.g., explosion hazard, transport of dangerous goods, and contamination of the environment and or product)?	
13 Contract activities		
13.1	• Which contracts or technical agreements are in place for all activities delegated to contractors? • How is contractor training organized and provided, where appropriate?	
13.2	• How has conformance to applicable GDP requirements by contract service providers been assured? • How are contractors approved, including facilities, equipment and quality system?	

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IPEC GDP Guide	Question	Comments/Notes
13.3	• How is it ensured that operations at contract providers do not present a risk of contamination to the excipient? • How is it ensured that traceability is maintained in contracted operations?	
13.4	• What evidence indicates that responsibilities for conformance to GDP, including quality measures are defined between contract giver and contract provider in a written agreement (contract, technical, service/quality agreement)?	
13.5	• How is it ensured that the contract provider receives approval from the contract giver for any activities subcontracted especially those involving sampling, analysis, repackaging, and relabelling?	

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