The IPEC Europe Good Distribution Practices Audit Guideline

FOR PHARMACEUTICAL EXCIPIENTS

2011

IPEC Europe Good Distribution Practices Audit Guideline for Pharmaceutical Excipients

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

This Audit Guideline should be used in conjunction with the IPEC Good Distribution Practices Guide. The explanatory notes in this guideline are provided to help the auditor obtain the maximum benefit in its application.

This document is a revised version of the IPEC Good Distribution Practice Audit Guideline for Pharmaceutical Excipients 2008 [1].

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I. Introductory Note

The International Pharmaceutical Excipients Council (IPEC) first published a *GMP Audit Guideline for Distributors of Bulk Pharmaceutical Excipients* in 2000. This document was designed as a questionnaire to assist 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, (re)processors, (re)packagers, transport and warehousing companies, forwarding agents, brokers, traders, and suppliers other than the original manufacturer.

It is recognised by IPEC Europe that other documents are available and widely applied throughout the distribution industry. With this in mind and in order to maintain consistency, IPEC Europe has utilised many aspects of the Safety and Quality Assessment Scheme - SQAS Distributor Questionnaire (ESAD system, primarily Section F and Sub Section G) [2]. As this document was revised during 2011 [3], IPEC Europe also adapted this audit guideline accordingly. Wherever possible, original ESAD 2011 questions have been used. However, there are occasions when the IPEC - Europe GDP Audit Guideline has additional questions not referenced in the ESAD 2011 questionnaire.
Some editorial changes have been made, some redundant questions deleted and additional questions inserted, which are highlighted in grey. Furthermore, this document is now a separate document of IPEC Europe. IPEC Americas published its own GDP audit guide reflecting the needs of the industry in North America [8].

For definition of technical terms, please refer to the Glossary in the *IPEC Good Distribution Practices Guide* [4].

More information on the SQAS ESAD Distributor system may be found at the following address
www.sqas.org

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

II. Scope

This Questionnaire is linked to the *IPEC Good Distribution Practices Guide [4] (*based on the *WHO Good Trade and Distribution Practices for Pharmaceutical Starting Materials [6])*, 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.

This document is meant 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 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 pharmaceutical grade when it is in compliance with pharmacopoeial specification and/or appropriate regulatory requirements (if existing for the relevant excipient) and is manufactured, repackaged, and handled in accordance with excipient GMPs (e.g. IPEC PQG GMP [5], WHO Excipient GMP [7]). Upgrading technical or industrial grade material to pharmaceutical grade quality based only on analytical results found in conformance with the requirements of a pharmacopoeial monograph is an unacceptable practice.

IV. Acknowledgements

The GDP Committee of the International Pharmaceutical Excipients Council – Europe (IPEC - Europe) prepared this document.

IPEC Europe, the International Pharmaceutical Excipients Council Europe, is an association that serves the interests of producers, distributors and users of pharmaceutical excipients. Together with its sister associations, IPEC Americas and IPEC Japan (JPEC), the Council is a member of IPEC Federation whose global membership extends to more than 200 companies.

IPEC Europe represents the views of its members to appropriate regulatory bodies (European Commission, EMA, European Pharmacopoeia) and is recognised by Government agencies around the world as the voice of European producers and users of pharmaceutical excipients. Combined advocacy is essential to ensure introduction to the market of safe new excipients which meet globally accepted standards.

Activities within IPEC Europe are organised through Committees or Working Parties, the activities of which are communicated during the Annual General Meeting and in IPEC Europe newsletter, which are regularly posted on the website (www.ipec-europe.org).

IPEC greatly appreciates the many hours of hard work by the following individuals devoted to developing this Audit Questionnaire and the generous support provided by their employers:

IPEC-EUROPE

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Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
1. Quality Management				
Q 1.1	Is there a quality management system implemented (Covered by an ISO 9001:2000 certification)?	1.1 1.2 1.3	G1.1	
Q 1.2	Are the GTDP*/HACCP** principles part of the quality system? * Good Trade and Distribution Practices ** Hazard Analysis and Critical Control Point	1.2	F1.1.1	
Q 1.3	Is there a quality manual and written procedures describing all GTDP related processes?	1.2		
Q 1.4	Is there a third party certification of the quality system (Covered by ISO 9001:2000 certification or third party HACCP verification)?	1.8	G1.2	
Q 1.5	Is there a library of relevant regulations on excipients for pharmaceuticals?	1.1	G1.3	
Q 1.6	Is a person designated or a source defined to keep the company informed about legislative developments in the area of starting materials for pharmaceuticals?	1.1	G1.4	
Q 1.7	Are responsibilities for assessing the impact of such legislative developments and for proposing actions to comply with these clearly defined?	1.1	G1.5	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 1.8	Is a regular review made of the system for compliance with legal requirements?	1.1	G1.6	
Q 1.9	Does the company have a written policy including management's active commitment to Quality?	1.1	G1.7	
Q 1.10	Is the policy signed by top management?	1.1	G1.8	
Q 1.11	Does the company operate a documented system for quarantining suspect product?	11.1	G1.9	
Q 1.12	Is there a procedure for internal audits of the management system including an audit plan?	1.9	G1.10	
Q 1.13	Do those carrying out auditing have training in auditing and evaluation techniques?	2.2	G1.11	
Q 1.14	Is a formal management review of the Quality Management System held at least once a year?	1.9	G1.12	
	Do management reviews consider:			
Q 1.15	- findings of internal audits, recommendations made and corrective actions taken?	1.9	G1.13a	
Q 1.16	- the overall effectiveness of the system in achieving quality objectives?	1.2	G1.13b	
Q 1.17	- opportunities for updating and/or improving the system?	1.9	G1.13c	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 1.18	Do management reviews consider trends in customer complaints?	1.2	G1.14	
Q 1.19	Do management reviews consider trends in supplier related non-conformance claims?	1.2	G1.15	
Q 1.20	Does the distributor demonstrate his responsibilities to assure compliance with Product Stewardship principles along the entire supply chain?	1.4	F7.1	
Q 1.21	Is there an adequate number personnel available either in-house or contracted out to carry out all the operations in compliance with the IPEC GDP Guide?	1.5	F1.2.5	
Q 1.22	Are there authorized release procedures in place?	1.7		
Q 1.23	Is there a copy of the manufacturers' documents (such as COA or COC) supplied with each delivery?	1.7		
2. Organisation and Personnel				
Q 2.1	Has the company a sufficient number of qualified employees for these operations?	2.1	F1.2.1	
Q 2.2	Have all (including administrative) personnel, involved in handling and distributing Food, Cosmetic or/and Pharma grade products been made aware of the risks for human health?	2.2	F1.2.2	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 2.3	Have all (including administrative) personnel, involved in handling and distributing Food, Cosmetic or/and Pharma grade products been formally qualified according to written criteria?	2.4	F1.2.3	
Q 2.4	Is there a person with the specific responsibility and the appropriate authority to deal with excipient related quality issues within the company?	2.1	F1.2.4	
Q 2.5	Are employees qualified according to GDP principles?	2.3	F1.2.6	
Q 2.6	Is there a specific qualification required for employees responsible for key activities in Health, Safety, Environment (HSE) and Quality?	2.5	F1.2.7	
Q 2.7	Are the HSE responsible persons providing regular training to employees dealing with hazardous materials?	2.5		
Q 2.8	Have job descriptions been made and regularly updated?	2.2	G2.1	
Q 2.9	Has an evaluation been made of all activities to identify training needs?	2.1 2.2	G2.2	
Q 2.10	Are personnel qualified for GTDP relevant operations with specific (technical) background/education?	2.2	G2.3	
Q 2.11	Is initial and ongoing training provided?	2.4		

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 2.12	Are GTDP principles part of regular training?	2.3	G2.4	
Q 2.13	Are employee training and qualification records maintained?	2.4	G2.5	
Q 2.14	Are internal and external training courses documented? (*Documentation of training should include records of training effectiveness.)*	2.4	G2.6	
Q 2.15	Are contracted service providers included in the training program?	2.2		
Q 2.16	Are contractors provided with information relevant to the job to be done?	2.2 2.3 13	G13.7a	
Q 2.17	Are contractors provided with appropriate training if necessary?	2.2 2.3 13	G13.7b	
Q 2.18	Are contractors provided with appropriate personal protective equipment?	2.5	G13.7c	
Q 2.19	Are there procedures in place ensuring good hygiene of the personnel where exposure to material in open containers may occur (e.g. monitoring of health conditions, wearing of protective clothes, respecting food/drink policy, etc.)?	2.6	G2.7	
3. Premises				
Q 3.1	Are areas where pharmaceutical starting materials are handled designed and operated	3.1	G3.1	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
	in a way to ensure cleanliness, appropriate hygiene and a minimisation of cross-contamination risks?			
Q 3.2	Are premises well constructed and in visibly good condition?	3.1	G3.2	
Q 3.3	Are appropriate laboratory facilities available?	3.1	F1.5.4	
Q 3.4	Has the site implemented security measures to control access of unauthorized persons?	3.2	G3.3 S1.1.1	
Q 3.5	Are the premises designed, operated, and maintained to avoid infestation by rodents, birds, insects, and other vermin?	3.3		
Q 3.6	Is there an effective pest control program in place?	3.3	G3.4	
Q 3.7	Is the warehouse well ventilated?	3.4	G4.7	
Q 3.8	If a heating/air-conditioning system is installed is it compatible with the stored products?	3.4	G4.8	
Q 3.9	Is there adequate lighting in the warehouse?	3.4	G4.10	
Q 3.10	Is the design and operation of the air handling system appropriate to avoid contamination and degradation of products?	3.4		
Q 3.11	Are the design, operation and maintenance of gas utility systems (e.g. nitrogen or compressed air) appropriate to avoid contamination of products?	3.4		

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 3.12	If sampling is performed, are sampling areas arranged and procedures in place to prevent contamination and cross-contamination?	3.5	G3.5	
Q 3.13	Is there a separate sampling area in a controlled environment?	3.5		
Q 3.14	Are cleaning procedures in place for sampling areas?	3.5		
Q 3.15	Are all samples taken and retained according to written procedures?	3.5	F1.6.1	
Q 3.16	Are sampling procedures sufficient to ensure representative samples for quality control?	3.5	F1.6.2	
Q 3.17	Are utensils and sampling devices cleaned and stored in a manner to prevent contamination?	3.5	F1.6.3	
Q 3.18	Do sampling processes ensure sufficient protection of product quality?	3.5	F1.6.4	
Q 3.19	Is it ensured that sampling installation is able to provide a representative sample?	3.5	F2.1.9	
4. Warehousing and Storage				
Q 4.1	Are all product receipts performed according to written procedures?	4.1	F1.4.1	
Q 4.2	Is product reception recorded/documented according to a written procedure?	4.1	F1.4.3	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 4.3	Are there appropriate intake control procedures in place with conformity inspection, including the seals?	4.1	F1.4.2	
Q 4.4	Are there appropriate written procedures for cleaning and maintenance of tanks/silos?	4.1	F2.1.8	
Q 4.5	Are there written procedures and documentation for loading of products?	4.1 12	F3.1.1	
Q 4.6	Are there written procedures and documentation for unloading of products?	4.1	F3.1.2	
Q 4.7	Are there written procedures to prevent contamination in the case that a container has to be opened?	4.1	F6.1.5	
Q 4.8	In the case that a container has to be opened, is there a quality re-certification and release procedure?	4.1	F6.1.6	
Q 4.9	Is there a procedure for re-sealing containers after opening?	4.1	F6.1.7	
Q 4.10	Are there written procedures for storage and warehousing of products?	4.1		
Q 4.11	Does the procedure for storage of packaged products consider the risk of incompatibilities between products?	4.1	G4.11	
Q 4.12	Is the product received in bulk checked and/or tested for quality and identification at the receiving site?	4.1	F1.5.1.	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 4.13	Is each product lot released and re-certified each time it is mixed with another lot?	4.1	F1.5.3	
Q 4.14	Are materials stored in compliance with safety requirements?	4.2		
Q 4.15	Are containers stored in dedicated areas with adequate separation from other products in order to prevent errors?	4.2	F6.1.1	
Q 4.16	Are the racking systems in good condition and protected from vehicle collision?	4.2	G4.9	
Q 4.17	Are containers of sensitive products stored under appropriate storage conditions that are adequately monitored?	4.7	F6.1.4	
Q 4.18	Are containers stored protected from adverse weather conditions?	4.3	F6.1.3	
Q 4.19	Are receipt and dispatch bays equipped with means to protect materials from weather?	4.3	G4.1	
Q 4.20	Are rejected and recalled materials stored in a defined segregated area?	4.4	G4.2	
Q 4.21	Are materials in segregated areas controlled with appropriate systems (e.g. physical or computerized)?	4.5		
Q 4.22	Are segregated materials appropriately labelled?	4.5	G4.3	
Q 4.23	Are specific storage conditions maintained, monitored and controlled where necessary?	4.6 4.7	G4.4	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 4.24	Are storage requirements for dangerous goods met on site and during transportation?	4.8		
Q 4.25	Is there a system in place to ensure that equipment for bulk storage is designed according to product requirements?	4.9	F2.1.1	
Q 4.26	Is the storage tank equipped with a monitored nitrogen blanketing system or a drying equipment, if necessary, to protect the product against oxidation and / or moisture?	4.9	F2.1.5	
Q 4.27	Is the quality of the blanketing gas, if used, compatible with the product?	4.9	F2.1.6	
Q 4.28	Is it ensured that the storage temperature is always kept within a defined range and controlled, if necessary for product quality or stability?	4.9	F2.1.7	
Q 4.29	Is adequate spill clean-up equipment available and are procedures in place for containing/collecting any spillage?	4.10	G4.5	
Q 4.30	Can spills be adequately contained?	4.10	G4.6	
Q 4.31	Are waste materials awaiting disposal stored safely and properly?	4.11		
Q 4.32	Does the company apply FIFO (First In First Out) or EEFO (Earliest Expiry First Out) principles in the warehouse?	4.12		
Q 4.33	Are containers stored subject to a shelf life control system?	4.12	F6.1.2	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 4.34	Is there a separate storage area provided for pharmaceutical starting materials? *(Acceptable practice is to store pharmaceutical starting materials together with other raw materials used for cosmetic, food and feed applications.)*	4.13	G4.12	
Q 4.35	Is there a written cleaning program in place?	4.13		
Q 4.36	Are there records for cleaning activities available?	4.13		
5. Equipment				
Q 5.1	Is there a documented approach for the design and modification of equipment for the handling of pharmaceutical starting materials including location, operation and maintenance of equipment?	5.1 5.2		
Q 5.2	Is each piece of equipment in contact with the product made of suitable materials (e.g. not reactive, additive, or absorptive and will not adversely affect the product)?	5.1 5.2	F1.7.3	
Q 5.3	Is the entire equipment in contact with products drained and capped after the operation, according to written procedures?	5.1	F3.2.5	
Q 5.4	Is each piece of equipment (specifically auxiliary equipment) designed and used in a manner that minimizes the potential for contamination of the product with lubricants, coolants, metal fragments, or other	5.1 5.2 5.6	F1.7.5	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
	extraneous materials e.g. from pressurised air?			
Q 5.5	Is defective equipment taken out of service, (e.g. either removed, disposed of or status labelled)?	5.1		
Q 5.6	Is the entire equipment in contact with products located in clean areas?	5.1 5.2	F3.2.1	
Q 5.7	Are there procedures in place to ensure compatibility of equipment with the products?	5.2	F5.1.3	
Q 5.8	Is pipe work (including devices) in contact with product labelled with direction of flow, where applicable (including name of material)?	5.3 5.4	G5.1 F1.7.2	
Q 5.9	Is the entire equipment in contact with products clearly labelled?	5.4	F3.2.4 F5.1.2	
Q 5.10	Are there a sufficient number of balances and measuring devices available which are necessary for the operation carried out?	5.5	G5.2	
Q 5.11	Is there evidence (records) of regular (quality-critical) equipment calibration?	5.5	G5.3	
Q 5.12	Is there a process in place to consider if deviations of calibration of quality critical equipment have had an impact on the quality of product since the last successful calibration?	5.5		
Q 5.13	Do operation procedures detail how each	5.6	G5.4	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
	piece of equipment critical to the processes should be used?			
Q 5.14	Is the maintenance policy covered by written procedures?	5.6	G5.5	
Q 5.15	Is there a Preventative Maintenance Plan?	5.6	G5.6	
Q 5.16	Are maintenance records available?	5.6	G5.7	
Q 5.17	Is there a process in place for monitoring and approving the quality of maintenance?	5.6	G5.8	
Q 5.18	Is each piece of equipment in contact with the product cleaned and maintained according to written procedures?	5.6 5.8	F1.7.4	
Q 5.19	If product exposure to, or contamination with, lubricants or coolants is possible, are these materials suitable for use in food applications?	5.6		
Q 5.20	Is appropriate cleaning equipment selected to avoid contamination of products?	5.7	G5.9	
Q 5.21	Is each piece of equipment in contact with the product dedicated to the product or effectively cleaned according to a written procedure?	5.8	F1.7.1	
Q 5.22	Are all pieces of equipment coming in contact with the product, compatible with the product and in compliance with legal requirements?	5.8	F2.1.2	
Q 5.23	(If equipment is not dedicated) is the	5.8	F2.1.3	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
	equipment only used for Food, Cosmetic, and/or Pharma grade products?			
Q 5.24	Is there an effective cleaning procedure in place, whenever product change is necessary?	5.8	F2.1.4	
Q 5.25	Is controlled testing equipment available?	5.5	F1.5.4	
Q 5.26	Is all the equipment in contact with products dedicated or are validated cleaning procedures applied in case of product changes?	5.8	F3.2.2 F3.2.3 F5.1.1	
Q 5.27	Is cleaning efficiency of non-dedicated equipment verified?	5.8		
6. Documentation				
Q 6.1	Is there a document control system in place ensuring proper design, approval, review, and distribution of necessary documentation? (Covered in the case of ISO 9001:2000 certification)	1.2 6.1 6.2 6.10	G6.1	
Q 6.2	Is there evidence that documents are laid out in an orderly manner and with clear and unambiguous content?	6.2	G6.2	
Q 6.3	Is every product lot accompanied by a certificate of analysis (COA) or certificate of conformity (COC)?	6.3	F1.4.4	
Q 6.4	Do COAs clearly indicate which tests are performed on every lot and which results are	6.3	F1.4.5	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
	obtained by skip lot testing?			
Q 6.5	Does this certificate provide information about the origin of the product?	6.3	F1.4.6	
Q 6.6	Are COAs from original manufacturers checked against agreed specifications?	1.7 6.4	G6.3	
Q 6.7	Is regulatory and quality information from the manufacturer transferred to customers?	6.6	G6.4	
Q 6.8	Is the company able to provide full traceability on product origin?	6.5 7.11	F1.3.1	
Q 6.9	Is the company able to provide full traceability in its own operations?	6.5 7.11	F1.3.2	
Q 6.10	Is the company able to provide full traceability on product destinations?	6.5 7.11	F1.3.3	
Q 6.11	Are distribution records kept for each shipment?	6.5	F4.1.9	
Q 6.12	Are loading/shipment data documented so that details can easily be traced back?	6.5	F6.2.2	
Q 6.13	When new updated information becomes available, is it dispatched in a timely manner?	6.6	G6.9	
Q 6.14	Is it ensured that no upgrading of industrial or technical grade products with identical names to food, cosmetic and/or pharma grade products can occur?	See III in the Guideline	F1.4.9	
Q 6.15	Are labels applied to containers clear, unambiguous, and permanently fixed?	6.7 1.7	G6.5	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
	Is it ensured that the following information is provided with each shipment, either on the label or on the COA:			
Q 6.16	- the name of product, including grade and amount?	6.8	G6.6a	
Q 6.17	- the batch number assigned by the original manufacturer or the batch number assigned by the re-packer, if the material has been repacked and re-labelled?	6.8	G6.6b	
Q 6.18	- the retest date or expiry date and storage conditions (where applicable)?	6.8	G6.6c	
Q 6.19	- identification of the original manufacturing site and contact details of the supplier?	6.8	G6.6d	
Q 6.20	Is the expiry date, re-test date or the shelf-life written on each container (drums, IBCs, bags, etc)?	6.8	F5.2.6	
	Is a Safety Data Sheet (SDS) provided in the local language:			
Q 6.21	- with each sample of a commercialised product?	6.9	G6.7a	
Q 6.22	- with a first order in a timely manner?	6.9	G6.7b	
Q 6.23	Are details recorded of the SDS dispatch showing addressee and date?	6.9	G6.8	
Q 6.24	Are records and documents for every delivered batch retained for a defined period	6.10	F1.4.7	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
	of time?			
Q 6.25	Is it ensured that COAs of the original manufacturer are only used for originally sealed and properly stored products?	6.5	F1.4.8	
7. Repackaging and re-labelling				
Q 7.1	Are there written procedures in place for each processing operation?	7.1	F5.4.1	
Q 7.2	Are batches of processed products sufficiently tested for quality and released?	7.1	F5.4.2	
Q 7.3	If hazardous (e.g. toxic, corrosive) products are present on the site, is there a written procedure for segregation or prevention of cross contamination? *(The scope of this question includes highly active material, e.g. cytotoxics, antibiotics.)*	7.2	F5.1.9	
Q 7.4	Is the environment of the re-packaging operation separated from other operations (or at least devoted to compatible products)?	7.2	F5.1.6	
Q 7.5	Are there written procedures in place for all packaging and labelling operations?	7.2	F5.2.3	
Q 7.6	Are line clearance checks and label controls carried out to avoid mislabelling?	7.2	G7.1	
Q 7.7	Are there appropriate hygiene procedures in place for repackaging operations and repackaging personnel?	7.2	G7.2	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 7.8	Are written procedures in place to ensure batch homogeneity in case of mixing different batches in tanks/silos?	7.2	F2.2.1	
Q 7.9	Is a sample for retention taken before unloading?	7.2	F3.2.14	
Q 7.10	Can liquid product be filtered prior to the re-packaging operation when required?	7.2	F5.1.4	
Q 7.11	Is there always a representative sample taken after batch mixing?	7.2	F2.2.2	
Q 7.12	Is there always a new batch number assigned in case of batch mixing?	7.2	F2.2.3	
Q 7.13	Is it ensured that analytical data on COAs for mixed batches are always based on new analyses?	7.2	F2.2.4	
Q 7.14	Is each packed lot fully traceable (including the packaging material)?	7.2	F5.2.1	
Q 7.15	Are there packaging and labelling records available for each packaging and/or labelling operation?	7.2	F5.2.4	
Q 7.16	Are samples of each batch of labels kept with the packaging/labelling records?	7.2	G7.3	
Q 7.17	Is mixing of lots from different manufacturers avoided?	6.3 7.2	G7.5	
Q 7.18	Is each lot homogeneous in quality?	7.3	F5.2.2	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 7.19	Is there a system in place to prevent mixing of lots that do not conform to the specification with conforming lots?	7.3	G7.6	
Q 7.20	Are key point analyses performed for positive identification and detection of evident contamination before unloading?	7.3	F3.2.13	
Q 7.21	Is the product checked and/or tested for quality and identification each time it is transferred from one container to another?	7.3	F1.5.2	
Q 7.22	Are there key point controls performed prior to each packaging process?	7.3	F5.2.7	
Q 7.23	Is it clearly indicated on COAs issued by the distributor on the basis of own analyses, which items are performed on the specific lot and which are created via skip lot testing?	7.4	F2.2.5	
Q 7.24	Is it clearly indicated on COAs issued by the distributor on the basis of own analyses, who performed the analyses and who released the product?	7.4	F2.2.6	
Q 7.25	Is the customer informed when mixed lots are supplied?	7.4	G7.4	
Q 7.26	Are the methods used for the analysis clearly indicated on the COAs issued by the distributor?	7.5		
Q 7.27	Prior to filling, is quality and cleanliness of containers controlled?	7.6	F5.3.1	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 7.28	Is there a written report for each cleanliness inspection?	7.6	F5.3.2	
Q 7.29	Is there a system to guarantee compatibility between product and packaging material?	7.6	F5.3.3	
Q 7.30	Is packaging material compatible with the product shelf-life?	7.6	F5.3.4	
Q 7.31	Are container suppliers selected according to quality criteria?	7.6	F5.3.5	
Q 7.32	Are container suppliers qualified and periodically assessed?	7.6	F5.3.6	
Q 7.33	Are container suppliers informed about the sensitive usage of the product?	7.6	F5.3.7	
Q 7.34	Is there an agreement about the primary packaging materials used with the original manufacturers?	7.6	G7.7	
Q 7.35	Are there written procedures on product shelf life control?	7.6	F1.3.4	
Q 7.36	Are stability studies carried out in case products are repackaged into container different from the containers used by the original manufacturer when this may be critical to product stability?	7.6 7.15	G7.13	
Q 7.37	Are the use of reconditioned containers and the re-use of primary packaging materials prohibited?	7.7	F5.3.8	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 7.38	In the event of reuse of primary packaging material, is a validated cleaning procedure followed and previous labelling removed?	7.7	G7.8	
Q 7.39	Is the environment of the re-packaging operation clean and dust free?	7.8	F5.1.7	
Q 7.40	Is the environment of the packaging operation pressurised with filtered air if necessary for the products?	7.8	F5.1.8	
Q 7.41	Is the re-labelling process consistent with legal requirements and industry standards?	7.9	Di4.7.1	
Q 7.42	Is there a review prior to use, of label contents against information from product suppliers?	7.9	Di4.7.2 G7.7	
Q 7.43	Is the name of the original manufacturer mentioned on product labels?	7.10		
Q 7.44	Are written testing procedures in place for all tests carried out?	7.12	F1.5.5	
Q 7.45	Are all test data recorded and archived in a traceable way?	7.12	F1.5.6	
Q 7.46	Are repackaged batches released by the quality unit or function, independent from operations?	7.12	G7.10	
Q 7.47	Are repackaging and quality records reviewed prior to batch release?	7.12	G7.11	
Q 7.48	Are only official pharmacopoeia methods or	7.13	G7.12	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
	validated analytical test methods used?			
Q 7.49	Is each packed lot linked to a retained sample?	7.14	F5.2.5	
Q 7.50	Are retained samples of sufficient size kept for each lot or shipment of repackaged or bulk products for a defined period?	7.14	F1.6.5	
Q 7.51	Are retained samples stored for at least one year after expiry date?	7.14		
8. Complaints				
Q 8.1	Does the company operate a complaint procedure that describes actions to be taken?	8.1		
Q 8.2	Does the complaint procedure contain recall criteria?	8.1	G8.1	
Q 8.3	Are complaints recorded and investigated to identify the origin and reason?	8.2 8.4	G8.2	
Q 8.4	Are other batches considered during an investigation of a complaint?	8.3	G8.3	
Q 8.5	Are appropriate follow-up actions including a possible recall taken?	8.4	G8.4	
Q 8.6	Is there a procedure ensuring the original manufacturer and customers are informed in case of serious quality problems including recalls?	8.5 9.2	G8.5	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
9. Recalls				
Q 9.1	Is there a written procedure for product recall in case of a quality concern?	9.1	F1.3.6	
Q 9.2	Is the recall procedure regularly reviewed and updated?	9.3	G9.1	
Q 9.3	Is there a procedure ensuring all customers and authorities are informed in case of serious or potentially life-threatening situations?	9.5	G9.2	
Q 9.4	Do records contain sufficient information to allow a recall?	9.6		
Q 9.5	Are records readily available to the designated person responsible for recalls?	9.6		
Q 9.6	Is the effectiveness of the recall system evaluated?	9.7	G9.3	
10. Returned Goods				
Q 10.1	Are returned products stored separately and appropriately handled according to written procedures?	10.1 4.4 9.4	F6.3.1	
Q 10.2	Is there a system in place to ensure that returned goods are placed in quarantine?	10.1	G10.1	
Q 10.3	Is there a procedure defining the process of deciding about the fate of returned goods?	10.1	G10.2	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
11. Handling of non-conforming materials				
Q 11.1	Are there written procedures on how to handle non-conforming, returned and rejected lots?	11.0	F1.3.5	
Q 11.2	Is there a procedure ensuring that non-conforming materials are prevented from reintroduction into market unless downgraded or reprocessed?	11.1	G11.1	
Q 11.3	Are activities with non-conforming products documented (including downgrading and disposition)?	11.1 11.3	G11.3	
Q 11.4	Are product non-conformances investigated including consideration of other batches?	11.2	G11.2	
Q 11.5	Is feedback from customers entered into the non-conformance system?	11.2	G11.4	
Q 11.6	Is there a procedure in place to prevent blending of non-conforming materials with compliant materials?	11.4	G11.5	
12. Dispatch and Transport				
Q 12.1	Are there procedures in place to ensure controlled conditions during transportation of products where necessary?	12.1	G12.1	
Q 12.2	For container loading/shipment is there a check list for final inspection?	12.1	F6.2.1	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 12.3	Are special transport conditions stated on the label where necessary?	12.2	G12.2	
Q 12.4	Is there an evaluation of transporters in accordance to SQAS or similar schemes?	12.3	F4.1.1	
Q 12.5	Is a key point analysis performed for positive identification and detection of evidence of contamination after loading?	12.3	F3.2.10	
Q 12.6	Are there formal agreements in place with transport contractors, specifying sealing requirements?	12.3 12.8	F4.1.7	
Q 12.7	Is the integrity of seals checked before unloading?	12.4	F3.2.12	
Q 12.8	Is dedicated transport equipment exclusively used?	12.4 12.5	F4.1.3	
Q 12.9	If non-dedicated equipment is used, are there any specific cleaning procedures with a cleaning certificate imposed?	12.4	F4.1.4	
Q 12.10	Are cleaning procedures validated?	12.4 12.7	F4.1.5	
Q 12.11	If non-dedicated equipment is used, is there a list imposed of prohibited or allowed last cargoes?	12.4 12.7	F4.1.6	
Q 12.12	Is there an inspection made of the transport equipment cleanliness before loading?	12.4	F3.2.7	
Q 12.13	Is inspection cleanliness documentation	12.4	F3.2.8	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
	available?			
Q 12.14	Are loading and unloading operations designed to avoid contamination of products?	12.4	F3.2.6	
Q 12.15	Is there a formal agreement with transport companies, specifying suitable materials in contact with the products?	12.5	F4.1.8	
Q 12.16	Is a retained sample from the filled transport equipment taken after loading?	12.5	F3.2.9	
Q 12.17	Are packaging materials used which prevent damage to the materials?	12.6	G12.3	
Q 12.18	Is it ensured that bulk transport equipment and containers received and delivered are properly sealed?	12.8	F1.4.10	
Q 12.19	Are all valves and openings sealed after loading?	12.8	F3.2.11	
Q 12.20	Are transport regulations applied?	12.9		
13. Contract Activities				
Q 13.1	Is there a written procedure for selection and use of contractors for handling of pharmaceutical starting materials?	13.1	G13.1	
Q 13.2	Does this procedure include safety and quality criteria for the selection of contractors?	13.2	G13.2	

Question Number	Question	Refer to IPEC GDP Guide section	Refer to SQAS Distributor ESAD 2011 section	Notes
Q 13.3	If a sub distributor is supplied, are they signatories to a Responsible Care or Responsible Distribution program?	13.2	F7.2	
Q 13.4	Does this procedure include performance evaluation of these contractors?	13.2	G13.3	
Q 13.5	Are contract acceptors evaluated to comply with GTDP principles prior to entering into the contract?	13.2 13.3	G13.4 F7.4	
Q 13.6	Are contract acceptors periodically re-evaluated according to GTDP principles?	13.3	G13.5 F7.4	
Q 13.7	Are contracts specifying the distribution of GTDP related task between contract giver and contract acceptor?	13.1 13.4	G13.6	
Q 13.8	Is sub-contracting prohibited unless specific controls are performed?	13.5	F4.1.2	

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