IPEC FEDERATION

The International Pharmaceutical Excipients Council

Excipient Information Package

User Guide and Template

Version 4
2020

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.

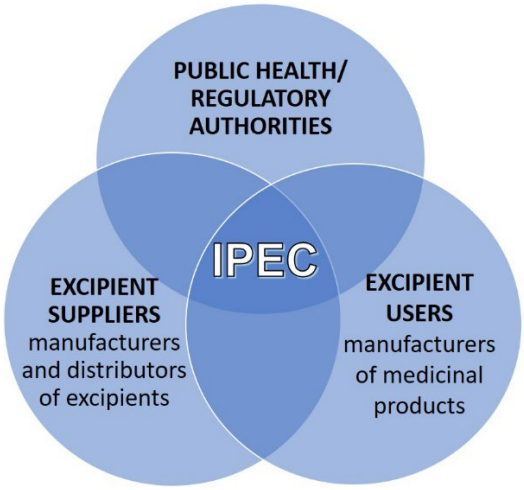
This guide was created to help companies understand current expectations on this topic and is not intended for use by third party certification bodies to conduct audits or to certify compliance with the guide.

FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient manufacturers, distributors, and end-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. Medicinal (drug) product manufacturers, defined as excipient users in this document, and
3. Public health and regulatory authorities.



This section of the guide is intended to be voluntary, to indicate best practice, and to be globally applicable. However, it should be recognized that the laws and regulations applying to excipients will vary from region to region and country to country. In addition, the rules and regulations are

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

continually evolving. It is the responsibility of the reader to review the most current version of any applicable regulatory requirement. Versions referenced in the guide were based on versions available at the time the guide was published.

In this guide, pharmaceutical excipient(s) will be referred as excipient(s). This guide may be applied to veterinary medicines, as appropriate and include reference to specific veterinary guidances and regulations.

Throughout the guide, justification implies that a decision is made based on a scientific, quality and/or regulatory considerations.

This guide offers best practice and guidance in the establishment of an excipient sustainability information package. It is not mandatory or binding and each company can make decisions on their focus areas and specific topics to be included in this section.

> *Note: Refer to the "International Pharmaceutical Excipients Council Glossary: General Glossary of Terms and Acronyms [1]" for definitions. The first use of a term found in the glossary will be in **BOLD**.*

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Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

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Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

ACKNOWLEDGEMENTS

This Guide was developed by representatives of the associations which constitute the IPEC Federation (IPEC). The IPEC Federation greatly appreciates the many hours devoted by the core team of individuals and other contributors listed below, to make this Guide available to IPEC members and the broader excipient community. Equally, IPEC extends its thanks to the employers of those same contributors who provided the necessary time and resources, without which, this Guide would not be possible.

List of Contributors from IPEC-Americas

Jane Bono, Ashland LLC

Jessica Cansler, BASF Corporation

Yani Gao, Ashland LLC

Ann Gulau, DuPont

Bretta Lichtenhan, MilliporeSigma

Mike Polito, MilliporeSigma

Meera Raghuram, Lubrizol Advanced Materials, Inc.

Alexa Smith, Colorcon

Priscilla Zawislak, DuPont

List of Contributors from IPEC Europe

Christian Becker, BASF Corporation

Klaus Buchweitz, Novartis

Endre Hogyes, Sanofi

Beverley Stout, GSK

Rebecca Teversham, Colorcon

Sophia Zhang, Kerry

List of Contributors from IPEC India

Vishakha Metkar, Colorcon

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

1 INTRODUCTION

1.1 Background

Users of excipients need to obtain a significant amount of information about the **excipient** manufacturer, the distributor (where applicable) and the excipient itself as part of their **supplier** and excipient qualification procedures. Many users send questionnaires to obtain this information using their own formats. Often these questionnaires address similar quality and regulatory concerns.

Excipient suppliers want to address customer requests quickly and effectively. However, many suppliers receive such a high volume of questionnaires that resource constraints prevent quick turnaround if they must individually complete each user-specific form. It is difficult in some cases, due to the phrasing of specific questions or the use of only yes/no checkboxes, for excipient manufacturers to interpret the user's intent or to provide adequate description of the topic. Since not all user questionnaires request the same information, when the excipient manufacturer makes a change, it is not feasible to determine which completed questionnaires are affected by the change. Significant time and resources are spent, both by the user and supplier, to send, complete, return, review, update (as necessary) and track these non-standardized questionnaires.

In the time since its first publication in 2009, the **Excipient Information Package** (EIP) described in this guide has become the industry norm because it addresses topics relevant specifically to excipients, ensures that the information is documented in a way that provides more detail than a yes/no format and is written by authors with expertise in these topics. Many excipient users now ask their suppliers for their EIP during the qualification process rather than using their own forms.

Questionnaires from other parties are often designed to be used for a variety of materials (e.g., active pharmaceutical ingredients, dietary ingredients, food additives, or other **raw material**s). These questionnaires are not adequate for addressing information in a context specific to excipients.

1.2 Purpose and Scope

The primary goal of this Guide is to facilitate the excipient supplier's sharing of information with the user in a standardized way. By replying to questionnaires and other requests for information with an EIP, excipient suppliers can respond in a timely and efficient manner while ensuring that consistent and accurate information is provided. Excipient users experience a faster turnaround time to their requests and can anticipate the type and format of the data they receive. This process assists both users and suppliers in the management of such information. In addition, the excipient supplier can assure that the information in the EIP is kept current.

This guide was developed to address the issues described above and provide users with the type of information needed for excipients. The recommended content is based on information typically

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Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
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requested by excipient users. It is not intended to cover all questions asked by excipient users, and supplemental information may need to be provided in some cases.

The EIP consists of:

- Product Regulatory Datasheet
- **Site** Quality Overview
- Supply Chain and Security Overview

Templates for each of these documents are available separately.

1.3 Format of the EIP

The EIP is set up much like a Safety Data Sheet (**SDS**) with designated sections to include specified data. The topics covered in each section are defined; however, additional related information can also be provided at the discretion of the excipient supplier. It is recommended that the excipient supplier considers the typical needs of their users when determining how much detail to provide for a specific topic. If some topics are not applicable to a particular excipient or site, these should be indicated as such in the document. If the excipient supplier is aware of new expectations that have developed since the last publication of this guide, they should consider adding such information to the appropriate EIP document. Where information is considered confidential, the document should explain how the excipient user might obtain this information. For example, the document may state that the information may only be obtained under a confidentiality agreement or viewed during a physical audit.

The content and format of the information is at the discretion of the supplier. Short, bulleted formats are encouraged. When referring to people, job titles, functions or roles should be used rather than names to minimize the need for updates. The document that is shared with the user should be in a file format that cannot be edited (for instance, pdf).

The EIP documents do not require signatures; however, they must be official company documents. EIP's should be managed within the excipient supplier's-controlled documents system, including effective dates and change history. EIP revisions should be aligned with the suppliers' **significant change** notification [2] and management of change procedures. Suppliers should review the EIP periodically and consider adding a review date even if no changes have been made to maintain a more current effective date. It is not expected that updating the EIP would require the supplier to proactively send an updated EIP to every company that has ever received a copy, as in most cases this is not manageable.

1.4 Application and Usage by Excipient Users

The completed EIP documents are intended to be used by individuals experienced and competent in the area of evaluating excipient suppliers and should not be viewed as a replacement for audits. While the Product Regulatory Datasheet, Site Quality Overview and Supply Chain and Security

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Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
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documents in combination create a complete package of information, each document within the EIP was designed to also function independently; therefore, some basic information may be common among the documents.

1.5 Excipients Purchased through Distribution

Distributors may want to provide information to their customers on their **good distribution practices (GDP)** [3] separate from the excipient manufacturer's EIP. Some distributors may perform **good manufacturing practices (GMP)** [4] activities, such as further processing, **repackaging**, or testing of the excipient. In cases such as these, the distributor should consider developing an EIP for the activities they perform to provide additional information about those activities.

These documents would supplement, rather than replace, the EIP documents created by the excipient manufacturer. The distributor should not modify the excipient manufacturer's EIP documents directly, as this would lead to concerns about authenticity of the information.

Users purchasing through distribution should use as their first point of contact, their immediate supplier (the distributor). In many cases the distributor can provide the manufacturer's EIP, as well as any supplemental documents regarding the distributor's activities. In other cases, the distributor may need to facilitate the excipient user's receipt of the EIP from the manufacturer.

2 DETAILED INFORMATION ON THE EIP

The following describes the type of information that should be provided to users in each of the EIP documents.

2.1 Product Regulatory Datasheet

The Product Regulatory Datasheet is designed to communicate to the user important physical, manufacturing and regulatory information specific to the excipient. This information is intended to facilitate the use of the excipient in drug products. Not every point is applicable to each excipient.

The following sections should be included in the Product Regulatory Datasheet.

Section 1 – General Product Information

This section provides identification information for the product.

Recommended contents for this section:

- Product name
- Scope of document (if additional description beyond product name is needed)
- Other general product information

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W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

Section 2 – Manufacturing Sites and Supplier Information

This section provides general information about the site(s) of **manufacture** and other supply chain information for the product.

Recommended contents for this section, where applicable:

- Original manufacturer's physical address and other locations where manufacture occurs. Off-site or **subcontractor** activities should be noted.
- Exclusive distribution channels
- GMP or GDP statement
- Multi-purpose / dedicated **equipment**

Section 3 – Compositional Information

This section provides general information about the chemistry and physical characteristics of the product and its manufacture.

Recommended contents for this section, where applicable:

- Brief description of manufacture and/or a process flow chart (e.g., blend, reaction, **continuous process** / **batch process**)
- **CAS number**
- Chemical formula or structure
- **Composition profile** [5]
- **Country of origin**
- **Mixed excipient** ingredient statement
- Morphological form
- Origin information regarding raw materials/**starting materials** (e.g., **synthetic**, **animal sourced**, **vegetable sourced**, **mineral based**, **product of biotechnology**)
- Synonyms

Section 4 - Regulatory Information

This section includes information related to the regulatory status of the excipient as well as addressing pertinent product specific topics of general regulatory concern.

Recommended contents for this section, where applicable:

- Compendial compliance (e.g., **USP-NF**, **Ph. Eur.**, **BP**, **ChP**, **JP**, **JPE**) and if available, other compendial status (for example if the product is also manufactured as food grade, compliance to e.g., **FCC**, **JSFA**, Codex Alimentarius), and regulatory status (e.g., **21 CFR**, **GRAS**)

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- **Drug Master Files, Certificates of Suitability to the European Pharmacopoeia** or excipient registrations in other countries [6]
- **Bovine Spongiform Encephalopathy (BSE)/ Transmissible Spongiform Encephalopathy (TSE)** (related to the product and the potential for **cross-contamination**); **EDQM** BSE/TSE **Certificate of Suitability** information, if applicable
- **Elemental Impurities** [7]
- **Residual Solvents**
- **Allergens** / **hypersensitivities** Information (related to the product and the potential for cross-contamination)
- **Genetically Modified Organism** information
- **Kosher / Halal status**
- **Precedence of use** (for non-compendial excipients)

Additional Information that may be of interest:

- **Aflatoxins/**other **Mycotoxins**
- **Bioburden**
- Irradiation treatment
- **Melamine**
- **Nitrosamines and related compounds** [8]
- **Proposition 65**
- Preservatives
- Pyrogens (e.g., **endotoxins**, **exotoxins**)
- Use of **nanotechnology**

The excipient manufacturer may consider adding statements referencing specific regulations rather than listing each chemical covered by the regulation.

Section 5 - Other Product Information

This section should be used by the supplier to provide any additional information that may be pertinent to the product but is not covered elsewhere in this document or in the other EIP documents.

Recommended contents for this section, where applicable:

- **Batch** definition statement
- Explanation of the **lot**/batch numbering system
- Microbial testing program
- **Nutritional information**
- Organic certification

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- **Packaging** e.g., size, types, new/recycled, bulk tankers, type of tamper evidence devices and labelling information
- Specific storage and shipping conditions which are required to assure excipient quality
- Statement as to **expiration date** and/or **recommended re-evaluation date** [9]
- **Technically Unavoidable Particle Profile** (**TUPP**) [10]

Section 6 – Revisions

This section provides information related to version control for the document. The document should have a date and/or a version number. This section should also describe the changes made since the last revision.

Section 7 - Contact Information

This section explains how to obtain additional information, if needed, regarding the topics covered in this document.

2.2 Site Quality Overview

The Site Quality Overview is intended to communicate a summary of the quality systems and GMPs/GDPs used to manufacture/distribute the excipient(s) at a particular site or sites. It is not expected to include all the details contained in company policies, or that would be covered during an audit.

This document is a tool to assist in evaluating the manufacturing and/or distribution practices and quality systems of suppliers, as well as a reference to inform users of the GMP and/or GDP systems in place. The Joint IPEC-**PQG** Good Manufacturing Practices Guide for Pharmaceutical Excipients [3], The International Pharmaceutical Excipients Council Good Distribution Practices Guide for Pharmaceutical Excipients [4], EXCiPACT™ Certification Standards for Pharmaceutical Excipient Suppliers [11] or **NSF**/IPEC/**ANSI** 363 Good Manufacturing Practices (GMP) for Pharmaceutical Excipients [12] should be the basis to construct the document. Users of the Site Quality Overview should be familiar with the contents of the excipient GMP/GDP guides and standards and should refer to those documents if further details are needed.

The following sections should be included in the Site Quality Overview.

Section 1 - Site Overview

The purpose of this section is to describe the site's organization and production capabilities.

Recommended contents for this section:

- Scope
  - Site name(s)

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  - Address(es)
  - Excipients covered by this document
- Corporate ownership (if different from site name identified in scope)
- Site Details
  - General site Information (e.g., size, history, number of employees, shift operations)
  - Site activities (e.g., **blending**, packaging, testing)
  - Primary applications of products produced at this site (pharmaceutical, food, cosmetic)
  - Facility production of antibiotics, steroids, sensitizing agents, cytotoxic or hormone products
  - Basic organizational structure

Section 2 - Compliance

This section should be used to describe any specific compliance information pertinent to the site being described.

Suggested examples of compliance information:

- ISO registration information e.g., **ISO 14000**, **ISO 9001** (e.g., number, registrar, copies of certificates)
- GMP and/or GDP certifications (e.g., NSF/IPEC/ANSI 363 or EXCiPACT™)
- General GMP or GDP statements
- Other certifications or external audit programs (e.g., **FSSC 22000**, **AIB**, **BRC**, **GFSI**, **Rx-360**)

Supplier should indicate how users can request copies of the certifications and audit reports. Suppliers may choose to attach copies of certifications to the EIP, which can reduce the amount of follow-up needed.

Section 3 – GMP or GDP Details:

This section should be used to describe how the supplier addresses each applicable element of the GMP or GDP guide or standard followed. Non-applicable elements should be noted as such. For more detail on the specific items that may be covered under each topic, please refer to the GMP or GDP reference used.

Section 4 - Other Site Information

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

This section should be used by the supplier to provide any additional information that may be pertinent to the site but is not covered elsewhere in this document or in other EIP documents.

Contents for this section could include:

- **Data integrity**
- Operational excellence program
- Risk management plan summaries such as **HACCP** or **FMEA** [13]
- **Statistical Process Control** / **Process Analytical Technology (PAT)**

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Section 6 - Contact Information

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2.3 Supply Chain and Security Overview

The Supply Chain and Security Overview is designed to provide users with information concerning the product supply chain from manufacturing site through delivery to the user site. It is intended to provide a high-level overview of the supply chain including security of the product while preserving confidential information.

The extent of detail provided in this section would be dependent on the mode of supply, i.e. for products sold through distribution, the information provided by the manufacturer might stop at the point of sale to their distributor.

The following sections should be included in the Supply Chain and Security Overview.

Section 1 - Scope

The purpose of this section is to identify the manufacturing site and distribution site(s) (where applicable) covered by this document. In some cases, suppliers might choose to include information on transportation providers.

Recommended contents for this section:

- Site name(s)
- Address(es)
- Excipients covered by this document, as applicable

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Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
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- Corporate ownership (if different from site name)

Section 2 - Supply Chain

The purpose of this section is to describe how the supplier assures the integrity of the excipient during storage/distribution and compliance with any appropriate supply chain regulations. Any arrangements to comply with appropriate regulations concerning the transportation of the excipient should also be covered. More details on these issues can be found in the IPEC Good Distribution Practices Guide [4].

Recommended topics for this section, where applicable:

- Description of supply chain that shows how the product moves from manufacturer to customer. This might be in the form of a list, a paragraph, a flow chart or other appropriate format.
- Controls to assure the integrity and security of the product in transit from manufacturer to end user. The following are suggested areas that may be discussed where applicable:
  - Details of packaging (type, new/reused)
  - Tamper-evident seals
  - Wood pallet certification statement
  - Environmental controls
  - Evaluation of carriers
  - Qualification of distributors
  - Qualification of forwarders/brokers
  - Qualification of intermediate storage locations
  - Repackaging/**relabeling** activities
- Registrations with the **FDA** under the **Bioterrorism Act**
- **C-TPAT**
- Approved distributors and how material **pedigree**/**traceability** is assured

Section 3 - Security Information

The purpose of this section is to describe the elements of the supplier's overall security program without going into the details which might compromise the intent of the program.

Recommended contents for this section, where applicable:

- Scope of security plan including:
  - Data and computer system protection
  - Details of any certification with regards to security (e.g., **AEO**)

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Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
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  - Potential for **economic adulteration**
  - Policies & procedures
  - Risk assessment
  - Roles and responsibilities, including title of person responsible for implementing security
  - Site access control (e.g., security fencing, visitor registration, employee badges, employee training, vehicular access, camera monitoring)
  - Training
- Personnel security
  - Prevention of site and computer system access by unauthorized or terminated personnel
  - Pre-employment background checks
  - Temporary and contract personnel background checks
  - Training

Section 4 - Safety & Environmental Information

The purpose of this section is to describe the supplier's personnel safety and environmental programs.

Recommended contents for this section:

- Description of documented health and safety program
- Registrations/certifications (e.g., ISO 14001, **OHSAS 18001**, **Responsible Care**)

Section 5 – Business Continuity Plan

This purpose of this section is to communicate to the user the availability of a business continuity plan that addresses continuation of supply in case of disaster, pandemic or other disruptions. Optionally, additional details regarding the elements of the plan may be included.

Section 6 - Other Supply Chain and Security Information

This section should be used by the supplier to provide any additional information e.g., corporate responsibility and/or sustainability programs that may be pertinent to the site but is not covered elsewhere in this document or in the other EIP documents. This section is optional and should only be used as needed.

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Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
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VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

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Section 8 - Contact Information

This section explains how to obtain additional information, if needed, regarding the topics covered in this document.

3 EIP USER GUIDE REVISION HISTORY

Changes since last revision:

Added references to new IPEC Guides and to the excipient GMP Standards and certification programs

Modified regulatory section based on new/obsolete regulations

Changes to improve clarity

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Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

4 REFERENCES

IPEC documents referenced below can be accessed at the following website links:

IPEC-Americas page : https://ipecamericas.org/

IPEC Europe page : https://www.ipec-europe.org/guidelines.html

1. The International Pharmaceutical Excipients Council: General Glossary of Terms and Acronyms.
2. The IPEC Significant Change Guide for Pharmaceutical Excipients, 2014.
3. The International Pharmaceutical Excipients Council & The Pharmaceutical Quality Group: The Joint Good Manufacturing Practices Guide for Pharmaceutical Excipients.
4. The International Pharmaceutical Excipient Council Good Distribution Practices Guide for Pharmaceutical Excipients.
5. The IPEC Excipient Composition Guide.
6. The International Pharmaceutical Excipient Council U.S. Drug Master File Guide for Pharmaceutical Excipients.
7. IPEC Elemental Impurities Template
8. IPEC-Americas Risk Assessment Template for Nitrosamines and IPEC Europe Questionnaire for Excipient Nitrosamines Risk Evaluation
9. The IPEC Excipient Stability Program Guide.
10. The International Pharmaceutical Excipient Council Technically Unavoidable Particle Profile (TUPP) Guide.
11. EXCiPACT™ Certification Standards for Pharmaceutical Excipients: Good Manufacturing Practices, Good Distribution Practices, 2017 (www.excipact.org)
12. ANSI Webstore https://webstore.ansi.org/Standards/NSF/NSFIPECANSI3632016
13. The IPEC Risk Assessment Guide for Pharmaceutical Excipients. Part 1 – Risk Assessment for Excipient Manufacturers.

Other IPEC Guides available:

- The International Pharmaceutical Excipients Council Qualification of Excipients for Use in Pharmaceuticals.
- The International Pharmaceutical Excipients Council Certificate of Analysis Guide for Pharmaceutical Excipients.
- The IPEC-Americas Quality by Design (QbD) Sampling Guide.

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Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73363068125160 - RPM Brussels Capital Region

- The International Pharmaceutical Excipient Council Co-Processed Excipient Guide for Pharmaceutical Excipients.
- The International Pharmaceutical Excipient Council Quality Agreement Guide and Template(s) for Pharmaceutical Excipients.

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Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
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