



The International Pharmaceutical Excipients Council

# Excipient

# Information

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**PRODUCT REGULATORY DATASHEET**

**Section 1 – General Product Information**

Product name

Scope of document (if additional description beyond product name is needed)

Other general product information

**Section 2 – Manufacturing Sites and Supplier Information**

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**

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

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**

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)

Drug Master Files, Certificates of Suitability to the European Pharmacopoeia or excipient registrations in other countries

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

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)

See User's Guide for additional information that may be of interest

### **Section 5 - Other Product Information**

Batch definition statement

Explanation of the lot/batch numbering system

Microbial testing program

Nutritional information

Organic certification

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

Technically Unavoidable Particle Profile (TUPP)

### **Section 6 - Revisions**

See User's Guide for suggested information to include in this section

### **Section 7 - Contact Information**

See User's Guide for suggested information to include in this section

**SITE QUALITY OVERVIEW**

**Section 1 - Site Overview**

Scope

- Site name(s)
- 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 (e.g., pharmaceutical, food, cosmetic)
- Facility production of antibiotics, steroids, sensitizing agents, cytotoxic or hormone products
- Basic organizational structure

**Section 2 - Compliance**

Include as applicable:

- 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)

**Section 3 GMP or GDP Details:**

This section is intended to describe the Site's compliance with the GMP guide or standard(s) followed. It is not intended to be a copy of the GMP guide/standard or copies of the company's policies/procedures. It is intended to provide summarized information on how the company addresses the various aspects of quality systems and GMPs.

Example topics are provided below. The company may choose to arrange this information consistent with the order of the topics in the GMP guide/standard to which they claim compliance.

## **Quality Management Systems-Excipient Quality Systems**

- General Requirements
- Documentation Requirements
- Change Control

## **Management Responsibility**

- Management Commitment
- Customer Focus
- Quality Policy
- Planning
- Responsibility, Authority and Communication
- Management Review

## **Resource Management**

- Provision of Resources
- Human Resources
- Infrastructure
- Work Environment

## **Product Realization**

- Planning of Product Realization
- Customer-Related Processes
- Design and Development
- Purchasing
- Production and Service Provision
- Control of Measuring and Monitoring Devices

## **Measurement, Analysis and Improvement**

- General
- Monitoring and Measurement

- Control of Nonconforming Product
- Analysis of Data
- Improvement

#### **Section 4 - Other Site Information**

See User's Guide for suggested information to include in this section

#### **Section 5 – Revisions**

See User's Guide for suggested information to include in this section

#### **Section 6 - Contact Information**

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**SUPPLY CHAIN AND SECURITY OVERVIEW**

**Section 1 - Scope**

Site name(s)

Address(es)

Excipients covered by this document, as applicable

Corporate ownership (if different from site name)

**Section 2 - Supply Chain**

Description of supply chain that shows how the product moves from manufacturer to customer.

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 (e.g., 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**

Scope of security plan including:

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

Description of documented health and safety program

Registrations/certifications, e.g., ISO 14001, OHSAS 18001, Responsible Care

### **Section 5 – Business Continuity Plan**

See User's Guide for suggested information to include in this section

### **Section 6 - Other Supply Chain and Security Information**

See User's Guide for suggested information to include in this section

### **Section 7 - Revisions**

See User's Guide for suggested information to include in this section

### **Section 8 - Contact Information**

See User's Guide for suggested information to include in this section