IPEC FEDERATION

The International Pharmaceutical Excipients Council

Excipient

Information

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COMPANY LOGO/LETTERHEAD/OFFICIAL STATIONERY/COMPANY DOCUMENT

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

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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

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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

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- 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

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- 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

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