**VALIDATION PHARMA**

The principles outlined in this Standard provide a comprehensive basis for the quality management system

used in the manufacture of pharmaceutical excipients. Implementation of these principles shall result

in the achievement of three main objectives:

a) achieve excipient realization – the organization shall implement and maintain a system

that delivers excipients with the quality attributes necessary to meet the requirements and

expectations of customers, pharmaceutical users, and regulatory authorities,

b) establish and maintain a state of control – the organization shall ensure the manufacture

and supply of excipients is in accordance with this Standard, thus providing customers

with some assurance of continued suitability and reliability of supply, and

c) facilitate continual improvement – the organization shall collect objective evidence to continually

develop and enhance the application of these quality management system principles

to further assure excipient consistency.

This Standard is intended to define Good Manufacturing Practices (GMP) for excipient manufacture and

distribution1 for use in drug products. It sets minimum requirements for GMP applicable to all commercially

available excipients.

This Standard includes the critical elements of a quality management system for excipient manufacture

drawing on principles of GMP and quality systems from other relevant standards such as those referenced

. At the time this Standard was written, the editions indicated were valid. All documents are

subject to revision, and parties are encouraged to investigate the possibility of applying the most recent

edition of the document indicated below. The most recent published edition of the document shall be

used for undated references.

The following documents are references that provide supplemental information to the provisions of this

Standard. At the time this Standard was written, the editions indicated were valid. All documents are subject

to revision, and parties are encouraged to investigate the possibility of applying the most recent edition

of the document indicated below.

**certificate of analysis (COA)**: A document listing the test methods, specifications, and results of

testing a representative sample from the batch to be delivered.

**certificate of conformity (COC)**: A document that confirms the product shipped to the customer

complies with a specific set of requirements or specifications. It does not contain actual test results.

**change control**: A process used for management review of proposed changes that may impact

the quality or regulatory conformance of the excipient.

**competency**: The demonstrated personal attributes and ability to apply knowledge and skills.

**component**: Any material present in the excipient that arises as a consequence of the raw materials

and/or manufacturing process.

**computer system**: A group of hardware components and associated software designed and assembled

to perform a specific function or group of functions.

**contaminant**: An undesired material of a chemical or microbiological nature, or foreign matter

introduced from a raw material, intermediate, or excipient during production, sampling, packaging,

storage or transport.

**contamination**: The undesired introduction of impurities of a chemical or microbiological nature,

or foreign matter into or onto a raw material, intermediate or excipient during production, sampling,

packaging or repackaging, storage, or transport.

**continual improvement**: Recurring activity to increase the ability to fulfill requirements.

**continuous process**: A process that continually produces material from a continuing supply of

raw material.

**corrective action**: The action taken to eliminate the cause of a detected non-conformity or other

undesirable situation. NOTE – Corrective action is taken to prevent recurrence whereas preventive

action is taken to prevent occurrence.

**critical**: A process step, process condition, test requirement, or other relevant parameter or item

that must be controlled within predetermined criteria to ensure that the excipient meets its specifications.

**customer**: The organization receiving the excipient once it has left the control of the excipient

manufacturer.

**documented procedure**: A written procedure meeting the requirements of 4.2.3.

**drug product**: Dosage form intended for use by a patient.

**effectiveness**: An expression of the degree to which activities have produced the effects

planned.

**excipient**: Substances other than the API that have been appropriately evaluated for safety and

are intentionally included in a drug delivery system.

**Control of Documents**

Documents required by this Standard and those determined by the organization as necessary to implement

GMP and the quality management system shall be controlled. Records are a special type of document

and shall be controlled according to the requirements specified in 4.2.4.

A documented procedure shall be established to define the controls needed to:

a) approve documents for adequacy by designated personnel prior to issue,

b) periodically review, update as necessary, and re-approve documents,

c) ensure that changes and the current revision status of documents are identified,

d) ensure that current versions of applicable documents are available at points of use,

e) ensure that documents remain legible and readily identifiable,

f) ensure that documents of external origin are identified and their distribution controlled,

and

g) prevent the unintended use of obsolete documents and to apply suitable identification to

them if they are retained for any purpose.

Procedures that impact excipient quality shall have a defined owner and be reviewed and approved by

the quality unit before issue including changes to these documents (see 5.5.1).

Electronic documentation shall meet the requirements for the document control system stated above. If

electronic signatures are used on documents they shall be controlled to provide equivalent security to that

given by a hand written signature.