IPEC Association (China) Limited
國際藥用輔料協会（中國）有限公司

为加强药用辅料的生产质量管理，保证药用辅料质量，国家局在充分征求各方面意见的基础上，于 2006 年 3 月 23 日制定了《药用辅料生产质量管理规范》。

To enhance manufacturing quality management of pharmaceutical excipients and ensure quality of pharmaceutical excipients, State Food and Drug Administration (SFDA), on the basis of extensive solicitation of opinions of all circles, has formulated *Good Manufacturing Practices for Pharmaceutical Excipients* on 23th March, 2006.

为进一步促进国内外关于药用辅料生产质量管理的法规交流，现 IPEC 中国组织会员单位对其进行了英文翻译。特此感谢参与此次翻译的 IPEC 中国会员：

To further promote the exchange of regulations on the manufacturing quality management of pharmaceutical excipients at home and abroad, IPEC China organize the members to translate the *Good Manufacturing Practices for Pharmaceutical Excipients (2006 version)* into English. Great thanks the members below for participating in this translation.

默克化工技术(上海) 有限公司-王昱	Merck Chemicals (Shanghai) Co.,Ltd.	Bree Wang
默克化工技术(上海) 有限公司-刘慧	Merck Chemicals (Shanghai) Co.,Ltd.	Helen Liu
科莱恩化工（中国）有限公司-李娜	Clariant Chemicals (China) Ltd.	Lina Li
罗辅医药科技（上海）有限公司-高闪	Ron Pharm(Shanghai) Co., Limited	Shine Gao
博爱新开源制药股份有限公司-王晓燕	BOAI NKY PHARMACEUTICALS LTD.	Xiaoyan Wang
赛诺菲（中国）投资有限公司-阮克萍	Sanofi China Investment Co., Ltd	Alice Ruan
杜邦（上海）实业有限公司-陶征宇	DuPont (Shanghai) Enterprise Co., Ltd.	Martin TAO
江苏力凡胶囊有限公司-汤瑛	Jiangsu Lefan Capsule Co.,L TD.	Ying Tang

同时感谢高闪进行了编辑整理。如果您认为该文件中有任何内容翻译不够准确或难以理解，请提出您宝贵的意见。我们将进行搜集和整理，确认后另行修订。

Meanwhile, thank Shine Gao for editing and summarizing. If you find any content in this document is not translated accurately or understandable, please give us your valuable comments. We will collect and revise them after confirmation.

附件：2006 版《药用辅料生产质量管理规范》（英文）

Attachment: *Good Manufacturing Practices for Pharmaceutical Excipients (2006 version)* in English

国际药用辅料协会（中国）IPEC Association (China) Limited

2019 年 11 月 27 日 27th November, 2019

联系人：高闪
电话：+86 15050219270
邮箱：shine@ronpharm.com

Contact person: Shine Gao
Tel: +86 15050219270
Email：shine@ronpharm.com

Notice on Printing and Distributing *Good Manufacturing Practice for Pharmaceutical Excipients*

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(Food and) Drug administration of each province, autonomous region and municipality directly under the Central Government,

To enhance manufacturing quality management of pharmaceutical excipients and ensure quality of pharmaceutical excipients, State Food and Drug Administration (SFDA), on the basis of extensive solicitation of opinions of all circles, has formulated *Good Manufacturing Practices for Pharmaceutical Excipients*, which is hereby printed and distributed to you for your reference in implementation with the local practical conditions taken into account. Should you have any opinion or suggestion in the process of implementation, please timely contact SFDA Department of Drug Safety & Inspection.

State Food and Drug Administration

March 23, 2006

Good Manufacturing Practices for Pharmaceutical Excipients

CONTENTS

Chapter I General Provisions

Article 1 *Good Manufacturing Practices for Pharmaceutical Excipients* (hereinafter referred to as "GMP") is established in accordance with the regulation of Article 11 in *Pharmaceutical Administration Law of the People's Republic of China* that "raw materials and excipients for manufacturing pharmaceutical products must comply with pharmaceutical requirements".

Article 2 This GMP is intended to establish the basic scope and main points of quality management to be implemented by pharmaceutical excipient (hereinafter referred to as "excipient") manufacturers, so as to make sure excipients possess the quality and safety which they purport to possess and are suitable for their intended use.

Article 3 Quality management requirements of excipient manufacturing gradually increase as the manufacturing process progresses. Based on the excipients manufacturing process and the product nature, the manufacturer should define the processing step where the GMP should be implemented.

Chapter II Organizations, Personnel and Responsibilities

Article 4 The manufacturer should establish organizations adapting to excipient manufacturing and clearly define the responsibilities of departments and personnel for quality assurance, quality control, production, materials, maintenance and engineering.

Article 5 The quality management department should be independent of the production and have the right to approve or reject raw materials, packaging materials, intermediates and finished products; review manufacturing records to make sure no errors have occurred or, if errors occur, that they are fully investigated and handled; participate in authorizing changes to processes, specifications, procedures and test methods, and in investigating failures and complaints.

Article 6 The head of quality management is responsible to ensure that the provisions of this GMP are properly implemented and periodically report to the head of the manufacturer on conformance to the Quality System, including changing excipient customer expectations and regulatory requirements. The head of the manufacturer should periodically assess the quality system to make sure it complies with requirements of this GMP.

Article 7 The manufacturer should be staffed with a certain quantity of administrators and technicians competent for the manufacturing of excipient. Personnel at all levels engaged in the manufacturing of excipient should have appropriate education, training and experience for their assigned tasks.

Article 8 The manufacturer should establish and implement training procedures. The training should cover corresponding professional technical knowledge, specific standard operating procedures, personnel hygiene and this GMP and so on. GMP training should be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that employees remain familiar with applicable GMP requirements. Training should be documented.

Chapter III Buildings and Facilities

Article 9 The manufacturer should have a clean manufacturing environment; the ground, road surface of the plant area and transportation should not cause contamination to excipient manufacturing.

Article 10 Cleanliness control requirements of manufacturing buildings and facilities should be established depending on purposes and characteristics of excipients. Buildings and facilities for manufacturing, packaging, testing and holding of the excipients should facilitate cleaning, repairing and maintenance to maintain them in good state.

Article 11 The manufacturing and the storage area should be of suitable size adapting to the manufacturing scale so that equipment, instruments and materials may be located in a suitable way to facilitate operations and maximize the errors and cross contamination.

Article 12 The air processing system should be designed to prevent the cross contamination. Return air must not be used in areas where large amounts of dust are produced and cross contamination are prone to occur.

Article 13 Temperature and humidity should be set and controlled according to the product characteristics and process requirements.

Article 14 Buildings should be free of infestation by rodents, birds, insects, and other vermin. Manufacturer should have sufficient control methods to prevent the contamination raw materials or infestation in holding areas, or its spread to other areas of the plant. Buildings should be provided with necessary anti-dust and dust-collection facilities according to the process requirements.

Article 15 Adequate light should be provided in all areas; emergency lighting should be set according to relevant regulations.

Article 16 Floor drains in manufacturing operation areas should be adapted to the manufacturing requirements; liquid seal or other mechanical devices should be used to prevent back siphoning and contamination.

Article 17 Measures should be taken to prevent the cross contamination of personnel and materials entering and/or leaving production workshop. Suitable washing facilities should be provided to ensure it’s easily accessible to working areas.

Chapter IV Equipment

Article 18 The design and installation of equipment for manufacturing, packaging, testing and storing excipients should facilitate operation, cleaning and maintenance. The design of the equipment should minimize the contamination due to direct contact of operators. Closed equipment and pipes can be located outside.

Article 19 The contact surface of the manufacturing equipment should be smooth, spotless and not adsorb or chemically react with materials and be easy to clean and sterilize.

Article 20 For excipients that residues are difficult to clean, dedicated manufacturing equipment should be used.

Article 21 Lubricant or refrigerant etc. used in the equipment should not be direct contact with raw materials, packaging materials, intermediates or finished products of excipients; the food grade of lubricants or refrigerant should at least be used where immediate contact cannot be avoided.

Article 22 Names and flow directions of materials in main fixed pipes connecting with equipment should be clearly labeled.

Article 23 The manufacturer should have plans and procedures for periodical calibration of critical equipment and instruments. Critical measuring and monitoring equipment and instruments, including laboratory testing instruments and in-process control instruments, should be calibrated following the established plans and procedures. Equipment and instruments that do not meet the established standards must not be used. Calibration standards should be traceable to recognized national standards.

Article 24 Maintenance and repair procedures should be established and implemented for critical equipment (including implements) for the manufacturing, packaging, testing and holding of excipients. Maintenance and repair record should cover at least the following information:

1. A detailed description of the maintenance and personnel implementing the maintenance or repair;
2. The name and batch No. of the products manufactured before and after maintenance or repair.

Article 25 Design, installation and maintenance of the water processing system and distribution systems should make sure the supplied water meets the established standard.

Chapter V Materials

Article 26 Comprehensive capacities of suppliers should be verified and assessed to make sure raw materials, packaging materials and services meet requirements in contracts.

Article 27 Management procedures should be established for purchase, storage, distribution and use of materials for manufacturing excipients. Specification should be available for materials; the manufacturer should test materials according to the specification and review certificates of analysis from supplier to make sure compliance with quality requirements for the manufacture of excipients.

Article 28 Finished products and critical materials making influence on the finished products should be clearly labeled so that they can be traced via the document system. The quality system should ensure bidirectional traceability of excipients. Identification of raw materials（product name and number ）used in batch production processes should be traceable through the batch numbering system or any other appropriate system. For raw materials manufactured by continuous processes, a certain quantity of raw materials should be defined as a batch and given a specific batch number. Bulk raw materials and solvents that cannot be separated accurately by the batch number should be numbered when warehoused, and corresponding management procedures should be established for their acceptance, distribution, storage and use.

Article 29 A management system for identifying test status of raw materials, packaging materials, intermediates and finished products should be established. Materials and finished products in quarantine, release or rejection should be clearly labeled to indicate the quality status and placed in areas with obvious marks. Rejected materials should be effectively isolated and must not be used before release.

Article 30 Labels of finished products should comply with requirements of relevant regulations. A label should provide product name, grade, lot number, and manufacturer of the excipient etc.

Article 31 Finished products, intermediates and raw materials should be handled and stored under conditions with suitable temperature, humidity and light. For storage of flammables, explosives and other dangerous materials, relevant national regulations should be strictly followed.

Article 32 For animal tissues or plants used for manufacturing pharmaceutical gelatins or other excipients, documents or records should be provided to prove that they haven’t been contaminated by harmful chemical substances. For example,

Animal Health Certificates issued by health and quarantine departments or other quarantine and inspection documents should be provided by suppliers

Article 33 Manufacturers using strains to manufacture excipients should establish management procedures for identification, management, use, storage, subculture and screening of strains and record accordingly.

Chapter VI Hygiene

Article 34 Hygienic measures should be taken to prevent contamination and hygiene management procedures should be established.

Article 35 Hygiene of production, test and warehousing areas should be maintained. Cleaning procedures of buildings, equipment, containers and implements should be established according to manufacturing and required air cleanliness level; cleaning methods, procedures, intervals, used detergents or disinfectants, cleaning methods and storage places of cleaning tools, etc. should be specified.

Article 36 Non-manufacturing articles and personal stuffs must not be stored in the production areas; production wastes should be timely disposed.

Article 37 Setting of changing rooms, bathrooms and toilets should not cause contamination to the production areas.

Article 38 Effective cleaning procedures should be established to clear product residues and contaminants; equipment cleanliness status should be appropriately marked and documented.

Article 39 Personnel of manufacturing, test, maintenance and warehousing should wear clean garments appropriate to the specific work conducted and should not wear ornaments. Garments should not generate static electricity and release foreign substances. Clean areas should be entered only by manufacturing operators of the areas and authorized persons.

Article 40 Manufacturing personnel should accept medical examination each year, and health archives should be established. Any personnel with disease or external wounds that may bring adverse influence to the safety and quality of excipients should be transferred away from areas which is in direct contact with raw materials, packaging materials, intermediates and finished products. Personnel at each level should keep good hygienic habits; when the personal health condition may cause adverse influence on products, initiative report to the person in charge is needed.

Chapter VII Validation

Article 41 A validation protocol should be made according to the object to be validated; the validation items, methods and acceptance criteria should be specified; the validation should be carried out as per the validation plan. After validation is completed, a validation report should be prepared and submitted to the person in charge of validation for review and approval.

Article 42 Design qualification, installation qualification, operation qualification and performance qualification should be carried out for manufacturing buildings, facilities and equipment.

Article 43 Process validation is the key to realization of the quality assurance target. The reaction process, process control parameters, sampling and in-process testing requirements should be specified in the process validation document to lay a foundation for smooth process validation. Re-validation should be performed when there is a change in major factors influencing the product quality, including any change in manufacturing process, testing method, primary starting materials and primary manufacturing equipment, etc.

Article 44 Cleaning validation should confirm the validity of cleaning and disinfection procedures of primary equipment and containers based on data. If cleaning and disinfection procedures are established according to the cleaning mode of representative products, it should meet the specific requirements of products and processes.

Article 45 Data and information obtained in the validation should be archived and stored in the form of documents. Validation documents should include validation master plan, validation protocols, validation reports and validation summaries. Validation protocol or report should specify the validated object/system, items, acceptance criteria, result assessment, references, suggestions, deviations and missing items, measures, result review and approval, etc.

Chapter VIII Documents

Article 46 A document management system should be established to comply with quality management requirements; Operation procedures should be established and implemented for labeling, drafting, review, distribution, archiving and revision of documents and retrieval of expired documents.

Article 47 Written procedures for manufacturing and quality control should be established and implemented. Approval, revision and distribution of procedures should be controlled to make sure procedures used throughout the manufacturing process are current versions. Drafting and revision of all documents should be reviewed and approved by designated personnel and then distributed within the specified scope. Procedures should make sure documents are correctly distributed and previous versions are retrieved.

Article 48 Controlled documents should be given exclusive numbers and marked with the distribution dates and version numbers. Documents should be distributed by designated departments; changes of all documents and reasons for the changes should be documented.

Article 49 All records of products should be clear and easy to read. All batch-related records should be kept until at least one year after expiry of the product. Record archives should be easy to trace and retrieve; the archiving environment should comply with relevant regulations.

Article 50 Manufacturing and quality control records should be made for all products manufactured using continuous processes or batch processes to document all information related to manufacturing and quality control of each batch of products. Records may be placed in different sites on the premise that convenient inquiry is ensured. Records usually include the following two types:

1. Directive documents: batch manufacturing directives or copies of controlled documents issued to manufacturing workshops.
2. Recording documents: records obtained after completion of important operating steps such as batch manufacturing, packaging or temporary storage. Document contents should include:

(1) Date/time of completion of each operating step;
(2) Numbers of primary equipment and production lines used;
(3) Names, numbers or lot numbers of each batch of raw materials or intermediates;
(4) Quantity (weight or other measurement unit) of raw materials used in the manufacturing process;
(5) Results of in-process control or laboratory control;
(6) Clearance records before and after using the packaging and labeling areas;

(7) Notes about actual yields or outputs of some processing step and percentages to the theoretical yields;
(8) Label control records, with attachment of samples of all labels used as much as possible;
(9) Detailed description of packaging materials, containers or seals;
(10) Detailed description of the sampling process;
(11) Signatures of important manufacturing step operators, review and supervision personnel;
(12) Deviation investigation and handling records;
(13) Test records of final products;
(14) Environment monitoring records of critical sites in aseptic operation areas where pharmaceutical excipients are manufactured using aseptic techniques.

Article 51 Batch production records should be filled in with clear handwriting, authentic contents and complete data and signed by operators and reviewers; records should be kept clean and tidy and must not be destructed or altered without permission; if correction is needed, the correction should be signed and the original data should be kept identifiable.

Chapter IX Production Management

Article 52 The manufacturer should make sure important manufacturing processes can be continually and stably conducted.

Article 53 Material balance test should be carried out for each batch of products manufactured. Significant discrepancy, if any, should be investigated to identify the reason. The products may be handled as normal products only after a justifiable explanation is obtained and no potential quality deviation is confirmed.

Article 54 For the same product of different grades manufactured in the same factory workshop or with the same equipment, it is allowable that a small quantity of products of the previous batch is commingled to the next batch on the premise without changing the quality and safety.

Article 55 Products to be exposed in the manufacturing process should be placed in a clean environment and, when necessary, the manufacturing environment should be monitored to avoid microbial contamination or quality change of the products due to exposure to heat, air or light. Inert gases in direct contact with products should be managed according to requirements for raw materials.

Article 56 The manufacturing environment of sterile pharmaceutical excipients should be similar to that of drug products, and corresponding environment monitoring procedures should be established. Aseptic techniques must be used for post-sterilization operation of sterile excipients; sterilization results and environment monitoring results of aseptic operation areas in the aseptic manufacturing process should be included in the batch process record and used as an important reference for quality assessment of the final product.

Article 57 Process water used in the manufacturing process should comply with requirements of the manufacturing process. Generally, process water should comply with the quality standard of drinking water. When the product process has higher requirements for water quality, the manufacturer should establish specifications for physicochemical properties, total bacterial count and absence of microorganisms. If the process water is independently treated by the manufacturer to make it comply with the standards, the water treatment process should be validated and the system running should be monitored. If a non-sterile excipient produced by the manufacturer is used for manufacturing sterile drug products, the process water for final separation and refining of the excipient should be monitored and, besides, the total bacterial count and endotoxin should be controlled.

Article 58 If the manufacturer uses heating or irradiation to reduce microbial contamination of non-sterile excipients, the excipients should meet the specified

microorganism limit criteria before sterilized, and the sterilization process should be in controlled state. The used sterilization method should be validated to prove that it meets the specified requirements. Terminal sterilization of excipient products must not be substituted for microbial control of the process.

Article 59 Particular requirements for storage conditions (e.g. protection from light, heat insulation, etc.), if any, should be specified on the package.

Article 60 When used in the same or different process procedures, recovered solvents must comply with the standards for reuse or commingling with other solvents.

Article 61 Bulks to be used repeatedly and filtrates containing recyclable excipients, reactants or intermediates should comply with the standard for feeding. Batch process records should contain recycling records complying with recycling procedures.

Article 62 In-process inspection and testing should be performed based upon monitoring the process or actual sample analysis at defined locations and times. The results should conform to established process parameters or acceptable tolerances. Whether the process is running normally should be determined on the basis of the in-process test results. Non-conforming intermediates should not be used in next process step.

Article 63 Each batch of excipients should be given a defined lot number. The principles of batching are as follows:
1. Continuously manufactured excipients: homogenous products manufactured within a certain time interval, with their quality and properties complying with specified limits.
2. Intermittently manufactured excipients: homogenous products obtained by finally mixing a certain quantity of products, with their quality and properties complying with specified limits.

Article 64 To ensure batch homogeneity or facilitate processing, intermediate mixing can be performed; the mixing process should be appropriately controlled and documented. Batch-to-batch repeatability should be ensured. Excipients of non-conforming and conforming batches must not be mixed together.

Article 65 To change the product variety, the equipment should be thoroughly cleaned; to change the batch in manufacturing the same product, clearance should be performed and documented. Material oddment carry-over in batch processes is allowed. When the residue may affect the product quality, the equipment should be thoroughly cleaned when changing the batch.

Article 66 Completion time and interval of each process procedure for manufacturing excipients should be specified. Additionally, the longest interval between cleaning,

drying, sterilization and use of equipment, containers, packaging materials and other articles in direct contact with products should be specified.

Article 67 In the packaging process, excipient quality and purity should be protected against damage and labels on all packaging containers should be correct without mistakes. Actions should be taken for preventing errors in packaging and labeling operations. For recyclable and reusable excipient containers, the original labels must be removed or cancelled for reuse. All previous lot numbers or labels on turnover containers used in manufacturing the same excipient should also be removed or cancelled.

Article 68 Excipient packaging systems should comply with the following requirements:
1. Package-related specification/standard documents, inspection or testing methods and cleaning procedures (if required) should be provided;
2. Seals or other safety measures for identifying whether the package is opened should be provided;
3. The container closure performance has been evaluated to prove the closure system can protect the excipient against deterioration and contamination;
4. Storage, transportation and handling procedures have been established to protect containers and closures, reduce contamination, damage and deterioration and avoid mixing-up.

Article 69 Relevant procedures should be formulated and implemented to make sure the quantity of labels printed and distributed is correct and information on the label is correct without any mistake. Written procedures should be established to specify that surplus labels are timely destructed or timely returned to the label storage area. Surplus labels with printed lot numbers should be destructed. Packaging and labeling equipment should be examined before use to make all materials unrelated to the next lot number have been cleared away. Whether the product is labeled on the excipient packaging line or packaged with previously printed packs or delivered with tank trucks, complete document and record systems should be established to satisfy the above relevant requirements.

Article 70 All non-conforming batches should be investigated to find out the root cause for non-conformity, and the investigation should be documented. Actions should be taken to prevent recurrence of similar problems. Evaluation and handling procedures of non-conforming products should be established, and non-conforming products should be reviewed following the procedures; the final handling plans of non-conforming products should be confirmed. Handling plans usually include:
1. Reprocessing to make the product comply with the specification;
2. Changing the use grade;
3. Destruction.

Article 71 Excipient products may be reprocessed or reworked, but reprocessing and reworking procedures should be followed. However, merely relying on final testing of the reprocessed excipient as a means of demonstrating compliance to specification and neglecting the investigation and evaluation of the manufacturing process is unacceptable.

The equivalence of the quality of reprocessed material to original material should also be evaluated and documented to ensure that the reprocessed lot/batch will conform with all established standards, specifications, and characteristics. There should be a sufficient investigation, evaluation, and documentation to demonstrate that the reprocessed excipient is at least equivalent to other acceptable product and that the nonconformance was not the result of an inadequate process. Reprocessing or reworking that is not a normal part of the approved manufacturing process should not be performed without the review and approval of quality department.

Article 72 When automated control systems or other complicated equipment are used, the following requirements should be met:

1. The system and procedures can prove the equipment and software performance can satisfy established requirements.
2. Procedures for periodic inspection and calibration of equipment have been established and followed.
3. Suitable documentation retention procedure and backup systems for keeping programs are available.
4. It is ensured that only authorized personnel can revise control programs; program revision should be validated and documented.

Chapter X Quality Assurance and Quality Control

Article 73 The quality management department should be responsible for quality management and test of the entire manufacturing process of excipients. The quality management department should be staffed with a certain quantity of personnel for quality management and quality control, and provided with place, instruments and equipment adapting to the excipient manufacturing scale, varieties and test requirements.

Article 74 The quality management department should have complete test records carried out to ensure products comply with legal or in-house specifications. The test records should cover:

1. A detailed description of the product examined, including the material name, lot/number or other specific code and sampling time;
2. The index number (or description) of each test method;
3. Original test data of material and product, including graphs, tables and instrument spectrum;
4. Calculation related to the test;
5. Test results and conclusion against the standard;
6.Dates and signatures of the persons who performed the testing.

Article 75 Written procedures for procurement and preparation of reagents and test solutions should be available. Purchased reagents and test solutions should be marked with the names, concentrations and shelf life. Preparation records of test solutions should be kept, covering names, preparation date and quantities of used materials. Volumetric solutions should be standardized according to the legal standards and the standardization records should be maintained.

Article 76 To make sure raw materials, intermediates and finished products comply with requirements of relevant specifications, the test protocol should address the specification, sampling procedures and test procedures.

Article 77 Finished products should be tested by the quality management department and comply with the specification. Before release of finished products, all manufacturing documents and records, including testing data, should be reviewed by the quality management department and comply with related requirements. Release of non-conforming products should be not allowed.

Article 78 If the test result is out of specification, investigation should be carried out following the written procedures and be documented. It is not allowed to retest samples and release products only according to retest sample results unless it has been identified that the original test result is erroneous; rather, whether the batch of products can be release should be determined according to statistical analysis

including both the original and retest data. These same principles apply when the sample is suspected of not being representative of the material from which it was taken.

Article 79 Retained samples should be kept until one year after the shelf life ; the amount of retained samples should not be less than twice the amount required to perform complete specification testing..

Article 80 Stability testing of retained samples of excipients should be documented and recorded. Tests should be carried out periodically following the stability testing program. The testing program usually include the following information:
1. The number of lots tested each year, quantity of samples and testing intervals.
2. Storage conditions for samples retained for testing.
3. Test methods used for stability testing.4. Storage of the excipient in containers that simulate the market container, where possible.

Article 81 Written procedures should be established for the identification, classification, documentation, appropriate review, and approval of changes including but not limited to raw material and quality specification, equipment, and production process. A group that is organizationally independent from production (such as Regulatory Affairs, Quality Assurance, etc.) should have the responsibility and authority for the final approval of changes. Significant operational changes should be supported by validation results. The effect of the changes should be communicated to both internal and external customers.

Chapter XI Distribution

Article 82 Distribution records of excipients should be kept. The record should include the excipient name, lot number, delivery site, receiver, delivered quantity, delivery date, etc. so that the product can be retrieved when necessary.

Article 83 Written procedures for storage, management, treatment, test and reworking of returned excipients should be established and implemented. Returned excipients should be properly labeled and arranged in the to-be-handled state. If the product safety, quality or purity is affected by various conditions in temporary storage, storage, delivery and return, the product should be rejected. The return should be documented well and the record should be kept; the record should cover such information as the product name, lot number, reason for return, quantity returned, handling result and disposal date.

Chapter XII Self-inspection and Improvement

Article 84 The manufacturer should perform self-inspection periodically to examine whether quality activities are carried out as planned and determine effectiveness of the quality management system. Self-inspection should be carried out and self-inspection results should be followed according to self-inspection procedures. The self-inspection result should be discussed with the person in charge of the inspected department. The inspected department should timely take measures against existing problems so as to make improvements.

Article 85 Weakness of the quality system should be identified and corresponding improvement measures should be formulated according to information obtained in customer complaints, product quality review, process capability study, self-inspection and customer auditing.

Article 86 Product quality attributes, customer complaints, process operation parameters and process faults should be periodically reviewed and summarized to determine the direction of quality system improvement.

Article 87 The manufacturer should establish and implement the following procedures:

1. Procedures for investigating product non-conformity, return and customer complaints and taking necessary measures for preventing such problems;
2. Procedures for analyzing processes, manufacturing operations, deviations, quality records and maintenance reports so as to identify and eliminate potential factors leading to non-conforming products;
3. Procedures for taking preventive measures and timely handling various problems that may lead to quality risks;
4. Procedures for taking suitable management measures to ensure efficient implementation of deviation correction plans;
5. Procedures for timely performing revision and approval of procedures after taking deviation correction measures.

Chapter XIII Appendix

Article 88 Definitions and glossaries in this GMP guideline:

Batch/lot: A defined quantity of raw material, intermediate material, packaging components, or final product produced in a process or series of processes so that it can be expected to be homogeneous. In the case of continuous processes, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.

Batch number/lot number: A distinctive combination of numbers and/or letters from which the complete history of the manufacture, processing, packing, coding and distribution of a batch can be determined.

Controlled documents: a component of the quality system, i.e. documents are approved， distributed and followed by the quality department and implemented by each department of the manufacturer for the purpose of efficient operation of the quality system.

Batch process: A manufacturing process that produces the excipient from a discrete supply of raw materials that are present before the completion of the reaction.

Batch records: Documentation that provides the history of a batch from the raw material stage to completion of the batch.

Preventive maintenance: planned maintenance, i.e. maintenance activities performed periodically according to equipment characteristics and running performance to prevent faults of the equipment in operation.

Commingling: The blending of trace carryover material from one grade or batch with another usually during batch alternating manufacturing or continuous processing.

Continuous process: a manufacturing process that continually produces material from a continuing supply of raw material.

Critical process: manufacturing process procedures that directly influences quality attributes.

Cross contamination: contamination of a raw material, intermediate or excipient product with another raw material, intermediate or excipient product during production.

Customers: includes users, intermediate traders, agents and other organizations involved in the supply chain for the pharmaceutical excipients.

Homogenous material: Material of uniform consistency and composition throughout a batch.

Model product: product that can represent a group of similar products with respect to composition, functionality or quality standard/specification.

Reprocessing: Introduction of previously processed materials that did not comply with standards or specifications back into the original process and repeating one or more necessary procedures of the routine manufacturing process.

Reworking: Introduction of processing previously processed materials that did not comply with standards or specifications back into the procedures different from the original process.

Standard operating procedures: written procedures approved for performing specific operation.

Validation: a documented program that provides a high degree of assurance that a specific process, method or system will consistently produce a result meeting predetermined acceptance criterion.

The person in charge of validation: person authorized by the manufacturer to take the responsibility for validation. **The person in charge of validation** may be a person responsible for validation in the project or is the head of validation in quality department or the head of the quality department.

Suppler: An organization contracted to supply a material or perform one or more services.