

Certification Pre-audit Questionnaire

Responses strictly confidential

INSTRUCTIONS: Please complete all sections of this questionnaire. Leave no section blank; if the item does not apply, say "not applicable" or "none". If the site produces excipients that require the use of different equipment, raw materials, or testing, please complete section 5 (Process Overview) and any other applicable sections for each differing excipient grade or type. Complete information will facilitate our audit of the facility and can result in a lower assessment cost.

| 1 Site Details | | | |
|---|---|-------------------------------------|-------------------------------------|
| A Name and address of the manufacturing location: | | | |
| B What is the size of the excipient production facility? | | | |
| C Are all excipient operations conducted within the manufacturing site? | | | |
| D Does this facility produce any types of the following bulk materials? (check those applicable) | <input type="checkbox"/> Penicillin | <input type="checkbox"/> Cytotoxics | <input type="checkbox"/> Hormones |
| | <input type="checkbox"/> Cephalosporine | <input type="checkbox"/> Steroids | <input type="checkbox"/> Pesticides |
| 2 Organization and Personnel | | | |
| A Number of employees at this site | | | |
| B Number of employees in production (all operations) | | | |
| C Number of employees in the quality unit (QA, QC, etc.) * Please provide a copy of the organization chart showing the reporting relationship of the quality unit. | | | |
| D Language spoken by employees | | | |
| E Language of work instructions, procedures, and other documents | | | |
| 3 Excipient Information | | | |
| A What is the excipient: | Monograph Name: | Chemical Name: | Name under which it is sold: |
| B How long has the site been producing this material for the pharmaceutical industry? | | | |
| C Is the manufacture of the excipient certified to ISO 9001? | | | |
| <i>If you answered Yes, please list the name of the ISO certifying authority:</i> | | | |
| D Please list any other certifications that reflect upon the quality system or excipient. | | | |
| E Please provide an index of the procedures and work instructions pertaining to the excipient being certified. | | | |

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| F What other products or product lines are made at the site? | | | |
| G Are reevaluation or shelf life dates assigned to the excipient? If so, what is the time interval? | | | |
| H Are excipient retain samples kept? | How long are they kept? | What conditions are they stored under? | |
| 4 Regulatory Information | | | |
| A Please list the date of the last excipient regulatory inspection (if any) and the name of the agency. | | | |
| B For the excipient, do you have a: | U.S. Drug Master File? | Certificate of Suitability ¹ ? | Other regulatory filing? (If so, list the name of the agency) |
| 5 Process Overview | | | |
| A Is there a process flow diagram? If one is available please provide a copy. (This diagram should clearly indicate the point at which full excipient GMPs are applied.) | Please list or indicate on the diagram any critical processing equipment | Please list or indicate on the diagram any in-process sampling | |
| B Is water used in the process? | If so, what type of water is used (non-drinking, potable, deionized, etc.)? | | |
| C Is the excipient manufactured using a batch or continuous process? | | | |
| <i>If a combination of batch and continuous processing, please indicate on the flow diagram or describe where the process is continuous.</i> | | | |
| <i>How is an excipient lot or batch defined?</i> | | | |
| <i>Please provide a description of the lot numbering system with explanation of the coding.</i> | | | |
| D Is the equipment dedicated to the manufacture of the excipient and its related non-pharmaceutical grades? If not, what other types of materials are manufactured in this equipment? | | | |
| E Are there any subcontractors or other company locations used in the manufacture of the excipient such as for: If so, please list the type of operation, subcontractor name, and their location. | Quality Control testing: | | |
| | Packaging: | | |
| | Warehousing: | | |

¹ A document issued by the EDQM either relating to a European Pharmacopoeia monograph, or excipient BSE/TSE requirement. Completed form can also be mailed or faxed to the attention of: IPEA/Office Manager, 1655 N. Ft. Myer Drive, Suite 700, Arlington, Virginia, 22209 Fax: (703) 525-5157. Call with any questions, (703) 351-5266