

## Requirements for Certification

Applicants must meet the following requirements for Excipient GMP Conformance Certification:

1. Have an established GMP quality system with documents that describe its operation and records that show conformance,
2. Assure the necessary arrangements for the conduct of the site audit, including the availability of documentation and access to all areas, records, and personnel for the purpose of evaluating the site for conformance,
3. Agree to notify IPEA of changes that may affect their quality system,
4. Agree to use the IPEA Certificate and Mark only in relation to the Quality System and not to infer the certification extends to the quality of the excipient. Proper use of the IPEA Certificate or Mark includes:
  - a. Public display of the original,
  - b. Photocopied in its entirety for display or to handout, and
  - c. Reproduced in its entirety for newsletters, advertisement, etc.

Examples of the inappropriate use of the Certificate or Mark are to indicate that certification:

- a. Assures the quality of the excipient.
  - b. Establishes that the excipient has met the specified requirements of a compendial monograph.
  - c. Establishes that the excipient quality is as stated in the Certificate of Analysis.
  - d. Extends beyond the scope listed on the certificate.
5. Agree to make payment of all fees related to the assessment as stipulated by the Certification Agreement.