

STANDARD OPERATING PROCEDURE
International Pharmaceutical Excipients Auditing, Inc.

Title Certification Agreement		Revision 0	SOP Number 28
Originator Irwin Silverstein	Approved By IPEA Management Committee	Effective Date July 7, 2011	Page Page 1 of 2

PURPOSE:

The content of the agreement to be executed between IPEA and the applicant relevant to conformance certification is governed by this procedure.

SCOPE:

The procedure describes the additional contractual provisions of an agreement that are relevant to Excipient GMP Conformance Certification.

RESPONSIBILITIES:

1. **IPEA Executive Management:** Assure the IPEA Certification Agreement contains the provisions discussed herein.

REFERENCES:

1. Policy 3, Requirements for Certification
2. Policy 4, Applicants Rights and Duties
3. SOP 11, Conflict of Interest
4. SOP 16, Appeals, Complaints, and Disputes
5. SOP 22, Confidentiality
6. SOP 25, Authorized Use of the Certificate and Mark

DEFINITIONS:

1. **Applicant:** The excipient manufacturer or distributor who is requesting certification of their site for substantial conformance to The Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients.

PROCEDURE:

1. The agreement between IPEA and the applicant for Excipient GMP Conformance Certification contains the following provisions for the applicant:
 - a. Notify IPEA of the receipt of any adverse regulatory actions such as U.S. FDA form 483 or Warning Letter.
 - b. Notify IPEA of any change in:
 - i. Ownership of the applicant site. The applicant will provide IPEA with a description of the relationship between the original owner and the new owner.
 - ii. Management at the applicant site concerning leadership of the Quality Unit up to the individual with overall responsibility for the site. The applicant will also notify IPEA of any change in whom the site head of the Quality Unit reports to above site.
 - iii. Organizational structure affecting the applicant site related to any department with responsibility for conformance to Excipient GMP.
 - c. Conform with the rules defined by IPEA as disclosed in:
 - i. Policy 3
 - ii. Policy 4

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- d. Comply with SOP 25
- 2. The agreement establishes the following rights for the applicant in the agreement:
 - a. Compliance with the rights afforded the applicant in Policy 4.
 - b. Compliance with SOP 11 concerning conflict of interest
 - c. Compliance with SOP 22 concerning confidentiality
 - d. Allow for appeals as established in SOP 16

HISTORY OF REVISIONS

Revision No.	Effective Date	Description of Changes
0	July 7, 2011	New Procedure