

STANDARD OPERATING PROCEDURE
International Pharmaceutical Excipients Auditing, Inc.

Title Confidentiality		Revision 1	SOP Number 22
Originator Irwin Silverstein	Approved By IPEA Management Committee	Date Approved March 25, 2011	Page Page 1 of 2

PURPOSE:

This procedure establishes the handling and protection of confidential information provided by the applicant.

SCOPE:

All documents provided by the applicant and information gathered for the purpose of evaluating the applicant for conformance to excipient GMP are to be treated as confidential information unless the applicant indicates otherwise.

RESPONSIBILITIES:

1. **IPEA Employees and Contractors:** Employees and contractors protect applicant confidential information as instructed herein.

REFERENCES:

1. **IPEA Auditor Agreement**

DEFINITIONS:

See Glossary

PROCEDURE:

1. IPEA handles applicant confidential information using the same degree of care, but no less than a reasonable degree of care, as IPEA uses to protect its own confidential information.
2. Applicant confidential information used solely for the Excipient GMP Conformance Certification is kept confidential for ten (10) years from the date the information was provided to IPEA.
3. IPEA protects all applicant confidential information such as data, documents, records, and other materials whether disclosed in writing, electronically, or orally and whether marked or identified as confidential or proprietary relating to Excipient GMP Conformance Certification. Such information is not used or disclosed to any third party other than in connection with the performance of certification.
 - a. Confidential information does not include and the duty of confidentiality and nonuse does not apply to any information which:
 - i. Is or becomes public information through no breach by IPEA,
 - ii. Was in the possession of IPEA at the time of disclosure,
 - iii. Is furnished to IPEA by a third party without restriction on disclosure, or
 - iv. Is developed by IPEA outside the scope of Excipient GMP Conformance Certification and without access to the applicant's confidential information.

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- v. Indicates any activity or situation that is a significant risk to consumers or that is a significant departure from good manufacturing practices at the facility.
- b. If required by law, regulation or order, confidential information received may be disclosed by IPEA to a court of law or other governmental agency provided that:
 - i. The confidential information is indicated as belonging to the applicant, and
 - ii. If reasonably possible, applicant is provided with an opportunity to contest such disclosure and/or obtain a protective order or other similar protection. IPEA will provide reasonable assistance as requested by the applicant in support of such efforts.
- 4. The IPEA Auditor Agreement instructs the auditor and other contract employees on the handling of confidential information.
- 5. The application for Certification and the audit report are confidential information. The audit report is only made available for sale after the site has been certified.
- 6. Any information that IPEA and the applicant agree is confidential are treated as confidential information.

HISTORY OF REVISIONS

Revision No.	Effective Date	Description of Changes
0	Mar 13, 2009	New Procedure
1	March 25, 2011	Added reference to the IPEA Auditor Agreement