

**STANDARD OPERATING PROCEDURE**  
**International Pharmaceutical Excipients Auditing, Inc.**

|  |  |                                       |                         |
|--|--|---------------------------------------|-------------------------|
| Title<br><b>Authorized Use of the Certificate and Mark</b> |  | Revision<br><b>1</b>                  | SOP Number<br><b>25</b> |
| Originator<br>Irwin Silverstein                            | Approved By<br>IPEA Management Committee | Effective Date<br><b>May 24, 2011</b> | Page<br>Page 1 of 4     |

**PURPOSE:**

This procedure establishes the provisions of use of the IPEA Certificate and Mark and illustrates uses that are not permitted.

**SCOPE:**

This procedure applies to use of the IPEA Mark and Excipient GMP Conformance Certificate.

**RESPONSIBILITIES:**

1. **Vice President and Chief Operating Officer (COO):** The COO assures that the applicant is notified promptly of the inappropriate use of the Certificate or Mark.

**REFERENCES:**

1. ISO/IEC Guide 23
2. Form 11, IPEA Certificate
3. SOP 16, Appeals, Complaints, and Disputes

**DEFINITIONS:**

1. **See the Glossary**

**PROCEDURE:**

**I. Certificate**

1. The Certificate provided to the certified applicant indicates:
  - a. Date of Certification,
  - b. Recertification date,
  - c. Recertification due date,
  - d. Certificate issue date,
  - e. Certificate number,
  - f. Name and address of the applicant site or sites,
  - g. Excipient or excipients that are covered by the certification,
    - i. The excipient names listed are preferably both their compendial monograph name and the trade name. Where a range of grades of the excipient are certified, the listing must correspond to all specifications for the grades certified.
  - h. The scope of the operations covered by the Certification,
    - i. Unless otherwise stated on the certificate, the scope is taken to mean all operations from the point where GMP begins through to warehousing and shipping from the site.
    - ii. Exclusions are to be noted on the certificate.
  - i. The statement “The excipients certified are produced in substantial conformance to the IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients [dated]”, and
  - j. IPEA Name and Address and certification mark.

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2. Proper use of the IPEA Certificate 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.
3. Examples of the inappropriate use of the certificate 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.
4. The IPEA listing of certified applicants on the IPEA website contains:
  - a. Applicant name,
  - b. Certificate number,
  - c. Location of the site or sites covered by the Certificate,
  - d. List of excipients covered by the Certificate,
  - e. Any exclusion noted in I.1.h.ii.
5. If the scope of the certification is changed, the applicant replaces the certificate with the updated certificate wherever the certificate has been displayed or published.
6. Upon withdrawal of certification, the applicant must discontinue use of the certificate wherever it is displayed or published.



## II. IPEA Mark

7. The IPEA Mark may be used by a certified organization only on the organization's stationery, brochures, literature, and advertising. Where the mark is used on labeling, the Mark must be accompanied by the statement "Certified Quality System" in a font size no smaller than 8 point.
8. The Mark may only be reproduced:
  - a. In its native color of maroon and red or in black and white,
  - b. In a size that makes the mark recognizable, and
  - c. Without distortion to its dimensions.
9. The IPEA Mark may not be used on a product without the statement "Certified Quality System" in a font size no smaller than 8 point, or in such a way as to suggest that IPEA has certified or approved the excipient, process, or service of the applicant or in any other misleading manner.

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- a. Where the scope of the certification includes exclusions, those exclusions must be clearly stated along with the Mark.
- 10. If the scope of the certification is reduced, the applicant amends all uses of the mark.
- 11. Upon withdrawal of certification, the applicant must discontinue within 30-days use of all materials that contain any reference to IPEA such as letterhead, labeling, and in any medium, including electronic media and Web sites. If after 30-days the applicant has continued use of these materials, IPEA contacts the site representative to request they cease their use. If after a second 30-day interval the applicant has not discontinued use of these materials.
  - a. Excipient produced prior to withdrawal of certification and in control of the manufacturer can continue to be offered for sale with the IPEA Mark, if the Mark has been used in compliance with this procedure.
- 12. IPEA notifies applicants when their use of the IPEA Mark contains incorrect references to certification status or is used in a misleading manner. The applicant either discontinues such use or can appeal (see SOP 16).

**HISTORY OF REVISIONS**

| <b>Revision No.</b> | <b>Effective Date</b> | <b>Description of Changes</b>       |
|---------------------|-----------------------|-------------------------------------|
| 0                   | <b>May 15, 2009</b>   | New Procedure                       |
| 1                   | <b>May 24, 2011</b>   | Updated with new Certification Mark |

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***Certificate of Excipient GMP  
Conformance***

**B u s i n e s s   N a m e   a n d  
A d d r e s s**

*This Certificate applies to  
the following excipients:*

Certificate Number:  
Date of Certification:

Recertification Date:  
Recertification Due Date:

The excipients certified are produced in substantial conformance to the IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients [dated] through warehousing and

***IPEA***  
***1655 N. Fort Myer***  
***Drive***

Signature

Date

***Date Issued***

