MEMORANDUM

TO: Joint Committee on Pharmaceutical Excipients

FROM: Brian Zamora, Chairperson

DATE: September 18, 2014

SUBJECT: Proposed revision to NSF/ANSI 363 – Good Manufacturing Practices for Pharmaceutical Excipients (363i1r7)

Draft 7 of NSF/ANSI 363 issue 1 is being forwarded to the Joint Committee for balloting. Please review the changes proposed to this standard and submit your ballot by October 2, 2014 via the NSF Online Workspace.

Purpose

The purpose of this ballot is revise section 8.2.4.5 to create better clarification.

Background

In a recent ballot of NSF 363 it was suggested that the document could be enhanced to create better clarification.

If you have any questions about the technical content of the ballot, you may contact me in care of:

Chairperson, Joint Committee
c/o Rachel M. Brooker
Joint Committee Secretariat
NSF International
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NSF/ANSI Standard for Pharmaceutical Excipients –

8 Measurement, analysis and improvement

8.2 Monitoring and measurement.

8.2.4 Monitoring and measurement of product

8.2.4.5 Certificates of analysis

The organization shall provide Certificates of Analysis to the required specification for each batch of excipient.

The Certificate of Analysis shall include, at a minimum:

a) excipient name (trade name), and, if applicable, grade, and compendial name and compendial reference, or reference to the excipient specification;

b) organization’s name and identity of the site of manufacture. If the site of manufacture is not detailed on the Certificate of Analysis then this information shall be communicated separately;

c) date of manufacture;

d) batch number;

e) expiration date or retest date, and, if previously retested, the date it was retested;

Reason: Changed suggested by J.Brambora in the 9/11/14 ballot
f) statement of conformance to the required specification;

g) statement of compliance to GMP as defined by this Standard (may be otherwise communicated with the customer);

h) analytical results representative of the batch\(^1\), otherwise the basis of the results shall be communicated to the customer, (see NOTE below for alternatives to finished excipient testing, as appropriate);

Reason: Removing for better clarification. (Suggested by S. Wolfgang in the 9/11/14 ballot)

i) acceptance criteria;

j) reference to the analytical method used; and

k) name and title of person whose signature appears on the Certificate of Analysis.

NOTE – See guidance as provided by the IPEC Americas® Certificate of Analysis Guide for Bulk Pharmaceutical Excipients.

\(^1\) A supplier may provide results on the CoA from a method that has been demonstrated to be either equivalent or better than the specified method. See PQRI joint position paper on control strategies. [http://www.pqri.org/pdfs/Excipient_Position_Paper_Final_06212007.pdf](http://www.pqri.org/pdfs/Excipient_Position_Paper_Final_06212007.pdf)