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Joint Committee on Pharmaceutical Excipients

March 20, 2024

**Proposed revision to NSF/IPEC/ANSI 363 – Pharmaceutical Excipients (363i16r1)**

Revision 1 of NSF/IPEC/ANSI 363, issue 16 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by April 10, 2024** via the NSF Online Workspace.

Please review all ballot materials. When adding comments, please include the section number applicable to your comment and add all comments under one comment number whenever possible. If you need additional space, please use the attached blank comment template in the reference documents and upload online via the browse function.

## Purpose

The proposed revision will update Section 7.1.4.3.

## Background

Clause 7.1.4.3 refers to section 8.4.2 for use of an inert gas whereas the proper reference is 7.1.3.6.

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

Rachel Brooker

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[Note – the recommended changes to the standard which include the current text of the relevant section(s) indicate deletions by use of ~~strikeout~~ and additions by grey highlighting. Rationale Statements are in *italics* and only used to add clarity; these statements will NOT be in the finished publication.]

NSF/IPEC/ANSI Standard
for Pharmaceutical Excipeints –

# Good Manufacturing Practices for Pharmaceutical Excipeints

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## 7 Support

### 7.1 Resources

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#### 7.1.4.3 Controlled environment

Where the risk assessment has identified the need for a controlled environment, it shall be monitored to assure excipient quality is maintained.

Where an inert atmosphere is required, the gas shall be ~~treated as~~ considered a raw material as defined in Section 8.4.2.

If interruptions in the controlled environment occur, the organization shall perform an investigation to document adequate evidence and appropriate rationale to show such interruptions have not compromised the quality of the excipient.

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