

The New Excipient GMP Standard

A Guide for Drugmakers

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A. NSF/IPEC/ANSI 363-2014: Good Manufacturing Practices (GMP) for Pharmaceutical Excipients

- B. EU Falsified Medicines Directive
- C. Food and Drug Administration Safety and Innovation Act (FDASIA)
- D. EU excipient risk assessment guidelines
- E. ICH Q10 Pharmaceutical Quality System guideline