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Annex 4 Supplementary Guidelines On
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Annex 4 Supplementary guidelines on good manufacturing ...
Annex 4 Supplementary guidelines on good manufacturing practices: validation

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Annex 4 91 A written protocol, procedure or programme should be followed, which includes, for example, the activities to be performed, test parameters and acceptance criteria appropriate to the material or product under test. The protocol and report should generally include the following: a title; reference

General guidance on hold-time studies
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Annex 4 153 4.11.2majorA deficiency may be defined as a non-critical observation that: a) has produced or may produce a product that does not comply with its marketing authorization and/or prequalification application (including variations); b) indicates a major deviation from the GMP guide;

Guidance on good manufacturing practices: inspection
Section 4 SUPPLEMENTARY TESTS 4.1 4.1 Earth continuity 4.1 4.2 Electric safety devices 4.2 4.3 Terminal speed reduction systems 4.2 4.4 Landing door interlocks 4.3 4.5 Lift machine 4.3 4.5.1...

Guidelines of supplementary tests of in-service lifts
SUPPLEMENTARY GUIDELINES ON GOOD MANUFACTURING PRACTICES (GMP): VALIDATION CONTENTS page 1. Introduction 4 2. Glossary 5 3. Scope of document 8 4. Relationship between validation and qualification 8 5. Validation 8 5.1. Approaches to validation 8 5.2. Scope of validation 9 6.

SUPPLEMENTARY GUIDELINES ON GOOD MANUFACTURING PRACTICES ...
Annex 2 Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms 45 Annex 3 Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines 85 Annex 4 Supplementary guidelines on good manufacturing practices: validation 107

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1 Supplementary guidelines on good manufacturing practices: validation. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fortieth report. Geneva: World Health Organization; 2006: Annex 4 (WHO Technical Report Series, No. 937).

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Supplementary Guidelines on Regulation of Six Group of ...
Annex 2 Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms 1. Introduction 2. Scope of document 3. Glossary 4. Protection 4.1 Products and personnel 4.2 Air fi ltration 4.3 Unidirectional airfl ow 4.4 Infi ltration 4.5 Cross-contamination

Annex 2 Supplementary guidelines on good manufacturing ...
Annex 4 General guidance on hold-time studies

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Supplementary Appendix This appendix has been provided by the authors to give readers additional information about their work. Supplement to: Cunningham AL, Lal H, Kovac M, et al. Efficacy of the ...

Supplementary Appendix
4. General guidelines for the establishment, maintenance and distribution of chemical reference substances. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fifth report. Geneva, World Health Organization, 1999, Annex 3 (WHO Technical Report Series, No. 885). 5.

The International Pharmacopoeia Eighth Edition ...
ANNEX 8 SAMPLING OF STARTING AND PACKAGING MATERIALS Principle Sampling is an important operation in which only a small fraction of a batch is taken. Valid conclusions on the whole cannot be based on tests which have been carried out on non-representative samples. Correct sampling is thus an essential part of a system of Quality

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WHO Technical Report Series, No. 885, Annex 5, 1999. Supplementary guidelines on g ood manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms (2011) WHO Technical Report Series, No. 961, Annex 5, 2011. Supplementary guidelines on good manufacturing practices: validation (2006)

WHO Technical Report Series | WHO - Prequalification of ...
Annex 4. Examples of indicators for monitoring adaptation actions 88 Annex 5. Sector-based climate change impact chain for agriculture in Thailand 90 ... Supplementary guidelines (NAP–Ag Guidelines), responds to a call issued in 2013 by the Least Developed Countries