Product Service

Submission Form on the completeness of sterilization validation documentation according to EN ISO 11137-1:2006 requirements

(If a specific point cannot be covered, EN ISO 11137 compliance may not be granted. If applicable: An explanation shall be documented how the EN ISO 11137 requirement is covered to meet the state of the art.)

1 General description

Topic	Data	Source of documented evidence	Reference
Product to be sterilized including short description (Product dimension, Packaging configuration, Dimensions) till sterilization tote			ISO 11137-1:2006 7.1 9.3.2, 9.3.8
Product Variations included in the same sterilization cycle or same validation. (Product dimension, Packaging configuration Dimensions)			ISO 11137-1:2006 7.4 9.3.7 9.4.3, 9.4.4
Materials			ISO 11137-1:2006 5.1.2,5.3 7.1

1.1 Validation Approach

Applicable validation method			ISO 11137-1:2006 8.1, 8.2 ISO 11137-2:2007/AC:2009 6

2 Equipment characterization

2.1 Sterilizer etc.

Topic	Data	Source of documented evidence	Reference
Statement on calibration available?			ISO 11137-1:2006 9.1, 9.2, 12.2
Pass mode through the sterilizer, (Transport pathway)			ISO 11137-1:2006 9.3.2

2.2 E-Beam

Topic	Data	Source of documented evidence	Reference
Conveyor speed			ISO 11137-1:2006 9.4.4,9.3.8

3 Microbial Performance qualification

3.1 Bioburden, Endotoxins, cultivation

Topic	Data	Source of documented evidence	Reference
Microbial methods validation, bioburden trending data and maximum amount of bioburden accepted to enter the sterilization process.			ISO 11137-1:2006 7.3 12.1.2 ISO 11137-2:2007/AC:2009 5.4.1, ISO 11737

Bacteriostasis and fungistasis investigated?			ISO 11737-1:2006 6.1.2 ISO 11737-2:2009 6.6
Bioburden recovery factor is applicable, frequency on bioburden determination.			ISO 11137-1:2006 12.1.1, 12.1.2
Size of SIP (Sample Item Proportion)			ISO 11137-2:2007/AC:2009 5.2

3.2 PCD/Worst case Product

Topic	Data	Source of documented evidence	Reference
used full load of worst case product			ISO 11137-1:2006 9.3.2, 9.3.8, 9.4.3, 9.4.4

3.3 Dose Verification Experiment

Topic	Data	Source of documented evidence	Reference
average bioburden			ISO 11137-1:2006 12.1.1, 12.1.2 ISO 11137-2:2007/AC:2009 6
Were three different lots with 10 products each tested for bioburden?			ISO 11137-2:2007/AC:2009

4 Physical Performance Qualification

4.1 Dose Mapping

Topic	Data	Source of documented evidence	Reference
PQ location of min max Dose available?			ISO 11137-1:2006 9.3.1,9.3.8
Orientation of load described?			ISO 11137-1:2006 9.3.2, 9.3.8, 9.4.3, 9.4.4
D_{min} D_{max} ratio			ISO 11137-1:2006 9.3.1, 9.3.8, 9.4.3, 9.4.4

4.2 Sensory system

Topic	Data	Source of documented evidence	Reference
What Dosimeters were used? Type / accuracy / transfer / calibration?			ISO 11137-1:2006 4.3.4