Product Service

Submission Form on the completeness of sterilization validation documentation according to EN ISO 17665-1:2006 requirements

(If a specific point cannot be covered, EN ISO 17665-1 compliance may not be granted. If applicable: An explanation shall be documented how the EN ISO 17665-1 requirement is covered to meet the state of the art.)

1 General description

Topic	Data	Source of documented evidence	Reference
Type of process			E.1, E.2, E.3, E.3.2, E.3.3
Product to be sterilized including short description (Product dimension, packaging configuration, dimensions)			7.1 6.1.3a
If saturated steam process: Any restrictions of steam penetration due to design or material? Is a steam penetration test necessary? If applicable: Is it tested every day before use of the sterilizer?			6.1.1c, 6.1.2, 12.1.6, E.1.1 E.2,

1.1 Validation Approach

Validation approach according to equivalence consideration?			8.10
What type of cycle validation approach was used (e.g minimum cycle according to			8.11 9.4.5, 5.2, 8.11

Eu.pharm?, half cycle approach/overkill, fractional cycle approach, F0 approach, bioburden related)			

2 Equipment characterization

2.1 Sterilizer etc.

Topic	Data	Source of documented evidence	Reference
If applicable: Name of preconditioning Chamber			6.2, 9 .4.1
If applicable: Type			6.2, 9 .4.1

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.			7.9 maximum bioburden, 7.10, 8.12, 9.5.2, 12.1.3, 12.1.4, 12.1.7 EN ISO 11737-1, EN ISO 11737-2

3.2 BIs (if applicable)

Topic	Data	Source of documented evidence	Reference
organism			6.1.1m, 8.5, D.4.3
lot code			6.1.1m

3.3 PCD/BI (if applicable)

Topic	Data	Source of documented evidence	Reference
Used full load of worst case product (size, orientation, support system etc.)			6.1.1j, 6.1.2e, 6.1.3, 9.5.2,

3.4 Short cycle (if applicable)

Topic	Data	Source of documented evidence	Reference
If BI/bioburden based method: Where 3 runs performed and did some BI survive? Calculation of the D-value provided? Relation natural bioburden to BI resistance known?			C 2.5, C 2.6, C2.7, C2.8

4 Physical Performance Qualification

4.1 Cycle Description and Data

Cycle Name:							
minimum cycle parameter	**Set-point/ tolerances**	**Data PPQ cycle1**	**Data PPQ cycle2**	**Data PPQ cycle3**	**Data MPQ cycle1**	**Data MPQ cycle2**	**Data MPQ cycle3**
Sterilization							
Min and Max Pressure allowed in an empty Chamber incl. fixed parts 6.1.1.f	*mbar±mbar*						
At plateau period (9.4.4e):							
Temperature at the reference measuring point (9.4.4e)	*°C±°C*						
Temperature within the load (9.4.4e)	*°C±°C*						

(6.1.1,8.1, 9.4, 9.5.2 If any data is out of tolerance or tolerance is set to an infinite value for the limits - a deviation will be assigned regarding PPQ process reliability/robustness)

4.2 Additional data for saturated steam process (if applicable)

Cycle Name:							
minimum cycle parameter	**Set-point/ tolerances**	**Data PPQ cycle1**	**Data PPQ cycle2**	**Data PPQ cycle3**	**Data MPQ cycle1**	**Data MPQ cycle2**	**Data MPQ cycle3**
Sterilization							
If product is affected: Maximum water content suspended in saturated steam entering the Chamber 6.1.2d	*ml/L±ml/L* *ml/m^3± ml/m^3*						
Holding time:	*Min±min*						

10.5, 9.5.2							
Description and frequency of Steam penetration test 6.1.2c, 10.3d, EN 285 17							

(6.1.2, 8.1, E.1, E.2 9.5.2 If any data is out of tolerance or tolerance is set to an infinite value for the limits - a deviation will be assigned regarding PPQ process reliability/robustness)

4.3 Additional data for contained product (if applicable)

Cycle Name:							
minimum cycle parameter	**Set-point/ tolerances**	**Data PPQ cycle1**	**Data PPQ cycle2**	**Data PPQ cycle3**	**Data MPQ cycle1**	**Data MPQ cycle2**	**Data MPQ cycle3**
Heating							
Position of the reference measurement point and how reference sensor if applied (e.g. in the simulated product/PCD?) 6.1.3e 10.6a							

6.1.3, 8.1, 9.5.2 If any data is out of tolerance or tolerance is set to an infinite value for the limits - a deviation will be assigned regarding PPQ process reliability/robustness)

4.4 Sensory system

Topic	Data	Source of documented evidence	Reference

Load configuration			9.5.2
Description of the location of reference measurement point:			6.1.1e

5 Revalidation criteria and maintenance

Topic	Data	Source of documented evidence	Reference
Criteria for revalidation			12.4, 12. 10.3e, 10.4

6 Routine release

Topic	Data	Source of documented evidence	Reference
Product release using biological indicators?			11 6.1.1
Parametric release?			11 6.1.1