



Product Service

Submission Form on the completeness of packaging validation documentation according to EN ISO 11607-1 and -2 requirements

(If a specific point cannot be covered, EN ISO 11607 compliance may not be granted. If applicable: An explanation shall be documented how the EN ISO 11607 requirement is covered to meet the state of the art.)

1 General description

Topic	Data	Source of documented evidence	Reference
Manufacturing place of product			
Name of product and product description:			EN ISO 11607-1:2009 5.1 EN ISO 11607-2:2006 6.3,7, EN ISO 11607-2:2006 5.3
description step by step how the packaging system is assembled: <ul style="list-style-type: none">- packaging configuration including amount of products included in each packaging (e.g. in a single pack, in a shelf box, in a shipment box)- Description of the sterile barrier packaging (including packaging materials and supplier),			EN ISO 11607-1:2009 5.1 EN ISO 11607-2:2006 6.3,7, EN ISO 11607-2:2006 5.3



Product Service

including sealed length and seal width			
--	--	--	--

1.1 Validation Approach

What is the rationale of the chosen methods used to show EN ISO 11607 compliance?			EN ISO 11607-1:2009 4.4.2, 6.3.3 6.3.5
---	--	--	---

1.2 Packaging design

Is the material evaluated in relation to the sterilization conditions? (Including microbial barrier properties after shelf life)			EN ISO 11607-1:2009 5.3, 6, 7
How is aseptic handling of the product assured?			EN ISO 11607-1 6.2.2
How shall the packaging system be distributed (Truck, airfreight...)?			EN ISO 11607-1 5.5 6.2.3, 7

1.3 Routine packaging process

Description of the sequence of manufacturing steps for each seal of the packaging			EN ISO 11607-1 5.1.3 5.1.4 EN ISO 11607-2:2006 6.3
What are the routine sealing parameters and tolerances of each packaging equipment involved in the manufacturing of this product (e.g. temperature, pressure, speed etc.)			EN ISO 11607-1 6.3.4, 5.1.3 EN ISO 11607-2:2006 5.4.5 5.6.1



Product Service

2 Packaging process Validation

2.1 OQ

Topic	Data	Source of documented evidence	Reference
What is the statistical approach for OQ, including sampling strategy? Does the sampling strategy include/consider each applicable individual position of the sealing tool? (e.g. cavity, longitudinal and cross sectional seal)			EN ISO 11607-1:2009 4.3 5.3 EN ISO 2859-1 or EN ISO 186 EN ISO 11607-2:2006 4.2
What sealing parameters to what ranges were tested to assess worst case tolerances of the routine production?			EN ISO 11607-2:2006 4.3 5.3 EN ISO 11607-1:2009 Annex B

2.2 PQ

Topic	Data	Source of documented evidence	Reference
What is the statistical approach for PQ, including sampling strategy? Does the sampling strategy include/consider each applicable individual position of the sealing tool? (e.g. cavity, longitudinal and cross sectional			EN ISO 11607-2:2006 4.2



Product Service

seal)			
-------	--	--	--

3 Packaging system design validation

(packaging produced by a/in a validated process?)

3.1 Testing after sealing and sterilization

Topic (Pouch inspection)	Data	Source of documented evidence	Reference
Was a visual inspection (continuity, seal width, packaging specification compliance) performed? Acceptance criteria defined (Standard/procedure, conditions for inspection specified)?			EN ISO 11607-1:2009 5.1 5.4 11607-2:2006 5.4.1
Was the seal integrity of the packaging tested? Acceptance criteria defined (Standard)?			EN ISO 11607-1:2009 6.2.2, 6.3.1, 6.3.4

3.2 Packaging system design validation testing after shelf life

Topic	Data	Source of documented evidence	Reference
What conditions were used at ageing of the packaging system			EN ISO 11607-1:2009 6.3.3 6.3.5, 6.4