# 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:<br>- packaging configuration including amount of products included in each packaging (e.g. in a single pack, in a shelf box, in a shipment box)<br>- 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 |

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

## 1.1 Validation Approach

| | | | |
|---|---|---|---|
| What is the rational 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 |

| | | | |
|---|---|---|---|
| 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 |