PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**1. OBJECTIVE:**

To demonstrate that the critical operation involved in container/bottle packing of _____ Tablets/ Capsules, B.No._____, B. Size_____ & Pack Size_____, are capable of consistently packing batch / batches which meet all quality parameters and the limits of acceptance criteria.

**2. JUSTIFICATION FOR SELECTION OF ITEM/ EQUIPMENT/ PROCESS/ PRODUCT/ SYSTEM:**

3. **SCOPE:**

Applicable to container/bottle packing line of XXXX tablets / capsules of XX / XXX count container/bottle.

4. **SITE OF STUDY:_____**

5. **RESPONSIBILITY**:

Representatives from,

Packaging :_____

Quality Assurance :_____

Engineering :_____

6. **** SOP AND BPR TO BE FOLLOWED:**

Master Batch Packing Record of Manufacturing Code: ,
Pack Code: _____ and Version No._____

6.1 SOP for Bottle un-scrambler and cleaning machine, SOP No.: _____

SOP for Tablet/Capsule Counting Machine, SOP No.: _____

SOP for Tablet/Capsule count verification Machine, SOP No.: _____

SOP for Silica gel bag insertion machine, SOP No.: _____

SOP for Cotton insertion machine, SOP No.: _____

SOP for weighing balance, SOP No.: _____

SOP for Capping Machine, SOP No.: _____

SOP for Bottle un-scrambler and cleaning machine, SOP No.: _____

SOP for Tablet/Capsule Counting Machine, SOP No.: _____

SOP for Bottle un-scrambler and cleaning machine, SOP No.: _____

SOP for Tablet/Capsule Counting Machine, SOP No.: _____

SOP for Tablet/Capsule count verification Machine, SOP No.: _____

SOP for Silica gel bag insertion machine, SOP No.: _____

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

SOP for Cotton insertion machine, SOP No.: _____

SOP for weighing balance, SOP No.: _____

SOP for Capping Machine, SOP No.: _____

SOP for Torque Testing Apparatus, SOP No.: _____

SOP for Induction Sealing Machine, SOP No.: _____

SOP for Bottle un-scrambler and cleaning machine, SOP No.: _____

SOP for Tablet/Capsule Counting Machine, SOP No.: _____

SOP for Tablet/Capsule count verification Machine, SOP No.: _____

** Machines as applicable to individual products should be mentioned.

**CONTROLS**:

** Qualification and Calibration details of machine:

| Equipment Name | Code No. | Qualification done on | Calibration done on | Calibration due on |
|---|---|---|---|---|
| Bottle un-scrambler and cleaning machine | | | | |
| Tablet/Capsule Counting Machine | | | | |
| Tablet/Capsule Count Verification Machine | | | | |
| Silica gel bag insertion machine | | | | |
| Cotton insertion machine | | | | |
| Weighing balance | | | | |
| Capping Machine | | | | |
| Torque Testing Apparatus | | | | |

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

| Equipment Name | | Code No. | Qualification done on | Calibration done on | Calibration due on |
|---|---|---|---|---|---|
| Induction Sealing Machine | % Power display | | | | |
| | Conveyer speed display | | | | |
| Leak test Apparatus | Timer | | | | |
| | Vacuum Indicator | | | | |
| Retorquer Machine | | | | | |
| Sticker labeling Machine | | | | | |
| Problue adhesive melter machine | | | | | |
| Leaflet (Pack insert) placement machine | | | | | |
| Cartonator | | | | | |
| Print check system | | | | | |
| Shrink wrapping machine | | | | | |
| Checkweigher | | | | | |
| Shipper sealing machine | | | | | |
| Shipper strapping machine | | | | | |
| Shipper weighing balance | | | | | |

** Machines as applicable to individual products should be mentioned.

**Identify each sampled container/bottle with interval no., date and time**

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

****Packing materials/ components :**

| Packaging Configuration | Item Code | Item Name | Description |
|---|---|---|---|
| xx- Count Container/bottles | | Container/bottle | |
| | | Cap | |
| | | Silica gel bag | |
| | | Cotton / Rayon Sani coil | |
| | | Sticker label | |
| | | Pack insert | |
| | | Patient information leaflet / Medication pad | |
| | | Inner Carton | |
| | | Outer carton | |
| | | Shipper | |
| | | Strap | |
| Xxx -Count Container/bottles | | Container/bottle | |
| | | Cap | |
| | | Silica gel bag | |
| | | Cotton / Rayon Sani coil | |
| | | Sticker label | |
| | | Pack insert | |
| | | Patient information leaflet / Medication pad | |
| | | Inner Carton | |
| | | Outer carton | |
| | | Shipper | |
| | | Strap | |

** Packing materials/ components as applicable to individual product should be mentioned.

**Training:**

| Name | Training reports availability | Status |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

**Precautions:** Safety aspects while operation of equipment and process should be ensured.

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

## VALIDATION PROCEDURE:

Note : Draw samples at frequencies given for individual test. Ensure sample is taken at the end of batch run also. In case of small batch size, ensure that minimum 3 intervals at start, middle and end at optimum batch run are considered for sample collection.

Speed setting of container/ bottle packing line will change as per the count, container/ bottle size and shape and tablet / capsule size and shape.

Same marked container/ bottle and cap (if applicable for that test) should be used throughout the batch for the following tests :

- No foil sensor challenge test
- Label absence challenge
- Functioning of Checkweigher

Upon completion of the above tests, the container/ bottle and cap (if applicable for that test) should be destroyed and recorded in the packing material reconciliation and destruction.

Batch packing should be carried out as per BPR :

Validation should be done as per validation protocol no. _____
Version no.:_____

| | | |
|---|---|---|
| Date(s) of Validation | | |
| Batch No. | | |
| Batch size (Tablets /Capsules) | | |
| Quantity to be packed (containers/bottles) | | |
| Fill count (Tablets /Capsules) | | |
| Container/bottle | Size | |
| | Code No. | |
| Cap | Size | |
| | Code No. | |

Packing process flow diagram : As per reference protocol no. :_____
Version no.:

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**SLOW SPEED SETTING:**

Set up parameters for slow speed
Equipment Setting time from _____to_____

| Date | Equipment Name | Speed Container/bottles per Minute | Done by | Checked by |
|---|---|---|---|---|
| | Tablets/capsule counting machine | Slow speed: | | |
| | Silica gel bag insertion machine | | | |
| | Cotton insertion machine | | | |
| | Capping machine | | | |
| | Induction Sealing machine | | | |
| | Retorquer machine | | | |
| | Sticker Labeling machine | | | |
| | Problue adhesive melter machine | | | |
| | Leaflet placement machine | | | |
| | Checkweigher | | | |
| | Cartonator (if applicable) | | | |
| | Print check system | | | |

Note : Write NA wherever not applicable

**Conduct following test on slow speed setting :**

** **Note:** Upon completion of the physical testing, container/bottles and tablet/ capsule used for nondestructive testing should be returned to the line officer for verification and addition to packing line /repacking.

**Fill Count**:**

| Sampling Time | Containers/Bottles | | | | | | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Side A1 | Side B1 | Side A2 | Side B2 | Side A3 | Side B3 | Side A4 | Side B4 | Side A5 | Side B5 | |
| | | | | | | | | | | | |

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Silica gel bag** **:

| **Sampling Time** | **Containers/bottles** | | | | | | | | | | **Sampled and Checked by** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **1** | | **2** | | **3** | | **4** | | **5** | | |
| | **Quality** | **Qty.** | **Quality** | **Qty.** | **Quality** | **Qty.** | **Quality** | **Qty.** | **Quality** | **Qty.** | |
| | | | | | | | | | | | |

Enter V if acceptable (intact bag) and x if Not acceptable

**Weighing of cotton / rayon sani coil**** :

Weighing balance code no._____ .

| Sampling Time | Containers/bottles | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|
| | 1 (in g) | 2 (in g) | 3(in g) | 4 (in g) | 5 (in g) | |
| | | | | | | |

**Closing and opening torque (for capped container/bottle)**:**

| Sampling Time | Closing torque | | | | | Opening torque | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 (in-lb) | 2 (in-lb) | 3 (in-lb) | 4 (in-lb) | 5 (in-lb) | 1 (in-lb) | 2 (in-lb) | 3 (in-lb) | 4 (in-lb) | 5 (in-lb) | |
| | | | | | | | | | | | |

**No foil sensor challenge:**

| Sampling Time | No foil sensor challenge | Sampled and Checked by |
|---|---|---|
| | | |

For no foil sensor challenge: X Rejected

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Induction sealing :**

**Starting time _____, Completion time :_____**

| | **Sealer Height (Between the induction sealer head and cap of container/ bottle)** | **Induction sealing quality** (5 Containers/ bottles)** | | | | | **Leak Test (containers/ bottles)** | **Checked by** |
|---|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | | |
| **Low conveyor speed:** | | | | | | | | |
| **Low Dower percentage:** | | | | | | | | |
| **Low conveyor speed:** | | | | | | | | |
| **High power percentage:** | | | | | | | | |

**For induction sealing:** Enter √ if acceptable and x if Not acceptable

**Note :** 1. Induction sealing height should be kept constant.
2. After completion of the leak test, container/bottle and cap of each parameter should be destroyed and recorded in the packing material reconciliation and destruction.

**Closing and opening torque (For re-torquing)**:**

| **Sampling Time** | **Closing Torque.** | | | | | **Opening Torque** | | | | | **Sampled and Checked by** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | |
| | | | | | | | | | | | |

**Challenge and quality inspection of labels by vision system :**

| **Challenge time** | **Pharmacode/code No. /issue date verification (label)** | **Overprinting verification (label)** | **Challenged by** |
|---|---|---|---|
| | | | |

Enter X if machine stopped / rejected

**Note :** After completion of test, label or container/bottle with label should be destroyed and recorded in the packing material reconciliation and destruction.

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Quality of label **:**

| Sampling Time | Container Bottles | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | |
| | | | | | | |

Enter √ if acceptable and X if not acceptable.

**Label absence challenge** :

| Challenge time | Containers/Bottles | | | | | Challenged by |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | |
| | | | | | | |

**Inspection of dispensing of hot melt glue on cap**:**

| Sampling Time | Containers/Bottles | | | | | Checked by |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | |
| | | | | | | |

**Position of pack insert (leaflet)**:**

| Sampling time | Container/bottle | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | |
| | | | | | | |

Enter √ if acceptable and X if Not acceptable

**Pharmacode verification of pack insert (leaflet):**

| Challenge Time | Pharmacode verification (Pack insert) | Challenged by |
|---|---|---|
| | | |

Enter X if machine stopped / rejected

**Note:** After completion of pharmacode verification test, pack insert should be destroyed and recorded in packing material reconciliation and destruction.

**Functioning of Checkweigher**

| Challenge Time | Functioning of checkweigher | Challenged by |
|---|---|---|
| | | |

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

Enter √ if acceptable and X if Not acceptable

**Challenge test for carton and pack insert (leaflet) in cartonator**

| In process Time | In process challenge test | | Result | Done by |
|---|---|---|---|---|
| | Challenge test for carton sensor (carton missing) | | | |
| | Challenge test **for** Leaflet sensor (Leaflet missing) | | | |
| | Challenge test for pharmacode of Pack insert (Leaflet) Back side and front side | | | |
| | Challenge test for pharmacode of carton | | | |
| | Visual inspection | Embossing/ overprinting quality on carton | | |
| | | Carton fill value | | |
| | | Carton quality | | |
| | | Pack insert (Leaflet) folding quality | | |

Enter X if machine stopped/rejected.
Enter √ if acceptable and x if Not acceptable.

**Note:** After completion of pharmacode verification test for carton and pack insert (leaflet), the same should be destroyed and recorded in packing material reconciliation and destruction.

**Inspection of defects (AQL inspection, Ref. SOP:_____ ):**
**For Container/bottle filling operation (Sample size (n): 50 Containers/Bottles):**
**Sampling Time:**

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

| Test | Critical AQL: 0.10) Accept: 0 Reject: 1 | Checked By |
|---|---|---|
| Fill count out of range | | |
| Improper Silica gel bag quality | | |
| Improper Cotton / Rayon Sani coil quality | | |
| Incorrect product | | |
| Hazardous foreign material (For example, glass, metal) | | |
| Incorrect component (container/bottle and cap) | | |
| Extraneous foreign material | | |

| Test | Critical AQL: 0.65 Accept: 1 Reject: 2 | Checked By |
|---|---|---|
| Damaged container/bottles and caps | | |
| Closing and opening torque out of range | | |
| Improper capping | | |
| Missing ribs closers/cap | | |
| Missing aluminium layer in cap | | |

| Test | Major AQL: 1.0 Accept: 1 Reject: 2 | Checked By |
|---|---|---|
| Excess powder | | |
| Improper Tablet / Capsule quality | | |

| Test | Minor AQL: 2.5 Accept: 3 Reject: 4 | Checked By |
|---|---|---|
| Scratches on containers/bottles and caps | | |

| Test | Critical AQL: 0.65 Accept: 1 Reject: 2 | Checked By |
|---|---|---|
| Incomplete seal | | |
| Burnt Induction sealing | | |

**For Labeling operation (Sample size (n): 50 container/bottles)**

**Sampling Time:**

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

| Test | Critical AQL: 0.10<br>Accept: 0 Reject: 1 | Checked By |
|---|---|---|
| Incorrect, Missing or Damaged Label | | |
| Incorrect, Missing or Illegible Lot no. | | |
| Incorrect, Missing or Illegible Expiration date | | |
| Incorrect NDC no. | | |
| Missing / Wrong Pack inserts and Patient information leaflet | | |
| Other product labels mix-up | | |

| Test | Major AQL: 2.5<br>Accept: 3 Reject: 4 | Checked By |
|---|---|---|
| Smudging of ink and ink lifting | | |

| Test | Minor AQL: 4.0<br>Accept: 5 Reject: 6 | Checked By |
|---|---|---|
| Non-Conforming Print | | |
| Presence of stains | | |
| Minor Scratches on Label | | |

**** Note:** Upon completion of the physical testing, container/bottles and tablet/ capsule used for non destructive testing should be returned to the line officer for verification and addition to packing line.

**HIGH SPEED SETTING :**

**Set up parameters for high speed**
**Equipment Setting time from_____ to _____**

**Note** : Write NA wherever not applicable

**Conduct following test on high speed setting :**

** **Note** :Upon completion of the physical testing, container/bottles and tablet / capsule used for non destructive testing should be returned to the line officer for verification and addition to packing line.

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

| Date | Equipment Name | Speed Containers/bottles per Minute | Done by | Checked by |
|---|---|---|---|---|
| | Tablets/capsule counting machine | High speed: | | |
| | Silica gel bag insertion machine | | | |
| | Cotton/ Rayon sani coil insertion machine | | | |
| | Capping machine | | | |
| | Induction Sealing machine | | | |
| | Retorquer machine | | | |
| | Sticker Labeling machine | | | |
| | Problue adhesive melter machine | | | |
| | Leaflet placement machine | | | |
| | Checkweigher | | | |
| | Cartonator (if applicable) | | | |
| | Print check system | | | |

**Fill Count**:**

| Sampling Time | Container/bottle | | | | | | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Side A1 | Side B1 | Side A2 | Side B2 | Side A3 | Side B3 | Side A4 | Side B4 | Side A5 | Side B5 | |
| | | | | | | | | | | | |

**Silica gel bag** **:

| Sampling Time | Container/bottle | | | | | | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | | 2 | | 3 | | 4 | | 5 | | |
| | Quality | Qty. | Quality | Qty. | Quality | Qty. | Quality | Qty. | Quality | Qty. | |
| | | | | | | | | | | | |

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

Enter √ if acceptable (intact bag) and x if Not acceptable

**Weighing of cotton / rayon sani coil:**

Weighing balance code no._____ .

| Sampling Time | Container/bottle | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|
| | 1 (in g) | 2 (in g) | 3 (in g) | 4 (in g) | 5 (in g) | |
| | | | | | | |

**Closing and opening torque (for capped container/bottle)**:**

| Sampling Time | Closing torque | | | | | Opening torque | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 (in-lb) | 2 (in-lb) | 3 (in-lb) | 4 (in-lb) | 5 (in-lb) | 1 (in-lb) | 2 (in-lb) | 3 (in-lb) | 4 (in-lb) | 5 (in-lb) | |
| | | | | | | | | | | | |

**No foil sensor challenge:**

| Sampling Time | No foil sensor challenge | Sampled and Checked by |
|---|---|---|
| | | |

For no foil sensor challenge: X Rejected

**Induction sealing :**

**Starting time:_____ , Completion time :_____**

| | **Sealer Height (Between the induction sealer head and cap of container/bottle)** | **Induction sealing quality** (5 Containers/ bottles)** | | | | | **Leak Test ( containers/ bottles)** | **Checked by** |
|---|---|---|---|---|---|---|---|---|
| | | **1** | **2** | **3** | **4** | **5** | | |
| **High conveyor speed:** | | | | | | | | |
| **High power percentage:** | | | | | | | | |
| **High conveyor speed:** | | | | | | | | |
| **Low power percentage:** | | | | | | | | |

**Note :** 1. Induction sealing height should be kept constant.

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

2. After completion of the leak test, container/bottle and cap of each parameter should be destroyed and recorded in the packing material reconciliation and destruction.

**Closing and opening torque (For re-torquing)**:**

| Sampling Time | Closing torque | | | | | Opening torque | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 (in-lb) | 2 (in-lb) | 3 (in-lb) | 4 (in-lb) | 5 (in-lb) | 1 (in-lb) | 2 (in-lb) | 3 (in-lb) | 4 (in-lb) | 5 (in-lb) | |
| | | | | | | | | | | | |

**Challenge and quality inspection of labels by vision system :**

| Challenge time | Pharmacode/ code No. /issue date verification (label) | Overprinting verification (label) | Challenged by |
|---|---|---|---|
| | | | |

**Enter X if machine stopped / rejected**

**Note:** After completion of test, label/Container/bottle with label should be destroyed and recorded in the packing material reconciliation and destruction.

**Quality of label **:**

| Sampling time | Containers/bottles | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | |
| | | | | | | |

Enter √ if acceptable and X if Not acceptable

**Label absence challenge:**

| Challenge time | Containers/bottles | | | | | Challenged by |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | |
| | | | | | | |

Enter X if machine stopped / rejected

**Inspection of dispensing of hot melt glue on cap**:**

| Sampling time | Containers/bottles | | | | | Checked by |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | |

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

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

Enter √ if acceptable and x if Not acceptable

**Position of pack insert (leaflet)**** :

| Sampling time | Containers/bottles | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | |
| | | | | | | |

Enter √ if acceptable and x if Not acceptable

**Pharmacode verification of pack insert (leaflet):**

| Challenge Time | Pharmacode verification (Pack insert) | Challenged by |
|---|---|---|
| | | |

Enter X if machine stopped / rejected

**Note:** After completion of pharmacode verification test, pack insert should be destroyed and recorded in packing material reconciliation and destruction.

**Functioning of checkweigher**:

| Challenge Time | Functioning of checkweigher | Challenged by |
|---|---|---|
| | | |

Enter √ if acceptable and x if Not acceptable

**Challenge test for carton and pack insert (leaflet) in cartonator**

| **In-process time** | **In-process challenge test** | | **Result** | **Done by** |
|---|---|---|---|---|
| | Challenge test for carton sensor (carton missing) | | | |
| | Challenge test for Leaflet sensor (Leaflet missing) | | | |
| | Challenge test for pharmacode of carton | | | |
| | Challenge test for pharmacode of pack insert (leaflet) Back side and front side | | | |
| | Visual inspection | Embossing/ overprinting quality | | |
| | | Carton fill value | | |
| | | Carton quality | | |
| | | Pack insert (leaflet) folding quality | | |

Enter X if machine stopped/rejected. Enter √ if acceptable and x if Not acceptable.

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Note:** After completion of the test, carton and pack insert (leaflet) should be destroyed and recorded in packing material reconciliation and destruction.

**Inspection for defects (AQL inspection):**

**For container/bottle filling operation (Sample size (n): 50 container/bottles, Ref. SOP:_____ )**

**Sampling Time**:

| Test | Critical AQL: 0.10 Accept: 0 Reject: 1 | Checked By |
|---|---|---|
| Fill count out of range | | |
| Improper Silica gel bag quality | | |
| Improper Cotton / Rayon Sani coil quality | | |
| Incorrect product | | |
| Hazardous foreign material (For example, glass, metal) | | |
| Incorrect component (container/bottle and cap) | | |
| Extraneous foreign material | | |

| Test | Critical AQL: 0.65 Accept: 1 Reject: 2 | Checked By |
|---|---|---|
| Damaged containers/bottles and caps | | |
| Closing and opening torque out of range | | |
| Improper capping | | |
| Missing ribs, closers/cap | | |
| Missing aluminium layer in cap | | |

| Test | Major AQL: 1.0 Accept: 1 Reject: 2 | Checked By |
|---|---|---|
| Excess powder | | |
| Improper Tablet / Capsule quality | | |

| Test | Minor AQL: 2.5 Accept: 3 Reject: 4 | Checked By |
|---|---|---|
| Scratches on containers/bottles and caps | | |

**Sampling Time:**

| Test | Critical AQL: 0.65 Accept: 1 Reject: 2 | Checked By |
|---|---|---|
| Incomplete seal | | |
| Burnt Induction sealing | | |

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**For Labeling operation (Sample size (n): 50 container/bottles)**
**(Ref. SOP:_____ )**

**Sampling Time:**

| **Test** | **Critical AQL: 0.10 Accept: 0 Reject: 1** | **Checked By** |
|---|---|---|
| Incorrect, Missing or Damaged Label | | |
| Incorrect, Missing or Illegible Lot no. | | |
| Incorrect, Missing or Illegible Expiration date | | |
| Incorrect NDC no. | | |
| Missing / Wrong Pack inserts and Patient information leaflet | | |
| Other product labels mix-up | | |

| **Test** | **Major AQL: 2.5 Accept: 3 Reject: 4** | **Checked By** |
|---|---|---|
| Smudging of ink and ink lifting | | |

| **Test** | **Minor AQL: 4.0 Accept: 5 Reject: 6** | **Checked By** |
|---|---|---|
| Non-Conforming Print | | |
| Presence of stains | | |
| Minor Scratches on Label | | |

** Note : Upon completion of the physical testing, container/bottles and tablet/capsule used for nondestructive testing should be returned to the line officer for verification and addition to packing line.

**OPTIMUM SPEED SETTING:**

**Note:** In case of small batch size, ensure that minimum 3 intervals at start, middle and end at Optimum batch run are considered for AQL sample collection.

**Set up parameters for optimum speed**

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Equipment Setting time from _____ to _____**

| Date | Equipment Name | Speed (Container/bottles per Minute) | Done by | Checked by |
|---|---|---|---|---|
| | Tablets/capsule counting machine | Optimum speed | | |
| | Silica gel bag insertion machine | | | |
| | Cotton/ Rayon Sani coil insertion machine | | | |
| | Capping machine | | | |
| | Induction Sealing machine | | | |
| | Retorquer machine | | | |
| | Sticker Labeling machine | | | |
| | Problue adhesive melter machine | | | |
| | Leaflet placement machine | | | |
| | Checkweigher | | | |
| | Cartonator (if applicable) | | | |
| | Print check system | | | |

**Note** : Write NA wherever not applicable

Conduct following test on optimum speed setting :

** **Note** : Upon completion of the physical testing, container/bottles and tablet/ capsule used for nondestructive testing should be returned to the line officer for verification and addition to packing line.

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Fill Count**:**

| Sr. No. | Date | Sampling Time | Container/bottle | | | | | | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Side A1 | Side B1 | Side A2 | Side B2 | Side A3 | Side B3 | Side A4 | Side B4 | Side A5 | Side B5 | |
| 1 | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | |
| **4** | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | |
| 7 | | | | | | | | | | | | | |
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| 33 | | | | | | | | | | | | | |
| 34 | | | | | | | | | | | | | |
| 35 | | | | | | | | | | | | | |
| Total No. of sample (Includes slow and High speed) : | | | | | | | | | | | | | |

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Silica gel bag ****

| Sr. No. | Date | Sampling Time | Container/bottle | | | | | | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | | 2 | | 3 | | 4 | | 5 | | |
| | | | Quality | Qty | Quality | Qty. | Quality | Qty. | Quality | Qty. | Quality | Qty. | |
| 1 | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | |
| 7 | | | | | | | | | | | | | |
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| 10 | | | | | | | | | | | | | |
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| 33 | | | | | | | | | | | | | |
| 34 | | | | | | | | | | | | | |
| 35 | | | | | | | | | | | | | |
| Total No. of Sample (Includes Slow and High Speed): | | | | | | | | | | | | | |

Enter √ if acceptable (intact bag) and X if not acceptable.

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Weighing of cotton / rayon sani coil **:**
**Weighing balance code no._____.**

| Sr. No. | Date | Sampling Time | Container/bottle | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|
| | | | 1 (in g) | 2 (in g) | 3 (in g) | 4 (in g) | 5 (in g) | |
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |
| 6 | | | | | | | | |
| *f* | | | | | | | | |
| 8 | | | | | | | | |
| 9 | | | | | | | | |
| 10 | | | | | | | | |
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| 32 | | | | | | | | |
| 33 | | | | | | | | |
| 34 | | | | | | | | |
| 35 | | | | | | | | |

**Total no. of sample (Includes slow and High speed):**

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Closing and opening torque (for capped container/bottle)** :**

| Sr. No. | Date | Sampling Time | Closing torque | | | | | Opening torque | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 [in-Ib] | 2 [in-Ib] | 3 [in-Ib] | 4 [in-Ib] | 5 [in-Ib] | 1 [in-Ib] | 2 [in-Ib] | 3 [in-Ib] | 4 [in-Ib] | 5 [in-Ib] | |
| 1 | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | |
| 7 | | | | | | | | | | | | | |
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| 33 | | | | | | | | | | | | | |
| 34 | | | | | | | | | | | | | |
| 35 | | | | | | | | | | | | | |
| **Total no. of sample (Includes slow and High speed):** | | | | | | | | | | | | | |

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**No foil sensor challenge :**

| Sr. No. | Date | Sampling Time | No foil sensor challenge | Sampled and Checked by |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| 5 | | | | |
| 6 | | | | |
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| 31 | | | | |
| 32 | | | | |
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| 34 | | | | |
| 35 | | | | |

**For no foil sensor challenge: X Rejected**

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Induction sealing :**

**** Induction sealing machine parameter and **induction sealing quality:**

| Sr. No. | Date | Time | Sealer Height (Between the induction sealer head and cap of the container) | Optimum % Power | Optimum Speed of conveyor belt (mpm) | Induction sealing quality | | | | | Checked by |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 1 | 2 | 3 | 4 | 5 | |
| 1 | | | | | | | | | | | |
| 2 | | | | | | | | | | | |
| 3 | | | | | | | | | | | |
| 4 | | | | | | | | | | | |
| 5 | | | | | | | | | | | |
| 6 | | | | | | | | | | | |
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| 33 | | | | | | | | | | | |
| 34 | | | | | | | | | | | |
| 35 | | | | | | | | | | | |
| Total no. of sample (Includes slow and High Speed) | | | | | | | | | | | |

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Leak test:**

| Sr. No. | Date | Sampling Time | Leak test on containers /bottles | Sampled and Checked by |
|---|---|---|---|---|
| 1 / Initial | | | | |
| 2 / Middle | | | | |
| 3/End | | | | |
| 4 | | | | |
| 5 | | | | |
| 6 | | | | |
| 7 | | | | |
| 8 | | | | |
| 9 | | | | |
| 10 | | | | |
| 11 | | | | |
| 12 | | | | |
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| 22 | | | | |
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| 25 | | | | |
| 26 | | | | |
| 27 | | | | |
| 28 | | | | |
| 29 | | | | |
| 30 | | | | |
| 31 | | | | |
| 32 | | | | |
| 33 | | | | |
| 34 | | | | |
| 35 | | | | |
| Total no. of samples (Includes slow and High speed): | | | | |

**Note:** Upon completion of the leak test, container/bottle and cap should be destroyed and recorded in the packing material reconciliation and destruction.

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Closing and opening torque (For re-torquing)**:**

| Sr. No. | Date | Sam-pling Time | Closing torque | | | | | Opening torque | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 (in-lb) | 2 (in-lb) | 3 (in-lb) | 4 (in-lb) | 5 (in-lb) | 1 (in-lb) | 2 (in-lb) | 3 (in-lb) | 4 (in-lb) | 5 (in-lb) | |
| 1 | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | |
| 7 | | | | | | | | | | | | | |
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| 33 | | | | | | | | | | | | | |
| 34 | | | | | | | | | | | | | |
| 35 | | | | | | | | | | | | | |
| Total no. of Sample (Includes Slow and High Speed) | | | | | | | | | | | | | |

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

Challenge and quality inspection of labels by vision system:

| Sr. No. | Date | Challenge time | Pharmacode/code No. /issue date verification (label) | Overprinting verification (label) | Challenged by |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | , | |
| 5 | | | | | |
| 6 | | | | | |
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| 31 | | | | | |
| 32 | | | | | |
| 33 | | | | | |
| 34 | | | | | |
| 35 | | | | | |
| Total no. of Sample (Includes Slow and High Speed) | | | | | |

Enter X if Machine Stopped/ Rejected

**Note** : After completion of test, label or Container/bottle with label should be destroyed and )\ recorded in the packing material reconciliation and destruction.

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Quality of label **:**

| Sr. No. | Date | Sampling time | Container/bottle | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | |
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |
| 6 | | | | | | | | |
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| 32 | | | | | | | | |
| 33 | | | | | | | | |
| 34 | | | | | | | | |
| 35 | | | | | | | | |
| Total no. of sample (includes Slow and High Speed) | | | | | | | | |

Enter √ if acceptable and X if not acceptable.

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Label absence challenge:**

| Sr. No. | Date | Challenge time | Container/bottle | | | | | Challenged by |
|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | |
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |
| 6 | | | | | | | | |
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| 31 | | | | | | | | |
| 32 | | | | | | | | |
| 33 | | | | | | | | |
| 34 | | | | | | | | |
| 35 | | | | | | | | |
| Total No. of Samples: | | | | | | | | |

Enter X if machine stopped / rejected

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Inspection of dispensing of hot melt glue on cap** :**

| Sr. No. | Date | Sampling Time | Container/bottle | | | | | Checked by |
|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | |
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |
| 6 | | | | | | | | |
| 7 | | | | | | | | |
| 8 | | | | | | | | |
| 9 | | | | | | | | |
| 10 | | | | | | | | |
| 11 | | | | | | | | |
| 12 | | | | | | | | |
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| 14 | | | | | | | | |
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| 16 | | | | | | | | |
| 17 | | | | | | | | |
| 18 | | | | | | | | |
| 19 | | | | | | | | |
| 20 | | | | | | | | |
| 21 | | | | | | | | |
| 22 | | | | | | | | |
| 23 | | | | | | | | |
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| 28 | | | | | | | | |
| 29 | | | | | | | | |
| 30 | | | | | | | | |
| 31 | | | | | | | | |
| 32 | | | | | | | | |
| 33 | | | | | | | | |
| 34 | | | | | | | | |
| 35 | | | | | | | | |
| Total no. of samples (includes Slow and high Speed ) | | | | | | | | |

Enter √ if acceptable and x if not acceptable

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Position of pack insert (leaflet)** :**

| Sr. No. | Date | Sampling time | Container/bottle | | | | | Sampled and Checked by |
|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | |
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |
| 6 | | | | | | | | |
| 7 | | | | | | | | |
| 8 | | | | | | | | |
| 9 | | | | | | | | |
| 10 | | | | | | | | |
| 11 | | | | | | | | |
| 12 | | | | | | | | |
| 13 | | | | | | | | |
| 14 | | | | | | | | |
| 15 | | | | | | | | |
| 16 | | | | | | | | |
| 17 | | | | | | | | |
| 18 | | | | | | | | |
| 19 | | | | | | | | |
| 20 | | | | | | | | |
| 21 | | | | | | | | |
| 22 | | | | | | | | |
| 23 | | | | | | | | |
| 24 | | | | | | | | |
| 25 | | | | | | | | |
| 26 | | | | | | | | |
| 27 | | | | | | | | |
| 28 | | | | | | | | |
| 29 | | | | | | | | |
| 30 | | | | | | | | |
| 31 | | | | | | | | |
| 32 | | | | | | | | |
| 33 | | | | | | | | |
| 34 | | | | | | | | |
| 35 | | | | | | | | |
| Total no. of samples (includes Slow and high Speed ) | | | | | | | | |

Enter √ if acceptable and x if not acceptable

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Pharmacode verification of pack insert (leaflet)**:

| Sr. No. | Date | Challenge Time | Pharmacode/ verification (Pack insert) | Challenged by |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| 5 | | | | |
| 6 | | | | |
| 7 | | | | |
| 8 | | | | |
| 9 | | | | |
| 10 | | | | |
| 11 | | | | |
| 12 | | | | |
| 13 | | | | |
| 14 | | | | |
| 15 | | | | |
| 16 | | | | |
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| 18 | | | | |
| 19 | | | | |
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| 25 | | | | |
| 26 | | | | |
| 27 | | | | |
| 28 | | | | |
| 29 | | | | |
| 30 | | | | |
| 31 | | | | |
| 32 | | | | |
| 33 | | | | |
| 34 | | | | |
| 35 | | | | |
| Total no. of samples (includes Slow and high Speed ) | | | | |

Enter X if machine stopped / rejected

**Note:** After completion of Pharmacode verification test pack insert should be destroyed and recorded in packing material reconciliation and Destruction.

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Functioning of checkweigher**:

| Sr. No. | Date | Challenge time | Functioning of checkweigher | Challenge by |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| 5 | | | | |
| 6 | | | | |
| 7 | | | | |
| 8 | | | | |
| 9 | | | | |
| 10 | | | | |
| 11 | | | | |
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| 28 | | | | |
| 29 | | | | |
| 30 | | | | |
| 31 | | | | |
| 32 | | | | |
| 33 | | | | |
| 34 | | | | |
| 35 | | | | |
| Total no. of samples (includes Slow and high Speed ) | | | | |

Enter √ if acceptable and x if not acceptable

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Challenge test for carton and pack insert (leaflet) in cartonator:**

| Sr. No. | Date | Challenge time | Challenge Test For | | | | Visual inspection | | | | Done by |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Carton Sensor (Carton Missing) | Leaflet sensor (Leaflet Missing) | Pharmacode of Carton | Pharmacode of Leaflet (Pack Insert) Back side and Front Side | Embossing /Overprinting Quality | Carton Fill Value | Carton Quality | Leaflet (Pack insert Folding quality) | |
| 1 | | | | | | | | | | | |
| 2 | | | | | | | | | | | |
| 3 | | | | | | | | | | | |
| 4 | | | | | | | | | | | |
| 5 | | | | | | | | | | | |
| 6 | | | | | | | | | | | |
| 7 | | | | | | | | | | | |
| 8 | | | | | | | | | | | |
| 9 | | | | | | | | | | | |
| 10 | | | | | | | | | | | |
| 11 | | | | | | | | | | | |
| 12 | | | | | | | | | | | |
| 3 | | | | | | | | | | | |
| 14 | | | | | | | | | | | |
| 15 | | | | | | | | | | | |
| 16 | | | | | | | | | | | |
| 17 | | | | | | | | | | | |
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| 24 | | | | | | | | | | | |
| 25 | | | | | | | | | | | |
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| 27 | | | | | | | | | | | |
| 28 | | | | | | | | | | | |
| 29 | | | | | | | | | | | |

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

| Sr. No. | Date | Challenge time | Challenge Test For | | | | Visual inspection | | | | Done by |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Carton Sensor (Carton Missing) | Leaflet sensor (Leaflet Missing) | Pharmacode of Carton | Pharmacode of Leaflet (Pack Insert) Back side and Front Side | Embossing /Overprinting Quality | Carton Fill Value | Carton Quality | Leaflet (Pack insert Folding quality) | |
| 31 | | | | | | | | | | | |
| 32 | | | | | | | | | | | |
| 33 | | | | | | | | | | | |
| 34 | | | | | | | | | | | |
| 35 | | | | | | | | | | | |
| Total no. of samples (includes Slow and high Speed ) | | | | | | | | | | | |

For challenge: Enter X if machine stopped / rejected

For visual inspection: Enter √ if acceptable and x if Not acceptable.

**Note:** After completion of test, carton and pack insert (leaflet) should be destroyed and recorded in packing material reconciliation and destruction.

Sampling and inspection of defects (AQL inspection, Ref. SOP:_____ ):

**Note :** In case of small batch size, ensure that minimum 3 intervals at start, middle and end of Optimum batch run are considered for AQL sample collection.

**Container/bottle filling** :

As per reference protocol No._____ , Version no._____

| Sampling Interval | Date | Interval Time | Sample Quantity | Sampled by |
|---|---|---|---|---|
| Optimum Speed 1. | | | | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |
| 5. | | | | |
| 6. | | | | |
| 7. | | | | |
| 8. | | | | |
| 9. | | | | |
| 10. | | | | |
| Total no. of Samples: | | | | |

**Note: Upon completion of the physical testing, container/bottles used for nondestructive testing should be returned to the line officer for verification and addition to packing line.

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

Inspection for defects during container/bottle filling operation :

| Time | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Interval No. | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Number of container/bottles inspected | | | | | | | | | | | |
| Sample size(n): _____ Critical AQL: 0.10 Accept: _____ Reject: _____ (Ref. SOP:____) | Fill count out of range | | | | | | | | | | |
| | Improper Silica gel bag quality | | | | | | | | | | |
| | Improper Cotton / Rayon Sani coil quality | | | | | | | | | | |
| | Incorrect product | | | | | | | | | | |
| | Hazardous foreign material (For example, glass, metal) | | | | | | | | | | |
| | Incorrect component (container/bottle and cap) | | | | | | | | | | |
| | Extraneous foreign material | | | | | | | | | | |
| Inspected By/Date | | | | | | | | | | | |

| **Time** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Interval No.** | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| **Number of container/bottles inspected** | | | | | | | | | | | |
| Sample size (n): Critical AQL: 0.65 Accept: _____ Reject: _____ (Ref. SOP:____) | Damaged container/bottles and caps | | | | | | | | | | |
| | Closing and opening torque | | | | | | | | | | |
| | Improper capping | | | | | | | | | | |
| | Missing aluminium layer in cap | | | | | | | | | | |
| | Missing ribs, closers/cap | | | | | | | | | | |
| Inspected By/Date | | | | | | | | | | | |
| Time | | | | | | | | | | | |
| Interval No. | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Number of container/bottles inspected | | | | | | | | | | | |

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Sample size(n):_____ Major AQL: 1.0 Accept: _____ Reject: _____ (Ref. SOP:_____) | Excess powder | | | | | | | | | | |
| | Improper Tablet/ Capsule quality | | | | | | | | | | |
| Minor AQL: 2.5 Accept: _____ Reject: _____ (Ref. SOP:_____) | Scratches on Container/ bottle and Cap | | | | | | | | | | |
| Inspected By/Date | | | | | | | | | | | |

| **Time** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Interval No.** | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| **Number of container/bottles inspected** | | | | | | | | | | | |
| Sample size (n):_____ Critical AQL: 0.65 Accept: _____ Reject: _____ (Ref. SOP:_____) | Incomplete Seal | | | | | | | | | | |
| | Burnt Induction Sealing | | | | | | | | | | |
| Inspected By/Date | | | | | | | | | | | |

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**Sealed and labeled container/bottle** :

As per reference protocol No._____ , Version no._____

| Sampling Interval | Date | Interval Time | Sample Quantity | Sampled by |
|---|---|---|---|---|
| Optimum Speed | | | | |
| 1. | | | | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |
| 5. | | | | |
| 6. | | | | |
| 7. | | | | |
| 8. | | | | |
| 9. | | | | |
| 10. | | | | |
| Total no. of samples: | | | | |

**Inspection of defects during container/bottle labeling operation :**

| **Time** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Interval No.** | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| **Number of container/bottles inspected** | | | | | | | | | | | |
| **Sample size (n):** _____ **Critical AQL: 0.10 Accept:** _____ Reject: _____ (Ref. SOP: _____) | Incorrect, Missing or Damaged Label | | | | | | | | | | |
| | Incorrect, Missing or Illegible Lot no. | | | | | | | | | | |
| | Incorrect, Missing or Illegible Expiration date. | | | | | | | | | | |
| | Incorrect NDC no. | | | | | | | | | | |
| | Missing / Wrong Pack inserts & Patient information leaflet | | | | | | | | | | |
| | Other product labels mix-up | | | | | | | | | | |
| Inspected By/Date | | | | | | | | | | | |

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

| Time | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Interval No. | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Number of container/bottles inspected | | | | | | | | | | | |
| Sample size **(n):** _____ **Major AQL: 2.5 Accept:** _____ **Reject:** _____ (Ref. SOP: _____) | Smudging of ink and ink lifting | | | | | | | | | | |
| **Sample** size **(n):** _____ Minor AQL: 4.0 Accept: _____ Reject: _____ (Ref. SOP: _____) | Non-Conforming Print | | | | | | | | | | |
| | Presence of stains | | | | | | | | | | |
| | Minor Scratches on Label | | | | | | | | | | |
| Inspected By/ Date: | | | | | | | | | | | |

| Tests | Date | | | |
|---|---|---|---|---|
| | Time | | | |
| | Initial | | Middle | End |
| Shipper fill value | | | | |
| Shrink quality | | | | |
| Carton quality | | | | |
| Shipper labeling quality | | | | |
| Transcription accuracy | | | | |
| Strapping quality | | | | |
| Checked by | | | | |

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**REQUIRED TESTING AND ACCEPTANCE/ EVALUATION CRITERIA**:

As per reference protocol No. _____, Version no._____

**DETAILS OF DEVIATIONS/ NON CONFORMANCE:**

**TYPE OF VALIDATION:**

Concurrent Validation / Revalidation.

**FREQUENCY:**

Three consecutive batches for each container/bottle configuration.

Three consecutive batches in case of change in any machine from the line.

Revalidation: Every three years on one batch for each configuration.

**RESULT AND OBSERVATIONS:**

**RISK MANAGEMENT STUDY :**

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# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

## SUMMARY OF FINDINGS OF VALIDATION ACTIVITY:

| | | |
|---|---|---|
| Fill count | : | |
| Silica gel bag quality and quantity | : | |
| Cotton/ Rayon sani coil weight | : | |
| Opening torque (after capping) | : | |
| Closing torque (for capping ) | : | |
| No foil sensor challenge | : | |
| Induction Sealing machine parameters | : | |
| Induction sealing quality | : | |
| Leak test | : | |
| Opening torque (after retorquing) | : | |
| Closing torque (for retorquing) | : | |
| Pharmacode/code No. /issue date verification (label) | : | |
| Overprinting verification (label) | : | |
| Quality of labeling | : | |
| Label absence challenge | : | |
| Dispensing of hot melt glue on cap | : | |
| Position of pack insert (leaflet) on cap | : | |
| Pharmacode verification of pack insert (leaflet) | : | |
| Functioning of checkweigher | : | |
| Carton sensor in cartonator challenge | : | |

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

| | | |
|---|---|---|
| Leaflet sensor in cartonator challenge | : | |
| Pharmacode verification of carton in cartonator | : | |
| Pharmacode verification of pack insert (leaflet) | : | |
| Back side and front side in cartonator | : | |
| Overprinting/Embossing quality of carton in cartonator | : | |
| AQL for container/bottle filling operation | : | |
| AQL for labeling operation | : | |

| | | | | | |
|---|---|---|---|---|---|
| √ | Within Acceptance Criteria | X | Not within Acceptance Criteria | NA | Not Applicable |

**RECOMMENDATIONS:**

**TEAM APPROVAL**

| | | |
|---|---|---|
| **User** | **Quality Assurance** | **Engineering** |
| **Date:** | **Date:** | **Date:** |

**REVIEW:**

# VALIDATION REPORT FOR GUIDELINE FOR CONTAINER/BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

**APPROVED BY:**

_____
**Unit Quality Assurance Head**

**Date:**

**NOTED BY:**

_____
**Unit Head**

**Date:**

**ANNEXURES:**

**VAL** **E**

## ABBREVIATIONS

| | | |
|---|---|---|
| mg | : | milligram |
| SOP | : | Standard Operating Procedure |
| BPR | : | Batch Packing Record |
| No. | : | Number |
| % | : | Percent |
| AQL | : | Acceptable Quality Level |
| Ref. | : | Reference |
| NDC | : | National Drug Code |
| NA | : | Not applicable |
| Qty. | : | Quantity |
| g | : | gram |
| In | : | inch |
| lb | : | pound |
| Sr. | : | Serial |
| mpm | : | Meter per minute |