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

1.0 OBJECTIVE:

To demonstrate that the critical operation involved in container/ bottle packing of Tablets / Capsules are capable of consistently packing batch / batches which meet all quality parameters and the limits of acceptance criteria.

2.0 JUSTIFICATION OF SELECTION OF ITEM / EQUIPMENT / PROCESS / PRODUCT / SYSTEM:

To be recorded in validation report.

3.0 SCOPE:

Applicable to container/ bottle packing line of Tablets/ capsules.

4.0 SITE OF STUDY:

Location should be recorded in the validation report.

5.0 RESPONSIBILITY:

5.1 Representatives from,

5.2 Packaging: Batch packing as per Batch Packing Record and setting of equipment at different variables.

5.3 Quality Assurance: Performing in-process test and sampling of validation samples. Execution of validation as per protocol and compilation of the findings / results in the report.

5.4 Engineering: Periodic qualification and calibration of equipment and maintaining records of the same. Maintenance of equipment and process. (Names of individuals to be recorded in validation report)

6.0 SOP AND BPR TO BE FOLLOWED:

6.1 Manufacturing Code, Pack Code and Version No. of the current Master Batch Packing Record should be recorded in the validation report.

6.2 SOP for Bottle Unscrambler and cleaning Machine

6.3 SOP for Tablet/Capsule Counting Machine

6.4 SOP for Tablet/Capsule count verification Machine

6.5 SOP for Silica gel bag insertion Machine

6.6 SOP for Cotton insertion machine

6.7 SOP for weighing balance

6.8 SOP for Capping Machine

6.9 SOP for Torque Testing Apparatus

6.10 SOP for Induction Sealing Machine

6.11 SOP for Leak test Apparatus

6.12 SOP for Re-torquer Machine

6.13 SOP for Sticker labeling Machine

6.14 SOP for Problue adhesive melter machine

6.15 SOP for Leaflet (Pack insert) placement machine

6.16 SOP for Cartonator

6.17 SOP for print check system

6.18 SOP for shrink wrapping machine

6.19 SOP for Checkweigher

6.20 SOP for Shipper sealing machine

6.21 SOP for shipper strapping machine

6.22 SOP for shipper weighing balance

(SOP no. Should be recorded in the validation report)

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

7.0 CONTROLS:

7.1 Qualified machines and if applicable calibrated machines should be used.

Qualification / calibration date including code number of the machine should be recorded in validation report.

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

7.3 Packing materials/components: Packing configuration, item code, item name and description applicable to individual product and count should be recorded in the report.

7.4 Training: Availability of training record of persons involved in validation exercise to be recorded in validation report.

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

8.0 VALIDATION PROCEDURE:

Note:

1. 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.
2. Speed setting of container/ bottle packing line will change as per the count, container/ bottle size and shape and tablet / capsule size and shape.
3. #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.

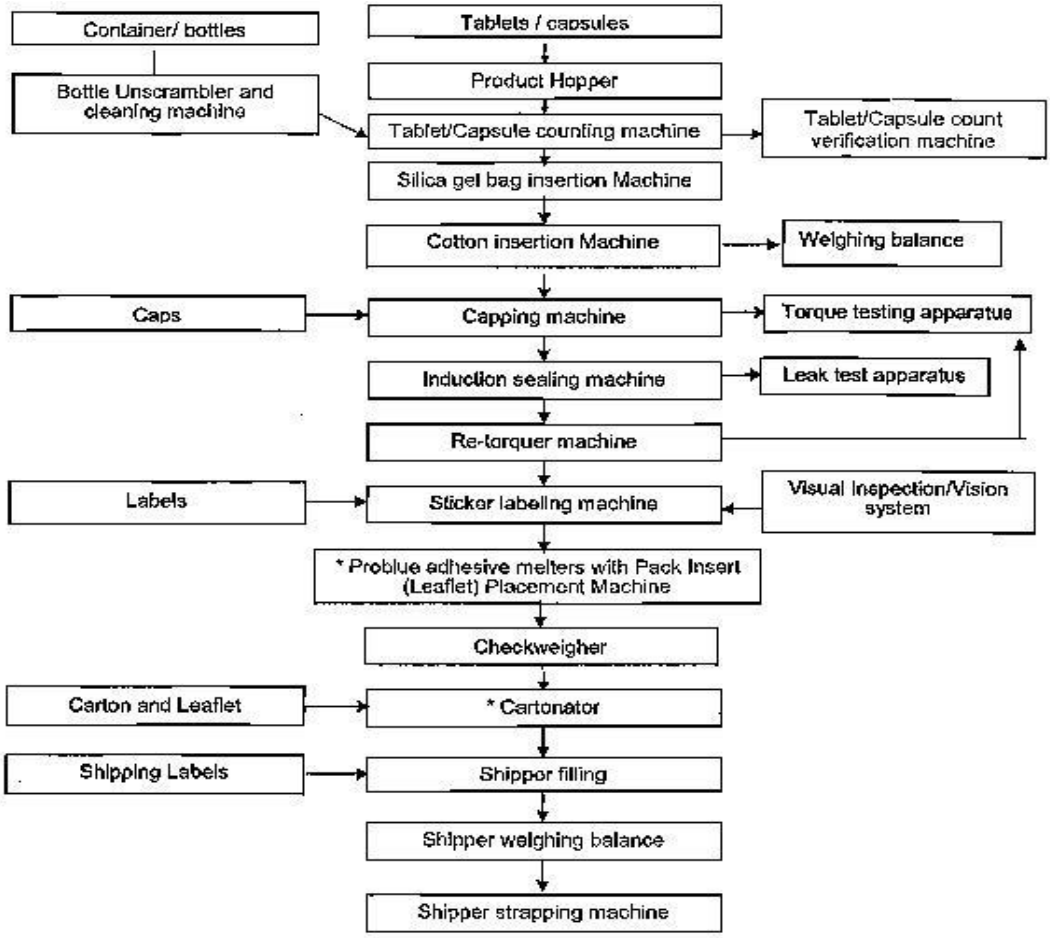
VALIDATION PROTOCOL FOR GUIDELINE FOR CONTAINER /BOTTLE PACKING LINE VALIDATION (TABLETS/CAPSULES)

8.1 Batch packing should be carried out as per BPR:

8.1.1 Date(s) of validation, Batch number, Batch Size, Quantity to be packed, fill count and code no. and size of container/ bottle and cap should be recorded in the validation report. Batch number should be mentioned on each page of the validation report.

Packing Process Flow Diagram

8.2



If applicable for the product

Note: *Packing process flow diagram or sequence and procedure should be as per respective packing process.*

8.3 Slow Speed Setting : Set the machines of the container/ bottle packing line to slow speed and verify the set-up mechanics of tablet / capsule counting machine, 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 and cartonator (lf applicable). (Record the time required for slow speed setting in the validation report).

8.4 Conduct the following test on Slow speed setting :

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

8.4.1 Fill Count:**

Collect 5 filled containers/ bottles from each counting head and check the fill count. Record the observation in the validation report.

8.4.2 Silica gel Bag** :

Collect 5 silica gel bag filled containers/ bottles. Check the quality and quantity of silica gel bag in each container/ bottle sampled. Record the observation in validation report.

8.4.3 Weighing of Cotton / Rayon sani coil:** Collect 5 cotton / rayon sani coil filled containers/ bottles and check the weight of cotton / rayon sani coil. Record the observation in the validation report.

8.4.4 Closing and opening torque (for Capped container/ bottle)** : Collect 5 capped containers/ bottles and check the closing and opening torque. Record observation in the validation report.

8.4.5 #No foil sensor challenge:

Take 1 container/bottle and remove aluminum foil of cap and conduct the No foil sensor challenge. Record the observation in validation report.

8.4.6 Induction sealing :

Set induction sealing machine as per below parameters : Low conveyor speed - low power percentage Low conveyor speed - high power percentage

Note: Induction sealing height should be kept constant.

8.4.6.1 Check 5 containers/bottles for induction sealing quality** and for leak test take at least 4 containers/ bottles or in case of multiple head capping machine, at least one empty container/ bottle from each of the capping head whichever is more should be taken and leak test should be performed. (After completion of the leak test, the containers/ bottles and cap of each parameter should be destroyed and recorded in the packing material reconciliation and destruction).

8.4.6.2 Closing and opening torque (For re-torquing)**: Collect 5 induction sealed and retorqued containers/ bottles and check the closing and opening torque after retorquing. Record the observation in the validation report.

8.4.8 Challenge and Quality inspection of labels by vision system:

Mark and challenge 1 label by addition of a bar for Pharmacode/code No. /issue date verification. On the same label block one of the line or block one of the characters or block complete overprinting zone for overprinting verification. Record the observation in the validation report.

(The labels or container/ bottle with label used for testing should be destroyed and recorded in the packing material reconciliation and destruction).

8.4.9 Quality of label** :

Collect 5 labeled containers/ bottles and check the quality of labeling for wrinkles, without fold and cross label. Record the observation in the validation report.

8.4.10 *Label absence challenge:

Pass 5 empty containers/ bottles (without cap and labels) for label absence challenge. Record the

observation in the validation report.

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

Observe 5 glue dispensed containers/ bottles for position of hot melt glue dispensed on cap. Record the observation in validation report.

8.4.12 Position of pack insert (leaflet)**:

Collect 5 pack insert placed container/ bottle and check for position of pack insert. Record the observation in validation report.

8.4.13 Pharmacode verification of pack insert (leaflet):

Challenge 1 pack insert by addition of a bar for Pharmacode verification. Record the observation in validation report. (Upon completion of testing the pack insert should be destroyed and recorded in the packing material reconciliation and destruction)

8.4.14 # Functioning of checkweigher:

Take 1 empty container/ bottle with cap and perform the checkweigher challenge. Record the observation in validation report.

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

8.4.15.1 Challenge test for carton sensor (Carton missing) Remove carton from magazine of cartonator.

8.4.15.2 Challenge test for leaflet sensor (Missing Leaflet) Remove leaflet from magazine of cartonator.

8.4.15.3 Challenge test for Pharmacode of pack insert (leaflet)

For Pharmacode verification, mark and challenge 1 leaflet by addition of a bar on back side and front side of Pharmacode.

Note: The carton and pack insert (leaflet) used for testing should be destroyed and recorded in the packing material reconciliation and destruction.

8.4.15.5 Visual inspection:

Check carton Embossing/Overprinting quality, Carton fill value, carton quality and leaflet (pack insert) folding quality Record the observations in validation report

8.4.16 Inspection of defects (AQL inspection):

For container/ bottle filling and labeling operation at slow speed perform as per point 8.9 of validation protocol.

8.5 High Speed Setting :

Set the machines of the container/ bottle packing line to high speed and verify the set-up mechanics of tablet / capsule counting machine, 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 and cartonator (if applicable)

(Record the time required for high speed setting in the validation report).

8.6 Conduct the following test on High speed setting :

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

8.6.1 **Fill Count**** :
Collect 5 filled containers/bottles from each counting head and
check the fill count. Record the observation in the validation report.

8.6.2 **Silica gel Bag**:**
Collect 5 silica gel bag filled containers/ bottles. Check the quality and quantity of silica gel bag in each container/ bottle sampled and record the observation in validation report.

8.6.3 **Weighing of Cotton / Rayon sani coil**:**
Collect 5 cotton / rayon sani coil filled containers/ bottles and check the weight of cotton / rayon sani coil. Record the observation in the validation report.

8.6.4 **Closing and opening torque (for Capped container/ bottle)**** : Collect 5 capped container/ bottles and check the closing and opening torque. Record observation in the validation report.

8.6.5 ***No foil sensor challenge:**
Take 1 container/bottle and remove aluminum foil of cap and conduct the No foil sensor challenge. Record the observation in validation report.

8.6.6 **Induction sealing**:
Set induction sealing machine as per below parameters:
High conveyor speed - high power percentage
High conveyor speed - low power percentage
Note: Induction sealing height should be kept constant.

8.6.6.1 Check 5 containers/ bottles for induction sealing quality** and for leak test take at least 4 containers/ bottles or in case of multiple head capping machine, at least one empty container/ bottle from each of the capping head whichever is more should be taken and leak test should be performed.
(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).

8.6.7 **Closing and opening torque (For re-torquing)**:**
Collect 5 induction sealed and retorqued containers/ bottles and checks the closing and opening torque after retorquing. Record the observation in the validation report.

8.6.8 **Challenge and Quality inspection of labels by vision system:**
Mark and challenge 1 label by addition of a bar for Pharmacode /code No. /issue date verification. On the same label block one of the line or block one of the characters or block complete overprinting zone for overprinting verification. Record
the observation in the validation report. (The labels or container/ bottle with label
used for testing should be destroyed and recorded in the packing material reconciliation and destruction).

8.6.9 **Quality of label** ** :
Collect 5 labeled containers/ bottles and check the quality of labeling for wrinkles, without fold and cross label. Record the observation in the validation report.

8.6.10 **#Label absence challenge :**
Pass 5 empty containers/ bottles (without cap and labels) for label absence challenge. Record the observation in validation report.

8.6.11 **Inspection of dispensing of hot melt glue on cap** :**
Observe 5 glue dispensed containers/ bottles for position of hot melt glue dispensed on cap. Record the observation in validation report.

8.6.12 **Position of pack insert (leaflet)** **:
Collect 5 pack inserts placed containers/ bottles and check for position of pack insert. Record the observation in validation report.

8.6.13 **Pharmacode verification of pack insert (leaflet)** :
Challenge 1 pack insert by addition of a bar for Pharmacode verification. Record the observation in validation report. (Upon completion of testing, the pack insert should be destroyed and recorded in the packing material reconciliation and destruction)

8.6.14 **Functioning of checkweigher:**
Take 1 empty container/ bottle with cap and perform the checkweigher challenge. Record the observation in validation report.

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

8.6.15.1 Challenge test for carton sensor (Carton missing) Remove carton from magazine of cartonator.

8.6.15.2 Challenge test for leaflet sensor (Missing Leaflet) Remove leaflet from magazine of cartonator.

8.6.15.3 Challenge test for Pharmacode of leaflet:
For Pharmacode verification mark and challenge 1 leaflet by addition of a bar on back side and front side of Pharmacode.

8.6.15.4 Challenge test for Pharmacode of carton:
Mark and challenge 1 carton by addition of a bar for Pharmacode verification.

Note: The carton and pack insert (leaflet) used for testing should be destroyed and recorded in the packing material reconciliation and destruction.

8.6.15.5 **Visual inspection:**
Check carton Embossing/Overprinting quality, Carton fill value, carton quality and leaflet folding quality.
Record the observations in validation report

8.6.16 **Inspection of defects (AQL inspection):**
For container/ bottle filling and labeling operation at high speed perform as per point 8.9 of validation protocol.

8.7 **Optimum speed setting :**
Set the machines of the container/ bottle packing line to optimum speed and verify the set-up mechanics of tablet/capsule counting machine, Silica gel bag insertion machine, cotton insertion machine, capping machine, induction sealing machine (Set induction sealing parameter at optimum % power and optimum speed of conveyor belt,), retorquer machine, sticker labeling machine, problue adhesive melter machine, leaflet placement machine, checkweigher and cartonator (if applicable)

8.8 After every xx min. collect container/ bottles as mentioned below except leak test till the packing process ends and do the following test.

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

8.8.1 **Fill Count**:**
Collect 5 filled containers/ bottles from each counting head and check the fill count. Record the

observation in the validation report.

8.8.2 **Silica gel Bag** :**
Collect 5 silica gel bag filled containers/ bottles. Check the quality and quantity of silica gel bag in each container/ bottle sampled and record the observation in validation report.

8.8.3 **Weighing of Cotton / Rayon sani coil**:**
Collect 5 cotton / rayon sani coil filled containers/ bottles and check the weight of cotton / rayon sani coil. Record the observation in the validation report.

8.8.4 **Closing and opening torque (for Capped container/ bottle)** :**
Collect 5 capped containers/ bottles and check the closing and opening torque. Record observation in the validation report.

8.8.5 **#No foil sensor challenge:**

8.8.5.1 Take 1 container/bottle and remove aluminum foil of cap and conduct the No foil sensor challenge. Record the observation in validation report.

8.8.6 **Induction sealing machine** :

8.8.6.1 ****Induction sealing machine parameters and "Induction Sealing quality:**
Set Induction Sealing machine per below parameter: Optimum conveyor speed - optimum power percentage.

8.8.6.2 Check and record % power of induction sealing machine, Speed of conveyor belt and the sealer height between the induction sealer head and cap of the container/ bottle in validation report.

8.8.6.3 Collect 5 sealed containers/ bottles and check induction sealing quality.

8.8.7 **Leak Test**:

Take at least 4 containers/ bottles or in case of multiple head capping machine, at least one empty container/ bottle from each of the capping head whichever is more should be taken and leak test should be performed. Record the observation in the validation report. (After completion of the leak test, containers/ bottles and cap should be destroyed and recorded in the packing material reconciliation and destruction).

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

Collect 5 induction sealed and retorqued container/ bottle and checks the closing and opening torque after retorquing. Record the observation in the validation report.

8.8.9 **Challenge and Quality inspection of labels by vision system:**

Mark and challenge 1 label by addition of a bar for Pharmacode/code No. /issue date verification. On the same label block one of the lines / block one of the characters / block complete overprinting zone for overprinting verification. Record the observation in the validation report. (The labels used for testing should be destroyed and included in the packing material reconciliation and destruction).

8.8.10 **Quality of label** ** :
Collect 5 labeled containers/ bottles and check the quality of labeling for wrinkles, without fold and cross label. Record the observation in the validation report.

8.8.11 **#Label absence challenge** :
Pass 5 empty containers/ bottles (without cap and labels) for label absence challenge. Record

the observation in the validation report.

8.8.12 Inspection of dispensing of hot melt glue on cap**:
Observe 5 glue dispensed containers/ bottles for position of hot melt glue dispensed on cap. Record the observation in validation report.

8.8.13 Position of pack insert (leaflet)**:
Collect 5 pack insert placed containers/ bottles and check for position of pack insert. Record the observation in validation report.

8.8.14 Pharmacode verification of pack insert (leaflet):
Challenge 1 pack insert by addition of a bar for Pharmacode verification. Record the observation in validation report. (Upon completion of testing the pack insert should be destroyed and recorded in the packing material reconciliation and destruction)

8.8.15 'Functioning of checkweigher:
Take 1 empty container/ bottle with cap and perform the checkweigher challenge. Record the observation in validation report.

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

8.8.16.1 Challenge test for carton sensor (Carton missing):
Remove carton from magazine of cartonator.

8.8.16.2 Challenge test for leaflet sensor (Missing Leaflet):
Remove leaflet from magazine of cartonator.

8.8.16.3 Challenge test for Pharmacode of leaflet:
For Pharmacode verification, mark 1 leaflet and challenge by addition of a bar on back side and front side of Pharmacode.

8.8.16.4 Challenge test for Pharmacode of carton:
Mark and challenge 1 carton by addition of a bar for Pharmacode verification.

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

8.8.16.5 Visual inspection:
Check carton Embossing/Overprinting quality, Carton fill value, carton quality and leaflet folding quality. Record the observations in validation report

8.9 Sampling and Inspection of defects:**
AQL checks for defects to be performed during container/ bottle filling operation and labeling operation. Sampling for slow speed and high speed, collect 50 containers/ bottles sample size for each speed. For optimum batch run divide the packing run (XX and or XXX count) at optimum speed into 10 sampling intervals and determine the cumulative sample size (n) based on the level of inspection and
batch size as per AQL (Refer relevant SOP No.). Sample $1/10^{th}$ of the cumulative
sample size per interval.
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.

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

8.9.1 Container/ bottle filling operation:

Process Stage	Test	Number of Samples	Acceptance / Evaluation Criteria
Container/ bottle Filling	Fill count out of range	As per AQL (Refer to SOP)*	Critical AQL = 0.10
	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		
Container/ bottle Filling	Damaged Container/ bottles and caps	As per AQL (Refer to SOP)*	Critical AQL = 0.65
	Opening and closing torque out of range		
	Improper capping		
	Missing ribs closers/ cap		
	Missing Aluminum layer in cap		
Container/ bottle Filling	Excess powder	As per AQL (Refer to SOP)*	Major AQL = 1.0
	Improper tablet/capsule quality		
Container/ bottle Filling	Scratches on container/ bottles and caps	As per AQL (Refer to SOP)*	Minor AQL = 2.5
Container/ bottle Filling	Incomplete Seal	As per AQL (Refer to SOP)*	Critical AQL = 0.65
	Burnt Induction Sealing		

8.9.2 Labeling operation:

Process Stage	Test	Number of Samples	Acceptance / Evaluation Criteria
Labeling	Incorrect, Missing or Damaged Label	As per AQL (Refer to SOP)*	Critical AQL = 0.10
	Incorrect, Missing or Illegible Lot No.		
	Incorrect, Missing or Illegible Expiration date		
	Incorrect NDC no.		
	Missing / Wrong Pack insert and Patient Information Leaflets		
	Other product labels mix-up		
Labeling	Smudging of ink and ink lifting	As per AQL (Refer to SOP)*	Major AQL = 2.5
Labeling	Non-Conforming Print	As per AQL (Refer to SOP)*	Minor AQL = 4.0
	Presence of stains		
	Minor scratches on labels		

The total number of container/ bottles inspected at optimum batch run throughout the container/ bottle filling and labeling processes must equal the sample size (n) as determined.
Record the observation for defects (as specified in table of acceptance criteria in AQL checks) in the validation report.
****Note:** Upon completion of the physical testing, return the container/ bottles and labeled container/ bottles used for nondestructive testing to the line officer for verification and addition to the packing line.

8.10 Shipper Packing : Check 1 filled and sealed shipper with respect to the following at initial, middle, and end period of packing process:

a. Shipper fill value
b. Shrink quality
c. Carton quality
d. Shipper labeling quality
e. Transcription accuracy
f. Strapping quality

Record the observations in the validation report.

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

8.11 REQUIRED TESTING AND ACCEPTANCE/ EVALUATION CRITERIA:

Process Stage	Test		Number of Samples	Acceptance Criteria
Container / Bottle Filling	Fill Count	XX-count Container/ bottles	Slow Speed: 5 containers/ bottles High Speed: 5 containers / bottles Optimum speed: 5 containers/ bottles after every xx min. until packing process ends.	XX tablets/capsule per container/ bottle
		Count Container/ bottles	Slow Speed: 5 containers/ bottles High Speed: 5 containers / bottles Optimum speed: 5 containers/ bottles after every xx min. until packing process ends.	Target: xx tablets / capsule per container/ bottle Minimum: xx tablets/capsule per container/ bottle Maximum: xxx tablets/capsule per container/ bottle
Silica gel bag Insertion	Silica gel bag Insertion	xx-Count Containers / bottles xxx-Count Containers / bottles	Slow Speed: 5 containers / bottles High Speed: 5 containers / bottles Optimum speed: 5 containers/ bottles after every xx min. until packing process ends.	x Silica gel bags (x g) per container/ bottle. Intact silica gel bag
			Slow Speed: 5 containers / bottles High Speed: 5 containers / bottles Optimum speed: 5 containers/ bottles after every xx min. until packing process ends.	x Silica gel bags (x g) per container/ bottle. Intact silica gel bag.
Cotton /Rayon Sani coil insertion	Cotton / Rayon Sani coil Weight	xx -Count Container/ bottles	Slow Speed: 5 containers / bottles High Speed: 5 containers / bottles Optimum speed: 5 containers/ bottles after every xx min. until packing process ends.	x g ± x % Cotton / Rayon Sani coil per container/ bottle. (x g to x g)
		xxx-Count Container/ bottles	Slow Speed: 5 containers / bottles High Speed: 5 containers/ bottles Optimum speed: 5 containers/ bottles after every xx min. until packing process ends.	x g ± x % Cotton / Rayon Sani coil per container/ bottle. (x g to x g)

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

Process Stage	Test		Number of Samples	Acceptance / Evaluation Criteria
Closing and Opening Torque (For capping)	Closing and Opening Torque Testing (For capping)	Xx - Count Container/ bottles	Slow Speed: 5 containers/ bottles High Speed: 5 containers/ bottles Optimum speed: 5 containers/ bottles after every xx min. until packing process ends.	Closing torque from xx to xx in-lb
				Opening Torque xx to xx in-lb
		xxx-Count Container/ bottles	Slow Speed: 5 containers/ bottles High Speed: 5 containers/ bottles Optimum speed: 5 containers/ bottles after every xx min. until packing process ends.	Closing torque from xx to xx in-lb
				Opening Torque xx to xx in-lb
Induction Sealing	Induction sealing machine setting parameters and Quality of Induction sealing		Slow Speed: 5 containers/ bottles High Speed: 5 containers/ bottles Optimum speed: 5 containers/ bottles after every xx min. until packing process ends.	Power % of induction sealer machine.
				Induction sealing height between induction sealer head and cap of the container/ bottle
				Speed of conveyor belt
				Complete sealing of container/bottle from all sides of container/ bottle lip. No significant colour changes from inner side of the cap after sealing, no sign of burning.
	[1]No foil sensor challenge		Slow Speed: 1 container/ bottle High Speed: 1 container/ bottle Optimum Speed: 1 container/ bottle every xx min. until packing process ends.	Container/ bottle without seal must be rejected.
	Leak Test		Slow Speed: *x containers High Speed: *x containers Optimum Speed: *x container for every xx hrs. till packing process ends. [2]At initial, middle and end period of packing activity if the batch size is small.	No container/ bottle should leak

[1]0ne container/ bottle and cap sampled Initially to be used for slow speed, for high speed and each time interval of optimum speed for No foil sensor challenge test.

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[2]**Note:** Initial Period: Samples taken immediately after machine setup.
Middle period: Samples taken when about 50 % of batch size is completed.
End period: Samples taken at the end of batch.

Process Stage	Test		Number of Samples	Acceptance / Evaluation Criteria
Closing and Opening Torque (For Re-torquing)	Closing and Opening Torque Testing (For Re-torquing)	xx-Count Container/ bottles	Slow Speed: 5 containers/ bottles High Speed: 5 containers/ bottles Optimum speed: 5 containers/ bottles after every xx min. until packing process ends.	Closing torque from xx to xx in-lb Opening Torque xx to xx in-lb
		xxx-Count Container/ bottles	Slow Speed: 5 containers/ bottles High Speed: 5 containers/ bottles Optimum speed: 5 containers/ bottles after every xx min. until packing process ends.	Closing torque from xx to xx in-lb Opening Torque xx to xx in-lb
[3]Labeling	Pharmacode /code No. / Issue date verification		Slow Speed: 1 label High Speed: 1 label Optimum Speed: 1 label after every xx min. until packing process ends.	Wrong Pharmacode /code No. /issue date must be detected by Reader and machine should display fault label on Vision system when challenged and machine should Stop (if machine in stoppage mode) or machine should reject the container/ bottle with label (if machine in reject mode).
	Overprinting verification		Slow Speed: 1 label High Speed: 1 label Optimum Speed: 1 label after every xx min. until packing process ends.	**Vision system:** Overprinting on labels must be correct and legible. Missing characters or missing line or absence of overprinting should be detected machine should display fault label on Vision system when challenged and machine should stop (if machine is in stoppage mode) or machine should reject container/ bottle with label (if machine is in reject mode).

[3] Same sticker label to be challenged for pharmacode/ code no. / issue date and overprinting verification.

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

Process Stage	Test	Number of Samples	Acceptance / Evaluation Criteria
Labeling	Quality of Labeling	Slow Speed: 5 containers/ bottles High Speed: 5 containers/ bottles Optimum Speed: 5 containers/ bottles after every xx min. until packing process ends.	All container/ bottles should be sensed by the sticker dispensing sensor and label should be affixed and pasted properly to the container/ bottle surface with no wrinkles, fold and cross label.
	[4]Label absence challenge	Slow Speed: 5 containers/ bottles High Speed: 5 containers/ bottles Optimum Speed: 5 containers/ bottles after every xx min. until packing process end.	Absence of label on container/ bottle must be identified by label absence sensor and machine should stop/Reject the same container/ bottle
Hot problue adhesive melter and Leaflet placement machine[5]	Dispensing of hot melt glue on cap	Slow Speed: 5 containers/ bottles High Speed: 5 containers/ bottles Optimum Speed: 5 containers/ bottles after every xx min. until packing process end.	The hot melt should be dispensed on the middle of cap.
	Position of Pack insert (leaflet) on the cap	Slow Speed: 5 containers/ bottles High Speed: 5 containers/ bottles Optimum Speed: 5 containers/ bottles after every xx min. until packing process end.	The Pack insert (leaflet) should be placed in the centre of the cap.
	Pharmacode verification (Pack insert)	Slow Speed: 1 Pack insert (leaflet) High Speed: 1 Pack inserts (leaflet) Optimum speed: 1 Pack insert (leaflet) after every xx min. until packing process ends.	Wrong Pharmacode must be detected by Reader and machine should stop/Reject the container/ bottle with fault and display on vision system when challenged.
[#]Checkweigher	Challenge of checkweigher	Slow Speed: 1 container/ bottle High Speed: 1 container/ bottle Optimum Speed: 1 container/ bottle every xx min. till packing process ends.	Container/ bottle should get rejected automatically

[4]5 container/ bottles sampled initially to be used for slow speed, for high speed and each time interval of optimum speed. [5] If applicable.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

Process Stage	Test		Number of Samples	Acceptance / Evaluation Criteria
Cartonator	Challenge test for Carton sensor (Missing carton)		Slow Speed: 1 carton High Speed: 1 carton Optimum speed: 1 carton after every xx min. until packing process ends.	If carton is missing, machine should stop or Leaflet with-container/ bottle (if applicable) should be rejected by the machine.
	Challenge test for Leaflet sensor(Leaflet missing)		Slow Speed: 1 Pack insert (leaflet) High Speed: 1 Pack insert (leaflet) Optimum speed: 1 Pack insert (leaflet) after every xx min. until packing process ends.	If leaflet is missing, machine should detect such carton with container/ bottle or such container/ bottle should be rejected by machine.
	[6] Pharmacode verification of carton in cartonator		Slow Speed: 1 carton High Speed: 1 carton Optimum speed: 1 carton after every xx min. until packing process ends.	Wrong Pharmacode must be detected by Reader and machine should stop/Reject with fault display when challenged.
	Pharmacode verification of Pack insert back side and front side in cartonator		Slow Speed: 1 Pack insert (leaflet) High Speed: 1 Pack insert (leaflet) Optimum speed: 1 Pack insert (leaflet) after every xx min. until packing process ends.	Wrong Pharmacode on back side and front side must be detected by Reader with display and machine should stop/Reject with fault display when challenged.
	Visual inspection	Embossing/ overprinting quality	Slow Speed: 1 filled carton High Speed: 1 filled carton Optimum speed: 1 filled carton after every xx min. until packing process ends.	Overprinting/ Embossing quality should be clear, legible and should not get smudged.
		Carton fill value		Cartons fill value as per BPR.
		Carton quality		Carton flap should be closed properly.
		Leaflet (pack insert) folding quality		Leaflet folding pattern and size should be proper.

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

Process Stage	Test	Number of Samples		Acceptance / Evaluation Criteria
Shipper packing	Shipper fill value	**1** filled and sealed shipper at initial, middle and end period of packing process,	Xx count container/ bottle	Component per shipper: XX container/ bottle with cap XX carton Xx pack insert Xx patient information leaflet XX medication pad
			Xxx count container/ bottle	Component per shipper: XX container/ bottle with cap XX carton Xx pack insert Xx patient information leaflet XX medication pad
	Shrink quality	1 filled and sealed shipper at initial, middle and end period of packing process,		Proper shrinking on pack without any damage.
	Carton quality	1 filled and sealed shipper at initial, middle and end period of packing process,		Carton with good overprinting without any damage to the carton.
	Shipper labeling quality	1 filled and sealed shipper at initial, middle and end period of packing process,		Proper aligned labeling with no creases, brittleness, loss on adhesion and wrinkles.
	Transcription accuracy	1 filled and sealed shipper at initial, middle and end period of packing process,		Clear legible and proper printing.
	Strapping quality	1 filled and sealed shipper at initial, middle and end period of packing process,		Check for loose or over tight strapping and deformation of shape of shipper due to strapping.

[6] One carton sampled initially to be used for slow speed, for high speed and each time interval of optimum speed **for** pharmacode verification of carton challenge test.

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

9.0 DETAILS OF DEVIATIONS/ NON CONFORMANCE :

Details of deviations/ non conformances to be recorded in validation report.

10.0 TYPE OF VALIDATION:

Concurrent Validation / Revalidation.

11.0 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.

12.0 RESULTS AND OBSERVATIONS:

To be recorded in validation report.

13.0 RISK MANAGEMENT STUDY:

To be recorded in validation report.

14.0 SUMMARY OF FINDINGS OF VALIDATION ACTIVITY:

Summarize the findings of the validation study to draw an inference.

15.0 RECOMMENDATIONS:

Record the recommendations based on the interpretation of the results in the validation report.

16.0 TEAM APPROVAL:

The individuals who have performed the validation, supervised the validation, completed records, performed the testing of the product should approve the Validation Report.

17.0 REVIEW :

The validation report should be reviewed by Unit Quality Assurance Head. The report should include any follow up action, if required.

18.0 APPROVED BY :

Validation Report should be approved by Unit Quality Assurance Head.

19.0 NOTED BY:

Unit Head should acknowledge the report by signing as Noted by.

20.0 ANNEXURES:

Annexure(s) (if any) attached should be recorded in the validation report

21.0 ABBREVIATIONS:

mg	:	milligram
SOP	:	Standard Operating Procedure
BPR	:	Batch Packing Record
No.	:	Number
AQL	:	Acceptable Quality Level
%	:	Percentage
NDC	:	National Drug Code
±	:	Plus or minus
in	:	inch
g	:	Gram
lb	:	pound
min.	:	minute
hrs.	:	Hours