



CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

1. Objective:

To validate the capsule filling process of _____ Batch.
No. _____ on Automatic capsule filling machine(AF-40T).

2 Scope:

Applicable to filling of Capsules on Automatic capsule filling machine (AF-40T).

3 Principle:

The machine works on intermittent tamping principle wherein the blend is fed into the holes of Dosing disc and then finally to the capsules. (AF-40T)

4. Site of study:

Hormone Capsule Department.

5. Responsibility:

Production : _____
Quality Assurance : _____
Quality Control : _____
Engineering : _____

6. Description of the equipment To be Used:

Automatic capsule filling machine (AF- 40T)

Code No.: _____

∂ Date of Equipment Qualification done on: _____ .

7. Standard Operating Procedure (SOP) & Batch Manufacturing Record (BMR) to be followed:

- i) SOP for operating capsule filling machine : SOP No _____
- ii) SOP for operating Disintegration Apparatus : SOP No _____
- iii) SOP for operating Vernier Caliper : SOP No _____
- iv) SOP for Pour Bulk and Tapped Density Apparatus : SOP No _____
- v) Batch Manufacturing Record : Formulation code no. : _____
Manufacturing code no.: _____



CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

8. Controls:

8.1 Requirements:

i) Status of Raw Materials to be used :

Raw Material	Quantity required in Nos.	Analytical Reference No.	Checked by

ii) Availability of Validated Analytical Methods:

Test	Analytical Method Validation Protocol No./Specification No.	Checked by

iii) Analytical Reference number for validation Technical Information Sheet (T.I. Sheet).

T. I. Sheet sent for analysis of	A. R. No.	Checked by

iv) Operating air pressure of AF-40T machine should be in the range of 6 to 7 kg/sq.cm

v) Operating vacuum range for capsule separation should be _____ inch to _____ Inch of Hg.

vi) In Capsule filling area temperature is maintained at _____°C and _____%RH.

8.2 Calibration details of apparatus



CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

S.No.	EQUIPMENT	CODE No.	CALIBRATION DONE ON	CALIBRATION DUE ON
1.	Filling Machine			
2.	Balance			
3.	Vernier Caliper			
4.	Tapped Density			

8.3 Training details of personnel involved in validation

Name	Training Status	Training reports availability	Checked by

8.4 Precautions:

Safety aspects while operation of equipment and process must be ensure.

9. Validation Procedure:

Carry out the experiment as per the Validation Protocol No.PVP/H/CFP/01
Record the following details:

Product:	Batch No.:
Equipment :	Code No.:
Batch size (Kgs.) :	Batch size (Nos.):
No. of capsules to be sampled :	Speed of the machine : _____SPM
Size and colour of empty capsule :	Printing on capsule:
Date/s of Validation :	

10. Acceptance criteria:



CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

The observations made during the validation should meet the acceptance criteria as given in the Validation Protocol.

11. Non Compliance:

11.1 Details of Deviations:

Deviation Report dated	Checked by

11.2 Details of OOS results:

OOS Report dated	Checked by

Reviewers Comments / Remarks:

12. Type of Validation:

Concurrent validation / Re-validation

13. Frequency:

- 1) Concurrent validation : Three consecutive successful validation exercises.
- 2) Re-validation (Periodic) : One validation exercise should not exceed five years.
- 3) Revalidation (after major change): Three consecutive successful validation exercises.

14. Results/Observations:

- 14.1 Results of Initial checks (Refer Page 6 of 13)
- 14.2 For empty capsule weights (Refer Page 6 of 13)
- 14.3 For in-process checks throughout the batch. (Refer Page 7 of 13)
- 14.4 For Observation and Results when machine speed set at speed of 64 SPM and 86 SPM (for AF-40T) (Refer Page 8 of 13)
- 14.5 For Observation and Results when machine set at upper and lower range of group weight at speed of 107 SPM (for AF-40T) (Refer Page 9 of 13)
- 14.6 For Assay, Content Uniformity and Dissolution results (Refer Page 10 of 13)
- 14.7 For individual weight variation record (by emptying out) (Refer Page 11 of 13)



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

i) Initial Checks:

Tapped density of the blend : _____ gm./ml	Speed of the machine : _____ SPM
Tamping pins positions: 1. _____ 2. _____ 3. _____ 4. _____ 5. _____	Dosing disc thickness: _____ mm. (AF-40T)

ii) Empty Capsules Details:

Box Number	Date of using	Time of using	Weight of 20	
			Empty capsules (g)	Filled capsules (g)

iii) Observation and Results (For Uniformity Throughout The Batch):

Speed of Machine: _____ SPM



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

DATE										ACCEPTANCE CRITERIA
TIME										---
TEMPERATURE OF ROOM										
% RH OF ROOM										
PHYSICAL APPEARANCE										Smooth surface free from scratches
DENTING ON CAPSULES										No Denting on capsules
TELESCOPIC CAPSULES										No Telescopic capsules
NOTCH ON CAPSULES										No Notch on Capsules
V-NOTCH ON CAPSULES										No V- Notch on Capsules
FLOW OF BLEND FROM HOPPER										Uniform Flow
GROUP WEIGHT OF 20 FILLED CAPSULES										
WEIGHT VARIATION										
DISINTEGRATION TIME										
LOCKED LENGTH OF CAPSULES										

Reviewers Comments / Remarks:

iv) **Observation and Results: (Machine Speed Set At 64 SPM And 86 SPM)**

SPEED OF MACHINE 64 SPM
DATE:- TIME :-

SPEED OF MACHINE 86 SPM
DATE :- TIME :-



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

PARAMETER	SPEED AT 64 SPM	SPEED AT 86 SPM	ACCEPTANCE CRITERIA
PHYSICAL APPEARANCE OF CAPSULES			Smooth surface free from scratches
DENTING ON CAPSULES			No Denting on capsules
TELESCOPIC CAPSULES			No Telescopic capsules
NOTCH ON CAPSULES			No Notch on Capsules
V-NOTCH ON CAPSULES			No V- Notch on Capsules
FLOW OF BLEND FROM HOPPER			Uniform Flow
GROUP WEIGHT OF 20 FILLED CAPSULES			
WEIGHT VARIATION			
DISINTEGRATION TIME			
LOCKED LENGTH OF CAPSULES			

Reviewers Comments / Remarks:

v) **Observation and Results:**
(Group Weight Set at Upper Range and Lower Range)

GROUP SET AT _____g
(Lower Range)

GROUP SET AT _____g
(Upper Range)

DATE :-

TIME :-

DATE :-

TIME :-



CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

Speed of the Machine:-107SPM

Speed of the Machine:-107SPM

PARAMETER	Lower Group weight	Higher Group weight	Acceptance Criteria
PHYSICAL APPEARANCE OF CAPSULES			Smooth surface free from scratches
DENTING ON CAPSULES			No Denting on capsules
TELESCOPIC CAPSULES			No Telescopic capsules
NOTCH ON CAPSULES			No Notch on Capsules
V-NOTCH ON CAPSULES			No V- Notch on Capsules
FLOW OF BLEND FROM HOPPER			Uniform Flow
GROUP WEIGHT OF 20 FILLED CAPSULES			
WEIGHT VARIATION			
DISINTEGRATION TIME			
LOCKED LENGTH OF CAPSULES			
CONTENT UNIFORMITY	Refer attached Annexure No.: _____ A.R. No.: _____	Refer attached Annexure No.: _____ A.R. No.: _____	

Reviewers Comments / Remarks:

vi) OBSERVATION AND RESULTS (ASSAY, CONTENT UNIFORMITY AND DISSOLUTION)

Refer Quality Control Report #

A.R.No.: _____ / _____ / _____

Annexure No.: _____



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

Remarks: _____ Checked by : _____

15. Summary of findings of experiment (inference):

16. Recommendations (Including requirements of any additional documentation):

17. Team approval:

Production Quality Assurance Quality Control Engineering
Date:

18. Review (inclusive of follow up action, if any):

19. Approved by:

UNIT QUALITY ASSURANCE UNIT HEAD
Date:

20. Attachments:

21. Abbreviations:

mg. : Milligram
Kg. : Kilogram
OOS : Out of Specification
Gms. : Grams
mm : Millimeter
A.R. No. : Analytical reference Number
Kg/sq.cm : Kilogram per square centimeter
% : Percent
°C : Degrees Centigrade



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

RH : Relative Humidity
SPM : Strokes Per Minute.
g / GM : Gram
SOP : Standard Operating Procedure.
BMR : Batch Manufacturing Record.
T.I Sheet : Technical Information sheet.