CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

1. Objective:

To validate the capsule filling process 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.

4. Site of study:

Hormone Capsule Department.
Location: To be recorded in the report

5. Responsibility:

Production :
Quality Assurance:
Quality Control :
Engineering :
(Individuals to be named in the report)

6. Description of the Equipment to Be Used:

Automatic capsule filling machine ∂ (As per BMR)
Code No.: To be recorded in the report
∂ Date of Equipment Qualification to be recorded in the Report.

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

i) SOP for operating capsule filling machine: SOP No. to be recorded in validation report.
ii) SOP for operating Disintegration Test Apparatus: SOP No. to be recorded in validation report.
iii) SOP for operating Vernier Caliper: SOP No. to be recorded in validation report
iv) SOP for Pour Bulk and Tapped Density Apparatus: SOP No. to be recorded in validation report
v) Batch Manufacturing Record: Formulation code no. and manufacturing code no. to be recorded in report.

8. Controls:

8.1 Requirements:

i) Raw Materials to be used should meet the requirement of specification. (Name of Raw materials, Quantity required, A. R. No. to be recorded in the report).
ii) Validated Analytical Methods for estimation of active ingredient (Reference Analytical Validation protocol number/Specification Number to be recorded in the report).
iii) Analytical Reference number for validation Technical Information Sheet (T. I. Sheet).

iv) Operating air pressure of Automatic Capsule Filling machine should be in the range of 6 to 7 kg/sq. cm.

v) Operating vacuum range for capsule separation should be within range as per Automatic Capsule Filling machine involved in filling process.

vi) In Capsule filling area temperature & RH is maintained as per specified in BMR and record the same in Validation report.

8.2 Calibration:

Calibrated Testing Equipment (Calibration details to be recorded in the report).

8.3 Training:

Availability of training records of personnel involved in the validation exercise should be recorded in the validation report.

8.4 Precautions:

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

9. Validation Procedure:

9.1 Check the Tapped density of the blend: Tapped density to be recorded in the report.

9.2 Dosing disc to be selected based on size of capsule used and thickness of dosing disc to be decided based on the Tapped density of the blend to be filled.

9.3 Assemble the parts of capsule filling M/C as per relevant SOP.

9.4 Load the blend in the hopper of capsule filling M/C.

9.5 Determine the average weight of the empty capsules by taking 20 empty capsules from each box and record in validation report.

9.6 Validation at standard speed

i) Operate Automatic capsule filling machine as per SOP at optimum speed.

ii) Perform the following tests on capsules collected in the container below the capsule ejection chute of the automatic capsule filling machine.

a. Physical appearance of capsules.
b. Colour of Capsule **@**
c. Printing on Capsule **@**
d. Denting on capsules.
e. Telescopic defect on capsules.
f. Notch on capsules.
g. V-notch on capsules.
h. Temperature and Relative Humidity of filling room

Frequency: Initial and every half an hour.
Note : @ To be done at the start of the batch only.

iii) Perform the following tests during the filling operation at optimum speed.

a. Flow of blend from hopper.
b. Group weight of 20 filled capsules.

Frequency: Initial and every half an hour.

*iv) Collect "50" filled capsules from the capsule ejection chute of the machine and perform the following tests

a. Individual weight variation by emptying out of "30" filled capsules.
b. Locked length on "6" (Depending on Automatic Capsule Filling Machine [AF-40T]) filled capsules.
c. Disintegration Test on 6 capsules.

Frequency: Initial and every one hour and at the end of the machine run.

***NOTE: If batch will complete within one hour, then the frequency should be at the Initial, Middle and End of the batch of the machine run.**

vi) Collect 40 capsules and perform Assay, dissolution and content uniformity of sample at initial, middle and end of the batch.

9.7 Following studies to be done for Speed and Group weight challenge.

9.7.1 Speed Challenge

Following studies to be done during filling of the batch. Set the machine speed at 64 and 86 SPM for Automatic capsule filling machine [AF-40T].

Collect "50" filled capsules from the capsule ejection chute of the filling Machine and perform the following tests:-

a. Physical appearance of capsules.
b. Flow of blend from hopper.
c. Denting on capsules.
d. Telescopic defect on capsules.
e. Notch on capsules
f. V-notch on capsules
g. Group weight of 20 filled capsules.
h. Individual weight variation by emptying out of "30" filled capsules.
I. Locked length on "6" (Depending on Automatic capsule filling machine [AF-40T] used) filled capsules.
j. Disintegration test on 6 capsules.

9.7.2 Group weight challenge:

Set the machine at upper and lower limit of group weight without disturbing other setting and speed at 107 SPM for Automatic capsule filling machine (As per BMR) [AF-40T].

Collect about "50" capsules from the locked capsule ejection chute of the filling machine, and check the following.

a. Physical appearance of capsules.
b. Flow of blend from hopper.
c. Denting on capsules.
d. Telescopic defect on capsules.
e. Notch on capsules
f. V-notch on capsules
g. Group weight of 20 filled capsules.
h. Individual weight variation by emptying out of "30 "filled capsules.
i. Locked length on "6" (Depending on Automatic capsule filling machine used) filled capsules.
j. Disintegration test on 6 capsules.
k. Uniformity of dosage unit on 10 capsules

(Note: Capsule filled for above validation i.e, running at upper and lower limit of group weight to be destroyed)

10. Acceptance criteria:

The observations made during the validation should meet the acceptance criteria.

IN-PROCESS TESTS	ACCEPTANCE CRITERIA
TEMPERATURE OF ROOM	As per BMR
% RH OF ROOM	As per BMR
PHYSICAL APPERANCE	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	As per BMR
WEIGHT VARIATION	As per BMR
LOCKED LENGTH OF CAPSULES	As per BMR
DISINTEGRATION	As per BMR
ASSAY	As per QC specification
CONTENT UNIFORMITY	As per QC specification
DISSOLUTION	As per QC specification

11. Non Compliances:

Details of deviations (including justification of acceptance) done to successfully carry out the validation exercise and any OOS results obtained should be checked. (Attach the details in the Validation report).

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:

Record the observations during the study and results obtained from Quality Control Department in the Validation Report.

15. Summary of findings of experiment (inference):

Summarize the findings of the Validation Study to draw an inference.

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

Record the recommendations based on the interpretation of the results of the Validation Report

17. Team approval:

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

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

The Validation Report should be reviewed by Unit Quality Assurance and Unit Head. The report should include any follow up action if required.

19. Approved by:

Validation Report should be finally approved by Unit Quality Assurance and Unit Head.

20. Attachments:

Annexures (if any) attached to the Validation Report should be recorded.

21. Abbreviations:

mg.	: Milligrams
OOS	: Out of specification
&	: and
No. / No's	: Number / Numbers
A.R. No.	: Analytical reference Number
Kg/ sq. cm	: Kilogram per square centimeter
Hg	: Mercury
%	: Percent

CAPSULE FILLING PROCESS ON AUTOMATIC CAPSULE FILLING MACHINE

^{0}C : Degrees Centigrade
RH : Relative Humidity
SPM : Strokes Per Minute.
KPa : Kilo-Pascal.
SOP : Standard Operating Procedure.
BMR : Batch Manufacturing Record.
T.I Sheet : Technical Information sheet.