VALIDATION PROTOCOL FOR COATING OF TABLETS

1. Objective:

Coating of tablets using Neocota/Coating pan.

To validate the process of coating by ensuring that the tablets when coated, as per the Batch Manufacturing Record are uniformly coated and confirm to the specifications.

2. Scope:

Applicable to all products undergoing coating (Aqueous, Film, Enteric and Seal).

3. Principle:

Coating of tablets using Neocota / Coating pan.

4. Site of the Study:

Hormone Coating Department.

5. Responsibility:

Representatives from: Production
Quality Control
Engineering
Quality Assurance
(Individuals to name to be recorded in the report)

6. Description of the Equipment to be used:

Equipment: Neocota/ Coating pan.

CODE No.: *Details to be recorded in the report*

CAPACITY: *Details to be recorded in the report.*

Date of equipment qualification to be recorded in the validation report.

7. BMR and SOP's to be followed:

7.1 **SOP for Operating Neocota:** SOP No. to be recorded in the report.
7.2 **SOP for Operating Vernier caliper:** SOP number to be recorded in the report.
7.3 **SOP for Operating Hardness tester:** SOP number to be recorded in the report.
7.4 **SOP for Operating DT apparatus:** SOP number to be recorded in the report.
7.5 **SOP for Operating Analytical balance:** SOP number to be recorded in the report.
7.6 **Batch Manufacturing Record:** *Manufacturing Code No. to be recorded in the report.*

8. Controls:

8.1 Requirement:

Validated Analytical Methods for estimation of active ingredient/s: *Details to be recorded in Report.*

8.2 Calibration:

Calibration of Equipment/Testing Apparatus. *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:

8.4.1 Ensure instrument Qualification is been done before use.
8.4.2 Ensure proper instructions are followed as laid down in BMR and SOP.
8.4.3 Ensure Calibration status of testing apparatus before use.
8.4.4 Safety Aspects while operation of equipment and process must be ensured.

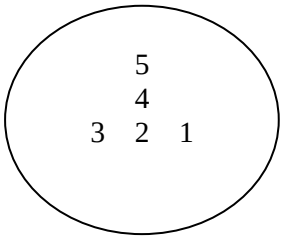
9. Validation Procedure:

9.1 Operate the equipment as per the SOP.

9.3 Record the following in the validation report.

9.3.1 Product Name
9.3.2 Batch Number
9.3.3 Equipment
9.3.4 Quantity loaded
9.3.5 Batch size in Kgs.
9.3.6 Volume occupied
9.3.7 Number of lots
9.3.8 Shape of pan
9.3.9 Number of baffles
9.3.10 Working capacity of pan
9.3.11 Number of spray guns
9.3.12 Ambient temperature of the coating cubicle/area
9.3.13 Date/s of experiment

9.4 Take a composite sample of 50 tablets from 5 positions as shown below from the tablet bed during the process, after time intervals of 1 hour.



Check the followings:

a. Average weight of 20 tabs. for weight rise.
b. Individual Weight and Thickness variation on 20 tabs.
c. Any visual defects.

9.5 Sample 100 tablets before and after coating, check the following:

a. Average weight of 50 tablets for weight rise
b. Individual Weight variation on 50 tabs.
c. Individual Thickness variation on 50 tabs.
d. Hardness (on 5 tabs).
e. Disintegration time of 6 tablets.
f. Any visual defects.

9.6 Check the dissolution of tablets. (Refer QC reports).

9.7 Record the process parameters.

9.8 Check and record the spray rate at a regular interval of one hour till the end of any one Lot.

9.10 Take a composite sample of 1000 tablets and do a rejection analysis to identify the types of defects.

9.11 Record the following process parameters at time intervals of every 1 hour (or) as per the intervals given in the BMR throughout the coating process for the Batch or lot.

9.11.1 Inlet, Exhaust and bed temperature

9.11.2 Pan RPM

9.11.3 Atomizing air pressure

9.11.4 Visual inspection for over wetting or under spraying or over drying.

9.11.5 Check the spray gun to tablet bed distance initially at the start of the batch/Lot.

9.11.6 Check and record the spray rate at a regular interval of one hour (or) as per the intervals given in the Batch Manufacturing Record till the end of the batch or lot.

9.12 Attach all data records to the validation report.

9.13 Compare the data with Acceptance Criteria.

Note: Tablets collected for in-process tests to be destroyed after Completion of in-process tests as per SOP.

10. Acceptance criteria:

10.1 The Average weight, average weight rise and thickness of coated tablets should comply to the standard limits given in the BMR.

10.2 Hardness and disintegration time of coated tablet should comply to the standard limits given in the Batch Manufacturing Record.

10.3 Visual inspection after every interval should not show signs of over wetting or under spraying or over drying.

10.4 The process parameters throughout the coating should comply to the standard limits given in the Batch Manufacturing record.

10.5 Dissolution results should comply to the QC specifications.

10.6 The quantity of rejection after inspection should not be more than 1.0% out of the total quantity sorted.

11. Non Compliance:

11.1 Deviation:

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

11.2 Out of Specification:

Any out of specification result observed should be recorded in the validation report and investigation should be done.

12. Type of validation:

Concurrent Validation/Revalidation.

13. Frequency of validation:

12.1 New Product: Three successful validation exercises.

12.2 Revalidation (Existing Product): One validation exercise within five years.

12.3 Revalidation (After major change): Three 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:

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

16. Recommendation:

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:

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

19. Approval by:

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

20. Attachment:

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

21. Abbreviations:

OOS	:	Out of specification
BMR	:	Batch Manufacturing Record
T.I Sheet	:	Technical Information Sheet
SOP	:	Standard Operating Procedure
A.R No.	:	Analytical Reference Number