DRY MIXING OF MATERIALS IN SAIZONER

1. **Objective:**
   To validate the process of Dry Mixing of Raw materials so as to establish that the blend uniformity of active ingredient is achieved at standard dry mixing time and the blend uniformity results are within the specified limit.

2. **Scope:**
   Applicable to Mixing of Raw materials in Saizoner.

3. **Principle:**
   Mixing of raw materials due to rotation of Agitator in Saizoner.

4. **Site of the Study:**
   Hormone Department.

5. **Responsibility:**
   Production
   Engineering
   Quality Control
   Quality Assurance
   (Individuals to be named in the report)

6. **Description of the Equipment to be used:**

   Equipment : SAIZONER λ
   Code No : To be recorded in report
   Capacity : To be recorded in report
   RPM (Agitator) : To be recorded in report
   RPM (Chopper) : To be recorded in report

   λ Date of equipment Qualification done to be recorded in the report.

   Sampling thief and Bulk sampler Code No. to be recorded in the validation report.

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

   i) SOP for operating Saizoner : To be recorded in report

   ii) SOP for sampling with Sampling thief : To be recorded in report

   iii) Batch Manufacturing Record : Formulation Code No. and Manufacturing code No.: To be recorded in the validation report

8. **Controls:**

   8.1 Requirements:

   i. Active Pharmaceutical Ingredient to be used should meet the requirement of Specification (Name of the active ingredient, Quantity required, Pharmacopoeia grade and the test involved for raw material testing with result and Analytical Reference number should be recorded in Validation report) .

ii. Validated Analytical Methods for estimation of active ingredient (Reference Analytical Validation protocol number / Reference Specification No. to be recorded in the report).

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

8.2 Calibration:

Calibration details of Saizoner: Details to be recorded in the report.

8.3 Training:

Availability of Training Record 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:

i. Load the Sifted materials in the Saizoner as per the sequence given in the Batch Manufacturing Record (BMR).

ii. Operate the Saizoner as per SOP.

iii. Sample approximately 1 - 3 unit doses in triplicate from 10 positions as shown in sampling plan on Page 5 with the help of a sampling thief, at standard Dry mixing time that specified in the BMR. Send these samples to Quality Control (QC) for content analysis.

iv. The results of content should be reported as Individual test results.

v. % RSD should be calculated for the results of content.

vi. Check the appearance of Mix visually after completion of mixing operation and record the observations in the report.

10. Acceptance criteria:

The Optimal time decided should conform to the following:

i) Uniform distribution of the mix, when checked visually.

ii) Content of Active Ingredient upon testing as per Quality Control Specification should be within the specified limit.

iii) The Relative Standard Deviation (RSD) of content of Active Ingredient sampled at the optimal time should be less than 5%.

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:

1) Concurrent validation
2) Re-validation

13. Frequency:

1) Concurrent validation : Three consecutive successful validation exercises.
2) Re-validation (Periodic) : One validation exercise within 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:

Unit Quality Assurance and Unit Head should finally approve validation Report.

20. Attachments:

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

21. Abbreviations:

Lts. : Litres
No. : Number
A.R.No. : Analytical Reference Number
RSD : Relative Standard Deviation
gms. : Grams
OOS : Out of Specification
mg. : Milligrams
QC : Quality Control
RPM : Revolutions Per Minute
% w/w : Percent weight by weight
BMR : Batch Manufacturing Record
T.I Sheet : Technical Information Sheet

DRY MIXING OF MATERIALS IN SAIZONER

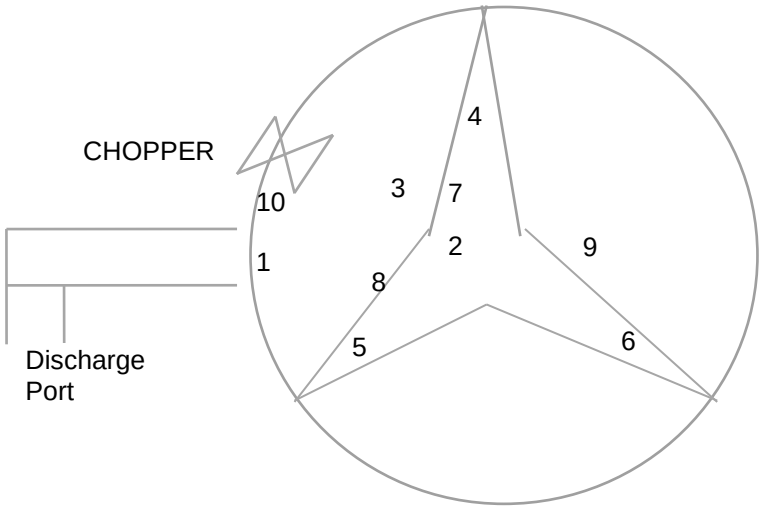
SOP : Standard Operating Procedure

MIXING VALIDATION

Sampling positions

1. Top of Discharge Port.
2. Near the cone, top layer.
3. Between cone and wall.
4. Above agitator.
5. Above agitator.
6. Above agitator.
7. Below agitator.
8. Below agitator.
9. Below agitator.
10. Below chopper.

TOP VIEW OF SAIZONER



SIDE VIEW OF SAIZONER