PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DRY MIXING OF RAW MATERIALS IN SAIZONER

1. Objective:

To validate the process of dry mixing of _____ B. No.: _____ & Batch Size_____ Kg. _____Nos., 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 : _____

6. Description of the Equipment to be used:

Equipment : SAIZONER λ
CODE No :
CAPACITY :
RPM (Agitator) : ____ RPM at slow speed and _____RPM at fast speed.
RPM (Chopper) : ____ RPM at slow speed and _____RPM at fast speed.

λ Equipment Qualification done as per protocol dated _____

Sampling Thief code No.: _____ Bullet No.: _____

Bulk Sampler Code no._____

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

i) SOP for operating Saizoner : _____

ii) SOP for sampling with Sampling thief : _____

iii) Batch Manufacturing Record : Formulation Code No.: _____

Manufacturing Code No.:_____

8. Control:

8.1 Requirements:

DRY MIXING OF RAW MATERIALS IN SAIZONER

i) ACTIVE PHARMACEUTICAL INGREDIENT:

Active Pharmaceutical Ingredient : _____

Pharmacopoeial grade : _____

Test ▼	Results A.R No.:	*Results A.R No.:	*Results A.R No.:	Acceptance Criteria

* In case material of two or more Analytical Reference Number is used

Active Pharmaceutical Ingredient	Quantity required in Kg.	Analytical Reference No.	Checked by

Analytical method validation protocol No.\Reference Specification No. _____

Note: if more than one active is present in the product then attached annexure,i.e, same of this page.

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

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

8.2 Calibration:

i) Calibration details of Saizoner

S.No.	Equipment	Code No.	Calibration Done on	Calibration Due on

8.3 Training:

Training details of personnel involved in validation:

DRY MIXING OF RAW MATERIALS IN SAIZONER

Name	Training Status	Training reports availability	Checked by

8.4 Precautions:

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

9. Validation Procedure:

Carry out the Validation as per the Validation Protocol

Equipment	
Product	
Mixing time as per BMR	
Sampling to be drawn at intervals of	
Date of Validation	

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 _____% to _____% (limit as specified specification).

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

11. Non Compliances:

i) Details of Deviations:

Deviation Report dated	Checked by

ii) Details of OOS results:

OOS Report dated	Checked by

DRY MIXING OF RAW MATERIALS IN SAIZONER

Reviewers Comments / Remarks:

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:

a) **CHEMICAL ANALYSIS**

Results of Content as per Quality Control Report # A.R.No.:_____
(Technical Information sheet attached)

Reviewers Comments / Remarks:

b) **APPEARANCE OF MIX AFTER MIXING**

Reviewers Comments / Remarks:

15. Summary of findings of experiment (inference):

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

17. Team approval:

Production	Engineering	Quality Control	Quality Assurance
Date:			

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

19. Approved by:

UNIT QUALITY ASSURANCE	UNIT HEAD
Date:	

20. Attachments:

21. Abbreviations:

%	: Percent
B.No.	: Batch Number
Lts.	: Litres
No. / Nos	: Number / Numbers
A.R.No.	: Analytical Reference Number
RSD	: Relative Standard Deviation

DRY MIXING OF RAW MATERIALS IN SAIZONER

OOS	: Out of Specification
mg.	: Milligram
Kg.	: Kilogram
RPM	: Revolutions Per Minute
%w/w	: Percent weight by weight
BMR	: Batch Manufacturing Record
T.I Sheet	: Technical Information Sheet
SOP	: Standard Operating Procedure
API	: Active Pharmaceutical Ingredients