

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Quality Assurance SOP No.:				
Title: Yield deviation at different stages of processing	Effective Date:			
Supersedes: Nil	Review Date:			
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1.0 OBJECTIVE:

To lay down the procedure for classifying yield deviation into normal and abnormal and to investigate the reasons for the abnormal deviations.

2.0 SCOPE:

This procedure shall be followed to classify and investigate yield deviations in the products.

3.0 RESPONSIBILITY:

Officer /Executive/Head of production department Officer /Executive/Head of QA department

4.0 **DEFINITION(S):**

NA

5.0 **PROCEDURE:**

- 5.1 Standard yield for each stage of the processing shall be calculated and shall be specified in Batch Manufacturing Record/Batch Packing Record.
- 5.2 Production Head shall compare the yield of each batch with standard yield to determine deviations.
- 5.3 Yield deviation shall be classified as 'ABNORMAL' in the following instances:

Blending stage	-	Less than 99.5%
Compression stage	-	Less than 99.0%
Coating stage	-	Less than 99.0%
Inspection stage	-	Less than 98.5%
Packing stage	-	Less than 98.0%

- 5.4 For all abnormal deviations, an investigation shall be carried out jointly by Production Head and Quality Assurance Head.
- 5.5 The investigation report shall give the reasons for deviations and corrective actions taken to



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prevent the recurrence.

ABBREVIATION(S): 6.0

QA – Quality Assurance

7.0 **REFERENCE(S):**

NA

ANNEXURE(S): 8.0

Nil

9.0 **REVISION CARD:**

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION