DECODING PHARMA

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:**
Issue Date:	**Page No.:**

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 prevent the recurrence.

6.0 ABBREVIATION(S):

QA – Quality Assurance

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Nil

9.0 REVISION CARD:

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