



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** SOP for Determination of Monocarton, Carton Pack, Shrink, Outer and Shipper Weight Range

<b>SOP No.:</b>		<b>Department:</b>	Production
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	1 of 4

### 1.0 OBJECTIVE:

To lay down a Procedure to determination of Mono carton, Carton pack, Shrink/Outer and Shipper weight range.

### 2.0 SCOPE:

This SOP is to determination of mono carton, Carton pack, Shrink/Outer and Shipper weight range in Packing Area of Injectable section.

### 3.0 RESPONSIBILITY:

Officer / Executive- Production.

Officer / Executive- IPQA.

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBREVIATIONS:

BPCR	Batch production and control record
Mfg.	Manufacturing
MRP	Maximum retail price
No.	Number
QA	Quality assurance
SOP	Standard Operating Procedure

### 6.0 PROCEDURE:

#### 6.1 PROCEDURE TO DETERMINATION OF MONO CARTON, CARTON PACK, SHRINK / OUTER AND SHIPPER WEIGHT RANGE:

**6.1.1** Check the "Status Board" of the Packing Area for Product Name, Batch No., Mfg. Date, Exp. Date, Batch Size, & MRP and ensure that the details are matching with the BPCR of Batch to be processed.

**6.1.2** Check the cleanliness of the Packing Area and ensure that it is free from the remains of the Previous Batch / Product.

**6.1.3** Take line clearance for packing and prepared the weigh range.

#### **6.1.4 Monocarton /Carton pack weight range:**

**6.1.4.1** Take 10 readings of mono carton(X1, X2.... UP TO X10)

**6.1.4.2** Take average of the same(  $A = X1 + X2 + \dots + X10 / 10$ )

**6.1.4.3** In case of Ampoule/Respules, Take weight of a single empty unit divide by two. ( $B = D / 2$ )

**6.1.4.4** In case of three piece / DPI, Consider 1.0 gram (B) to determine the weight range.



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**6.1.4.5** Then deduct (B) and plus (B) with the average weight for determine minimum and maximum value ( $C1=A-B$  and  $C2=A+B$ ), here C1 is minimum weight and C2 is maximum weight

**6.1.4.6** Fill the **Annexure-I**.

**6.1.5 Shrink/ Outer weight range :**

**6.1.5.1** Take 10 readings of shrink/outer ( $X1, X2, \dots, UP\ TO\ X10$ )

**6.1.5.2** Take average of the same ( $A = X1+X2+\dots X10/10$ )

**6.1.5.3** In case of Ampoule/Respules Take filled weight of a mono carton and divide by two or empty weight of single unit divide by two ( $B=D/2$ ).

**6.1.5.4** In case of DPI Take filled weight of solvent and divided by two ( $B=D/2$ ).

**6.1.5.5** In case of three piece / DPI, Consider 1.0 gram (B) to determine the weight range.

**6.1.5.6** Then deduct (B) and plus (B) with the average weight for determine minimum and maximum value ( $C1=A-B$  and  $C2=A+B$ ), here C1 is minimum weight and C2 is maximum weight.

**6.1.5.7** Fill the **Annexure-I**.

**6.1.6 Shipper weight range :**

**6.1.6.1** Take 10 readings of shipper ( $X1, X2, \dots, UP\ TO\ X10$ )

**6.1.6.2** Take average of the same( $A = X1+X2+\dots X10/10$ )

**6.1.6.3** Take filled weight of a single carton/2 or weight of a single carton (B) and carton pack/shrink/outer and divide by four (B).

**6.1.6.4** Then deduct (B) and plus (B) with the average weight for determine minimum and maximum value ( $C1=A-B$  and  $C2=A+B$ ), here C1 is minimum weight and C2 is maximum weight. (Ampoule, Respules, DPI and Three piece sections)

**6.1.6.5** Fill the **Annexure-I**.

**6.1.7 Instructions :**

**6.1.7.1** Take weighing printout of Shrink pack/Outer box and Shipper. Attach this printout in the respective BPR.

**6.1.7.2** Make a weight range status label and shall be verified by QA and same entry shall be done in respective BPCR then proceed.

**6.1.7.3** Weighing printout of all the shrink pack/outer box and shipper shall be checked hourly by production and QA alternatively.



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**6.1.7.4** If weight of any Shrink pack/Outer box or shipper is observed out of prepared range limit, then open it and recheck the particular Shrink pack/Outer box or shipper to ensure the availability of all required material like product & leaflet and remark shall be mention on print out with sign, date and counter checked by QA also.

**6.1.7.5** Prepared weight rage can be change if required due to uneven weight of packing materials, proper remarks shall be mentioned on respective BPCR, separate print shall be taken for new weight range, proper entry shall be done in BPCR for new weight range and separate status shall be prepared.

**6.1.7.6** Consider the weight of leaf let whenever it applicable and also include in weight range procedures if required.

**6.1.7.7** After completion of packing weight of Minimum and maximum shipper should be encircled in printout and the same shipper should be verified in presence of IPQA. The details of the same with remark to be mentioned in the printout/BPR.

### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Preparation of Weight Range	

**ENCLOSURES:** SOP Training Record.

### 8.0 DISTRIBUTION:

- Controlled Copy No. 01      Quality Assurance
- Controlled Copy No. 02      Production
- Master Copy                      Quality Assurance

### 9.0 REFERENCES:

Not Applicable

### 10.0 REVISION HISTORY:

#### CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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### ANNEXURE – I PREPARATION OF WEIGHT RANGE

<b>BLOCK:</b>		<b>SECTION:</b>	
<b>PRODUCT NAME:</b>		<b>BATCH NO. :</b>	
<b>BATCH SIZE:</b>		<b>WEIGHT RANGE FOR :</b>	

S.No. (Unit.....)	Weight (In Gm /Kg)
1 (X1)	
2 (X2)	
3 (X3)	
4 (X4)	
5 (X5)	
6 (X6)	
7 (X7)	
8 (X8)	
9 (X9)	
10 (X10)	
<b>Total Weight X (X1+X2+....X10)</b>	
<b>Average Weight A (X/10)</b>	

**Note: - B (Minimum accountable weight) as per following details, Can be consider on the type of case.**

**B=**

**Minimum Weight C1=A-B**

**C1=**

**Maximum Weight C2=A+B**

**C2=**

**Prepared By: -  
(Production)**

**Verified By:-  
(QA)**