STANDARD OPERATING PROCEDURE

Title: Handling of Tubular and Moulded Vials

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 2	

1.0 OBJECTIVE:

To lay down a procedure for Handling of Tubular and Moulded vials.

2.0 SCOPE:

This SOP is applicable for Handling of Tubular and Moulded vials in Production area of Dry Powder Injection Section.

3.0 RESPONSIBILITY:

Officer/Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
DPI	Dry Powder Injection
Ltd.	Limited
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure
WFI	Water for Injection

6.0 PROCEDURE:

6.1 Before de-cartoning the vials (10 ml/20 ml/30 ml Tubular/Moulded vials), if any broken vial found in the pack, the packed inner has to be quarantined.

6.2 Empty vials before washing to be inspected.

6.3 Before washing, if vial breaks at the in feed of washing machine, adjacent vials should (Approx. 20 vials) be removed and destroyed and it has been recorded in BMR with the reason.

6.4 Cleaning of conveyor of Tunnel sterilizer should be checked daily with High Beam Torch i.e. before and after end of activity.

6.5 After Tunnel sterilization, empty sterilized vials to be inspected before Filling.

6.6 If any breakages of empty sterilized vials found during filling then immediately stop filling and closed vicinity vials should be discarded. And this has to be recorded in BMR with the reason of breakage.

6.7 After filling and sealing, vials has to be checked for sealing quality and sealing pressure.

6.8 Filled and sealed vials to be checked after reconstitution with their respective sterile diluting agents every hourly as an in process checks of filling and sealing operation.

6.9 Filled and sealed vials to be inspected on semiautomatic visual inspection machine.

6.10 If any glass particles observed during the visual inspection, batch should be inspected 100% offline.

6.11 After packing of batch, 20% pack stock inspection should be carried out prior to dispatch of batch.

7.0 ANNEXURES:

Not Applicable

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