



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: Online Rejection

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

### 1.0 OBJECTIVE:

To lay down a procedure for On-Line Rejection.

### 2.0 SCOPE:

This SOP is applicable for On-Line Rejection of approved packing material on shop floor or during dispensing for any discrepancy at .....

### 3.0 RESPONSIBILITY:

Officer/Executive Concerned Department

### 4.0 ACCOUNTABILITY:

Head-QA

### 5.0 DEFINITION:

Dismiss as inadequate, unacceptable, or faulty material rejects on shop floor for any discrepancy is called “On-Line Rejection”.

### 6.0 PROCEDURE:

- 6.1 In case of Packaging Material, if fails in machine suitability during Packaging Operation, Production Officer/Executive shall initiate Online Rejection Note as shown in **Annexure-I**, Titled “**On-Line Rejection Note**”.
- 6.2 On completion of Online Rejection Note, Production shall submit the Online Rejection Note to IPQA for verification.
- 6.3 IPQA person shall verify the material/consignment for Online Rejection and sign the On-Line Rejection Note by green ink.
- 6.4 Production Officer/Executive shall submit the Note to Head QA for approval.
- 6.5 On receipt of Online Rejection Note, QA shall make an entry in Online Rejection Record as shown in **Annexure-II**, Titled “**On-Line Rejection Record**”.
- 6.6 Head QA shall give the approval on Online Rejection Note by confirming the material / consignment.



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- 6.7 QA shall take three photo copies of On-Line Rejection Note and submit back the original Note along with one photo copy to Production.
- 6.8 On receiving the Note copy form QA, Production shall affix filled “**On-Line Rejection**” label on a rejected material as per format with reference to SOP, titled “**Status Labeling**”.
- 6.9 Original copy shall be attached with BMR & BPR and a photocopy shall be send to store along with the rejected material.
- 6.10 QA Officer/Executive shall send one copy of Online Rejection Note to PPIC Department.
- 6.11 QA officer/Executive shall retained one photocopy with on line rejection record in IPQA.
- 6.12 Online Rejected material shall be considering as a rejected material and should be kept in rejected room.
- 6.13 A unique number shall be assigned to Online Rejection Note as per below numbering system:

### **OLR/YY/NNNN**

#### **Where,**

**OLR** - stands for Online Rejection

**/** - stands for separator

**YY** - stands for last digit of the year (i.e. 19 stands for 2019, 20 stands for 2020 and so on.

**NNNN-** stands for the continuous serial number of Online Rejection Note raised in the respective year (i.e. 0001, 0002, 0003,.....so on).

- 6.14 Record the On-line Rejection details in **Annexure-II**, Titled “**On-Line Rejection Record**”.

### **7.0 ABBREVIATIONS:**

SOP	Standard Operating Procedure
QA	Quality Assurance
QC	Quality Control
No.	Number
OLR	Online Rejection Note
RM	Raw Material
PM	Packaging Material
Ltd.	Limited





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### ANNEXURE-I

#### Online Rejection Note

<b>Date:</b>		
<b>Online Rejection Note No.:</b>		
<b>Product/Material Name:</b>	<b>GRN No./Issue No.:</b>	
<b>Batch No.:</b>	<b>Batch Size:</b>	
<b>Mfg. Date:</b>	<b>Exp. Date:</b>	
<b>Rejected Product/Material Name:</b>		
<b>A.R. No.:</b>		
<b>Manufacturer/ Supplier:</b>		
<b>Quantity Received:</b>		
<b>Quantity Rejected:</b>		
<b>Reason for Rejection:</b>		
<b>Remarks:</b>		
<b>Rejection Note Prepared By</b> Production Officer/Executive Sign & Date	<b>Verified by</b> QA Officer/Executive Sign & Date	<b>Approved By</b> Head QA Sign & Date

