PHARMA DEVILS

PRODUCTION DEPARTMENT

| STANDARD OPERATING PROCEDURE | |
|---|---|
| **Department:** Production | **SOP No.:** |
| **Title:** Lotwise/Batchwise allocation of API in Exhibit Batches for USA | **Effective Date:** |
| **Supersedes:** Nil | **Review Date:** |
| **Issue Date:** | **Page No.:** |

**Vernacular SOP:** No

**1.0 OBJECTIVE:**

1.1 To lay down a procedure for Lot wise/ Batch wise allocation of API in Exhibit Batches for USA.

**2.0 SCOPE:**

2.1 The procedure is applicable to the Lotwise/ Batch wise allocation of API in Exhibit Batches for USA in Production area.

**3.0 RESPONSIBILITY:**

3.1 Officer and Executive Production: Calculate and ensure the Lotwise/Batch wise allocation of API.

3.2 Officer and Executive Store: Provide and ensure the Lotwise/ Batch wise allocation of API.

3.3 Officer and Executive: Quality Assurance ensure the Lotwise/Batch wise allocation of API.

3.4 Head Production: Shall ensure compliance and implementation of the SOP.

3.5 Head Store: Shall ensure compliance and implementation of the SOP.

**4.0 DEFINITION (S):**

4.1 Exhibit Batch: All Registration related batches to be manufactured for US market registration.

**5.0 PROCEDURE:**

5.1 Request for number of Exhibit batches raised by production department on the batch record requisition slip as per SOP "Requisition, Issuance and Archival of Batch Manufacturing and Packing Records".

5.2 Request will be given to store for allocation of Vendor lot no./ Batch no. for the batches as per requirement of exhibit batches describe below-

5.2.1 If we are making 3 exhibit batches, 2 exhibit batches should be made with 2 different API lot numbers whereas 3rd batch should be made from either of two or mix of two lots.

**For Example:** If we are making 2 exhibit batches, one exhibit batch should be made with 2 different API lot numbers whereas 2nd batch should be made from either of two or mix of two lots.

5.2.2 If we are making common blend of 3 exhibit batches, 2 exhibit batches common blends to be made from 2 different lots of APIs and 3rd common blend should be from either of two or mix of two lots.

**For Example:** If we are making common blend of 2 exhibit batches, one exhibit batch common blend to be made from 2 different lots of APIs and 2nd common blend should be from either of two or mix of two lots.

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Store allocates the lot no. for exhibit batches on BMR requisition slip and API vendor lot allocation sheet (Annexure I, "API vendor lot Allocation Sheet").

5.3 After allocation of Vendor lot no./Batch no. by store request will given to QA department for issuance of BMR.

5.4 During the generation of work order in ERP. Allocated Vendor lot no. / Batch no. for these batches to be selected manually by production supervisor.

**Note:** During the work order generation and their FIRM PLAN production supervisor will ensure the option for selection of API Lot no. in ERP.

5.5 After confirmation of ERP operation initiate the calculation of the batch record by production officer and verified by QA officer.

**6.0 ABBREVIATION (S):**

6.1 Q.A. : Quality Assurance

6.2 API : Active pharmaceutical ingredient

6.3 SOP : Standard operating procedure

6.4 BMR : Batch manufacturing record

6.5 ERP : Enterprise Resource Planning

**7.0 REFERENCE (S):**

7.1 SOP: Requisition, Issuance and Archival of Batch Manufacturing and Packing Records.

**8.0 ANNEXURE (S):**

| Annexure no. | Title of Annexure | Format No. | Mode of execution |
|---|---|---|---|
| Annexure-I | API vendor lot Allocation Sheet | | Log Book |

**9.0 DISTRIBUTION:**

9.1 **Master Copy:** Quality Assurance

9.2 **Controlled Copy (S):** Production Department (01), Store Department (01), Quality Control (01), Quality Assurance (01)

9.3 **Reference Copy (S):** Production department (02)

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**10.0 REVISION HISTORY:**

| S.No. | Version No. | Change Control No. | Reason (s) for Revision | Details of Revision | Effective Date |
|---|---|---|---|---|---|
| 1. | 00 | | New SOP | NA | |

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## ANNEXURE I

## API VENDOR LOT ALLOCATION SHEET

**PRODUCT NAME :**_____

**API NAME :**_____ **RM CODE:** _____ _____

| Exhibit Batch Details | AR. No. | Vendor Batch No. | Quantity (kg) | Provided By | Checked By | Batch No. | Done By | Verified By (QA) |
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