

WAREHOUSE DEPARTMENT

STANDARD OPERATING PROCEDURE			
Department: Warehouse	SOP No.:		
Title: Operation and Cleaning of Deep Freezer	Effective Date:		
Supersedes: Nil	Review Date:		
Issue Date:	Page No.:		

#### 1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Deep Freezer.

#### 2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Deep Freezer at Raw Material Store.

#### 3.0 RESPONSIBILITY:

Operating Person-Warehouse

#### **4.0 ACCOUNTABILITY:**

Head-Warehouse

#### **5.0 ABBREVIATIONS:**

IPA Isopropyl Alcohol

Ltd. Limited No. Number

QA Quality Assurance

SOP Standard Operating Procedure

Temp. Temperature

WFI Water for Injection

#### **6.0 PROCEDURE:**

#### 6.1 Operation:

- **6.1.1** Switch "ON" the Main Switch.
- **6.1.2** Set the Temperature 2°C to 8°C of all deep Freezer.
- **6.1.3** According Temperature requirement concern person can use any deep freezer with QA approval.
- **6.1.4** Ensure the condition of deep freezer by note down its temp.
- **6.1.5** If the temperature goes beyond to the given below action limit table, warehouse person shall inform to engineering department for rectification by telephonically.
- **6.1.6** In case if temperature excursion is not rectified at same time by engineering person than breakdown notification shall be raised and all materials stored in said deep freezer shall be transferred to other deep freezer.

Equipment Name	Alert Limit		Action Limit		
<b>Equipment Name</b>	Lower	Upper	Lower	Upper	
Deep Freezer (Limit: 2°C to 8°C)	3°C	7°C	2°C	8°C	

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- **6.1.7** Sanitize external surface of all the containers or objects to be kept in this Deep Freezer with 70% IPA Solution.
- **6.1.8** Transfer all the sanitized container or objects inside the Deep Freezer to be stored as per storage Condition i.e. Defreeze condition.
- **6.1.9** Close the door of Deep Freezer.
- **6.1.10** Let the containers be inside the Deep Freezer toll its use.
- **6.1.11** If any 2°C To 8°C Raw Material large qty. receipt then store person will be transfer all consignment to G Block store in cold room with proper status.
- **6.1.12** Record the Operation details in "Materials Receipt / Storage & Dispensed Log Book" as per Format shown in **Annexure -I**.
- **6.1.13** If any raw materials which are stored under 2°C To 8°C storage rejected by Q.C shall be stored in lock & key box inside 2°C To 8°C deep freezer with proper label of rejected raw material.
- **6.1.14** Record the rejected material details in "Rejected Material Log" as per format.
- 6.1.15 Temperature Monitoring Frequency: Every 2Hrs.±15Min/Breakdown.
- **Remark: I.** If any 2°C To 8°C Raw Material large qty. receipt then store person will be transfer all consignment to G Block store cold room with proper status & process the all sampling activity.
  - **II.** If any large qty. raw materials which are stored under 2°C to 8°C storage rejected by QC shall be stored in G-Block cold room 2°C to 8°C with proper label of rejected Raw Material.

#### 6.2 Cleaning:

- **6.2.1** Switch "OFF" the Main Switch.
- **6.2.2** Open the Door of Deep Freezer.
- **6.2.3** Take all containers of objects out from Deep Freezer and keep them at other Cold Area in Proper Condition.
- **6.2.4** Mop the internal surface of Deep Freezer with Clean Wet Cloth with WFI.
- **6.2.5** Then Mop the internal surface of Deep Freezer with lint free cloth.
- **6.2.6** Clean the all material container with lint free cloth with 70% IPA.
- **6.2.7** Transfer the all containers or objects inside the Deep Freezer duly Sanitized.
- **6.2.8** Close the Door of Deep Freezer.



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- **6.2.9** Switch "ON" the Main Switch and set the Temperature as per requirement.
- **6.2.10 Deep Freezer cleaning Frequency:** Weekly.
- **6.2.11 Material cleaning Frequency:** Weekly.
- **6.2.12** Record the Receipt & Storage in deep freezer details show in **Annexure-I**.
- **6.2.13** Record the Temperature details show in **Annexure-II**.
- **6.2.14** Record the cleaning details of Deep Freezer show in **Annexure-III.**

#### **7.0** ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Materials Receipt / Storage & Dispensed Log Book	
Annexure – II	Temperature Record of Deep Freezer	
Annexure – III	Cleaning Record Of Deep Freezer	

**ENCLOSURES:** SOP Training Record

#### **8.0 DISTRIBUTION:**

• Controlled Copy No.01 Quality Assurance

• Controlled Copy No.02 Warehouse

• Master Copy Quality Assurance

#### 9.0 **REFERENCES**:

Not Applicable.

#### 10.0 REVISION HISTORY:

#### **CHANGE HISTORY LOG**

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



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### ANNEXURE-I MATERIALS RECEIPT / STORAGE & DISPENSED LOG BOOK

Block : Equipment ID No.:

Location : Month/Year :

_		Vendor /	No. of Nos /Box	Opera Deta	ation ails	Done By	Checked By	
Date	Material Description	SAP Batch No.		From	То	Sign & Date	Sign & Date	Remark



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#### ANNEXURE II TEMPERATURE RECORD OF DEEP FREEZER

Block : Month/Year :

**Location** : **Frequency** : **Every** 2 hrs. ± 15Min/ Breakdown

Temperature Limit: Equipment ID No. :

Date	Time	Observed Temperature (°C)	Checked By Sign & Date	Verified By Sign & Date	Remark



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#### ANNEXURE-III CLEANING RECORD OF DEEP FREEZER

Block : Frequency : Weekly

Location : Month/Year :

Date	Equipment	Cleaning Status	Status Operation		Cleaning Done By	Checked By Sign & Date	Remark
	ID. No.	OK/NOT OK	From	То	Sign & Date	Sign & Date	
					1		