



STANDARD OPERATING PROCEDURE

Department: Warehouse	SOP No.:
Title: Dispensing of Cyclosporine	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a Procedure for the Dispensing of Cyclosporine.

2.0 SCOPE:

This SOP is applicable for Dispensing of Cyclosporine at Raw Material Store in Injection Section.

3.0 RESPONSIBILITY:

Officer / Executive-Warehouse

4.0 ACCOUNTABILITY:

Head-Warehouse

5.0 ABBREVIATIONS:

A.R. No.	Analytical Report Number
BPCR	Batch Production and Control Record
BOM	Bill of Material
FIFO	First in First Out
FEFO	First Expiry First Out
IPQA	In process Quality Assurance
Ltd.	Limited
PAPR	Power Air Purifying Respirator
Pvt.	Private
QA	Quality Assurance
Qty.	Quantity
RLAF	Reverse Laminar Air flow
RH	Relative Humidity
SOP	Standard Operating Procedure
WH	Warehouse

6.0 PROCEDURE:

6.1 GENERAL INSTRUCTIONS:

6.1.1 Ensure the cleaning status of dispensing area.

6.1.2 Ensure the room temperature, RH and pressure differential are in acceptable range.

6.1.3 Ensure the RLAF is started before 15 minutes.

6.1.4 All excipients shall be dispensed first and cyclosporine molecule shall be dispensed in last stage.

6.1.5 Ensure that personnel involved in dispensing of Cyclosporine are wearing PAPR gowning.



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6.1.6 Dedicated dispensing tools to be used during dispensing.

6.1.7 Freshly prepared Sodium Hypochlorite shall be used only for decontamination of area.

6.2 PROCEDURE FOR DISPENSING OF CYCLOSPORINE:

6.2.1 Production shall provide the respective BPCR to Store for Dispensing.

6.2.2 Warehouse Officer / Executive shall check the Product Name, Batch No., Batch Size and Control Stamp by QA.

6.2.3 Before start of Dispensing Store shall check for the availability of released approved raw material in stock both physically and in software.

6.2.4 If any shortage Dispensing should not be start and shall inform to Head QA.

6.2.5 Before starting the dispensing activity for Cyclosporine, dispense the required quantity of ethanol as per BPCR.

6.2.6 Warehouse Officer / Executive shall transfer the approved material of cyclosporine and dispensed ethanol to Dispensing Area on Pallates as per the BOM of BPCR through pass box.

6.2.7 Warehouse shall ensure for the details of Approved Material for:

- Identity of the Material.
- Item Code Number
- Batch Number
- Manufacturing Date
- Expiry Date
- Retest Date

6.2.8 Start RLAF before 15 mints of Dispensing Activity.

6.2.9 Take Line Clearance from QA before start of Dispensing Activity.

6.2.10 Warehouse, Production, IPQA officer / executive shall enter dispensing Area from airlocks by proper gowning procedure as per the respective SOP followed by PAPR gowning.

6.2.11 De-dusted material Containers shall be entering inside through the Pass Box.

6.2.12 Record the A.R. No. and quantity of material dispensed in BPCR.

6.2.13 Dispensing activity shall be carried out under RLAF by taking one container at a time under RLAF and transfer the material in to a container carrying double poly bag.



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6.2.14 Simultaneously Dispensed Cyclosporine shall be transferred in dispensed ethanol with continuous stirring by using spatula as per BOM in respective BPCR.

6.2.15 Label the container by affixing for ethanol & cyclosporine both "**Raw Material Dispensing Label**" as per format shown in (**Annexure-II**).

6.2.16 Ware house person shall ensure the material are dispensed following FEFO system strictly and shall check the material for its details.

6.2.17 Gross, Tare and Net Weight shall be recorded in Material identification tag.

6.2.18 Dispensing labels shall be affixed to the dispensed material with cable tie.

6.2.19 IPQA person shall verify the dispensed material for name of material, AR. No., weight and sign the dispensing label and BPCR.

6.2.20 At the same time update the stock of the material in the stock register.

6.2.21 Dispensed material shall be placed on trolley and handed over to the production along with the BPCR.

6.2.22 Used dedicated dispensing tools shall be kept in a separate polybag labeled with "**To be Cleaned**" and transferred to the equipment washing area for cleaning.

6.2.23 All Loose Containers bin card fill up as shown in **Annexure-I** in SOP.

6.3 POST OPERATION:

6.3.1 Completion of dispensing shall be followed by switch off of RLAF and cleaning of RLAF and all the details of dispensing activity will be recorded "**RLAF Utilization Record**" as per Annexure-II "**Title Dispensing of Raw Materials to Production in oral solid dosage section**".

6.3.2 After dispensing, Dispensing area and weighing balance shall be decontaminated with 2.5% of Sodium Hypochlorite.

6.3.3 All dedicated tools used in dispensing of cyclosporine shall be transferred in 2.5 % of Sodium Hypochlorite solution for 30 minutes for decontamination before cleaning in equipment washing area of Raw Material store.

6.3.4 Production department prepared the Sodium Hypochlorite solution 2.5% before Dispensing activity related of Cyclosporine as per requirement and transfer to warehouse.



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6.3.5 Warehouse person Record the Sodium Hypochlorite solution in “**Preparation & Consumption Record of Sodium Hypochlorite Solution**”, Annexure-I.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Preparation & Consumption Record of Sodium Hypochlorite Solution	

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 Changes	Reason for Change	Effective Date	Updated By

