

PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Transfer of Dispensed Container of Cyclosporine from Dispensing Area to Manufacturing Area

SOP No.:		Department:	Production
SOP No.:		Effective Date:	
Revision No.:	00	Revision Date:	
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1.0 **OBJECTIVE**:

To lay down a procedure for Transfer of dispensed container of Cyclosporine from dispensing area to manufacturing area.

2.0 SCOPE:

This SOP is applicable for Transfer of dispensed container of Cyclosporine from dispensing area to manufacturing area of Three Piece Section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BMR Batch Manufacturing Record

IPA Isopropyl Alcohol

Ltd Limitted
Pvt Private

QA Quality Assurance

SOP Standard Operating Procedure

UV Ultra Violet

6.0 PROCEDURE:

6.1 PRECAUTIONS:

6.1.1 TRANSFER OF DISPENSED CONTAINER OF CYCLOSPORINE:

- **6.1.1.1** Production person shall verify that dispensed material quantity is as per Material Requisition Slip & BMR before its transfer to manufacturing area.
- **6.1.1.2** Check & ensure that each container has "Raw Material Identification Slip".
- **6.1.1.3** Production person shall insure that the Raw Material container is close or not.
- **6.1.1.4** Dispensed material shall be transferred through lift to production area RM Day store.
- 6.1.1.5 Sanitize the outside surface of containers by mopping with 70% IPA solution and keep it for 5 minutes inside Dynamic Pass Box under UV light and transfer it into manufacturing area.
- **6.1.1.6** Unload the containers by opening the Dynamic Pass Box cabinet from manufacturing area side.
- **6.1.1.7** Switch 'OFF' the UV light of Dynamic Pass Box.



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6.1.1.8 Clean the Dynamic Pass Box with mopping pad by using 70% IPA solution.

6.1.1.9 Decontaminate the empty used container with 2.5 % Sodium Hypochlorite.

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