PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning of Medicament Vessel	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Cleaning of Medicament Vessel.

2.0 SCOPE:

This SOP is applicable for Cleaning of Medicament Vessel used in Soft Gelatin Capsule Section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

IPA	Isopropyl Alcohol
Ltd.	Limited
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 PRODUCT CHANGEOVER (TYPE B CLEANING):

6.1.1 Take the medicament vessel to the washing area.

6.1.2 Take the potable water in the medicament vessel and rub the inner surface using nylon brush. Drain the washed water.

6.1.3 Wash the medicament vessel using 2% v/v Extran MA-02 solution with potable water using nylon brush.

6.1.4 Drain the washed water.

6.1.5 Clean the medicament vessel with plenty of potable water and finally rinse with purified water.

6.1.6 Again rinse the medicament vessel with purified water and examine the water visually for any turbidity.

6.1.7 If there is no any turbidity, Officer/Executive QA shall collect the rinse sample with intimation slip cum analysis report and send to QC for analysis.

6.1.8 Wipe the medicament vessel with dry lint free cloth.

6.1.9 Dry the medicament vessel with compressed air.

6.1.10 Take the cleaned medicament vessel to production area.

6.1.11 Mop the medicament vessel with 70% IPA solution.

6.1.12 Use the medicament vessel after receiving rinse water intimation slip cum analysis report from QC showing negative identification.

6.1.13 If the QC report showing positive identification then repeat the above procedure.

6.1.14 Affix a status label as "Cleaned".

6.1.15 Enter the cleaning details in "Machine Utilization Record".

6.2 BATCH CHANGEOVER (TYPE A CLEANING):

6.2.1 Clean the medicament vessel with dry lint free cloth.

6.2.2 Enter the cleaning details in "Machine Utilization Report".

6.3 FREQUENCY OF CLEANING:

6.3.1 Type-B Cleaning shall be done in following cases:

(a) Product to Product Changeover.

(b) After 5 batches of the same product.

(c) If cleaned equipment is kept idle more than 72 hours.

(d) If Dirty equipment is kept idle more than 24 hours.

(e) After any Maintenance of Product Contact Parts.

(f) Changeover of one Batch to Next Batch of the same Product with Descending Potency.

(g) In case of colour change.

6.3.2 Type-A Cleaning shall be done in following cases:

(a) Changeover from one Batch to Next Batch of the same Product with Same Potency.

(b) Changeover from one batch to next Batch of the same Product with Higher Potency with same composition.

7.0 ANNEXURES:

Not Applicable.

ENCLOSURES: SOP Training Record

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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