



STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Preparation and Usage of Cleaning Solutions	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for preparation and usage of Cleaning Solutions.

2.0 SCOPE:

This SOP is applicable for preparation and usage of Cleaning Solutions in Ointment section.

3.0 RESPONSIBILITY:

Officer/Executive – Production

4.0 ACCOUNTABILITY:

Head - Production

5.0 ABBREVIATIONS:

HDPE	High Density Poly Ethylene
IPA	Isopropyl Alcohol
QA	Quality Assurance
SAP	Systems, Applications, Product in Data Processing
SOP	Standard Operating Procedure
SS	Stainless Steel

6.0 PROCEDURE:

6.1 PREPARATION AND USAGE OF EXTRAN MA 02 SOLUTION 2% v/v:

6.1.1 Officer / Executive Production shall generate requisition slip in SAP system and send duly signed requisition slip to Officer / Executive General Warehouse for issuance of Extran MA 02 solution.

6.1.2 Officer / Executive Production shall prepare the cleaning solution as per given below method:

METHOD FOR PREPARATION OF EXTRAN MA 02 SOLUTION (2% v/v):

Preparation of Extran MA 02 Solution		Storage	Purpose	Self life
Extran MA 02	20 ml	SS Vessel / HDPE Container	Equipments Cleaning	48 hours
Purified Water	980 ml			
20 ml Extran MA 02 → 980 ml with Purified Water				



STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Preparation and Usage of Cleaning Solutions	Effective Date:
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Issue Date:	Page No.:

- 6.1.3 Take 980 ml purified water in a SS Vessel/HDPE Container, add 20 ml Extran MA 02 and mix well.
- 6.1.4 Affix the status label as “**Extran MA 02 solution 2%v/v**”.
- 6.1.5 Prepared solution shall be used within 48 hours from the time of preparation if required.
- 6.1.6 Officer / Executive Production shall issue the 2.0 % Extran MA 02 solution to section wise and maintain the record as per **Annexure – I, “Preparation Usage and Destruction Record of Cleaning Agent (Extran MA 02) 2%v/v”**.
- 6.1.7 Officer/Executive Production shall use the solution and maintain the record as per **Annexure-I**.

6.2 PREPARATION AND USAGE OF ISOPROPYL ALCOHOL SOLUTION 70% v/v:

- 6.2.1 Officer/Executive Production shall generate requisition slip in SAP system and send duly signed requisition slip to Officer/Executive General Warehouse for issuance of Isopropyl Alcohol.
- 6.2.2 Officer / Executive Production shall prepare the 70% v/v solution as per given below method:

METHOD FOR PREPARATION OF ISOPROPYL ALCOHOL SOLUTION (70% v/v):

Preparation of Isopropyl Alcohol Solution		Storage	Purpose	Self life
IPA	1400 ml	SS Vessel / HDPE Container	Equipments Cleaning	24 hours
Purified Water	600 ml.			
1400 ml IPA → 600 ml with Purified Water				

- 6.2.3 Take 600 ml purified water in a SS Vessel / HDPE Container, add 1400 ml IPA and mix well.
- 6.2.4 Affix the status label as “**Isopropyl Alcohol Solution 70%v/v**”.
- 6.2.5 Prepared solution shall be used within 24 hours from the time of preparation if required.
- 6.2.6 Officer/Executive Production shall issue the Isopropyl Alcohol solution 70 %v/v to section wise and maintain the record as per **Annexure – II, “Preparation, Usage and destruction Record of Isopropyl Alcohol 70%v/v”**.
- 6.2.7 Officer/Executive Production shall use the solution and maintain the record as per **Annexure-II**.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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Supersedes: Nil	Review Date:
Issue Date:	Page No.:

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Preparation Usage and Destruction Record of Cleaning Agent (Extran MA 02) 2% v/v	
Annexure-II	Preparation Usage and Destruction Record of Isopropyl Alcohol 70 % v/v	

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

