



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Dispensing of Sorbitol	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Dispensing of Sorbitol in Liquid Oral Department.

2.0 SCOPE:

2.1 This procedure is applicable for dispensing of Sorbitol in Liquid Oral Department.

3.0 RESPONSIBILITY:

3.1 Technical associate Production: For Execution

3.2 Officer/ Executive IPQA, Production & store: For verification and implementation of SOP

3.3 Head Production: Shall ensure compliance of the SOP

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 Take Line Clearance from QA to start the manufacturing or Dispensing Activity whichever is applicable.

5.2 Before dispensing check that Valve of Sorbitol pipe line, it shall be closed.

5.3 Attach the one end of the sorbitol flexible pipe to the pneumatic valve and other end to the manufacturing tank. (in which the sorbitol is to be taken)

5.4 Check the reading of the load cell it shall be '0' of the respective tank as per reference SOP ("Cleaning, verification & operation of load cell").

5.5 The selector switch on the Panel board must be at 'AUTO' mode.

5.6 The functional key switch is provided separately on the load cell panel board of manufacturing tank 1000 liters & manufacturing tank 3000 liters for dispensing of Sorbitol into manufacturing tank.

5.7 If sorbitol is to be taken into manufacturing tank 1000 Liters from Sorbitol storage tank then operate the panel board and the screen of the manufacturing tank 1000 liters. Turn 'ON' the functional switch provided on the panel board of manufacturing tank 1000 Liters to start the sorbitol dispensing.

5.8 If sorbitol is to be taken into manufacturing tank 3000 Liters from sorbitol storage tank then operate the panel board and the screen of the manufacturing tank 3000 liters. Turn 'ON' the functional switch provided on the panel board of manufacturing tank 1000 Liters to start the sorbitol dispensing.



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- 5.9 Operate the functions provided on the load cell panel and screen for dispensing of sorbitol as per required quantity mentioned in Batch Manufacturing Record as per Reference SOP (“Cleaning, verification & operation of load cell”).
- 5.10 Open the cover box of sorbitol valve and open the Sorbitol valve.
- 5.11 Push the Auto Start button on the panel, touch the screen option on the main screen (the screen will show the required quantity and actual quantity in the tank) the Sorbitol dispensing is started into the tank. The pneumatic valve is fully open, as the quantity reaches to the fine value the pneumatic valve will close half and as the quantity completed the valve will close completely. Turn the functional switch ‘OFF’ to stop the sorbitol dispensing. On completion of sorbitol dispensing, automatic print generated containing total dispensed quantity of sorbitol.
- 5.12 Close the Sorbitol valve put dummy on it. Clean the S.S. connection pipe and valve with sufficient quantity of purified water with cleaning of manufacturing tank 1000 liters or 3000 liters whichever is under cleaning and dry it with the help of dry lint free from outside & with compressed air from inner side .
- 5.13 After cleaning put dummy or aluminum foil on the opening of the pipe.
- 5.14 Record the actual dispensed quantity of sorbitol in to the respective Batch manufacturing record.

NOTE: Variance quantity of sorbitol shall be allowed ± 1 kg (approximately) for 3000 liters manufacturing tank due to the least count of load cell in this tank is 1 kg and for 1000 liter manufacturing tank Variance quantity of sorbitol shall be allowed ± 0.5 kg (Approximately) due to the least count of the load cell is 0.5 kg.

Precaution:

- 1) Ensure that there is no obstacle between SS platform and tank surface during dispensing of sorbitol.
- 2) Ensure that there will not be any movement on manufacturing platform during dispensing of sorbitol.
- 3) After complete dispensing of sorbitol check the dispensed quantity of sorbitol on load cell panel and the print out of dispensed quantity of sorbitol. If any discrepancy is observed then investigate the cause and verify the cause with the help of QA Officer and mark it on the print out duly signed with production and QA Officer and proceed for further step of manufacturing process. This process is applicable if the print out quantity consist discrepancy from the Dosed quantity (Quantity required as per respective Batch manufacturing record beyond the Variance limit.)



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- 4) Ensure that during dispensing of sorbitol, software installed should be in running condition.
- 5) If automatic printout is not generated by software then reprint the printout slip through installed software.
- 6) If automatic printout at the time of dispensing and offline printout of the same is not generated, then both production and QA officer shall verify the dispensed quantity of sorbitol, with the help of weight displayed on screen of dispensing system and attach investigation report regarding this discrepancy.

6.0 ABBREVIATION (S):

- 6.1 Q.A : Quality Assurance.
- 6.2 SOP : Standard operating procedure

7.0 REFERENCE (S):

- 7.1 SOP: Cleaning, Verification & Operation of Load Cell

8.0 ANNEXURE (S):

- 8.1 NIL

9.0 DISTRIBUTION (S):

- 9.1 **Master copy (S)** : Quality Assurance.
- 9.2 **Controlled copy (S):** Production department (01), Quality Assurance (01)
- 9.3 **Reference copy (S)** : Production department (01)

10.0 REVISION HISTORY

S.No.	REVISION No.	CHANGE CONTROL No.	REASON (S) FOR REVISION	DETAILS OF REVISION	EFFECTIVE DATE
01	00	NA	New SOP	NA	NA