



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Handling of LDPE Granules in FFS Section

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	1 of 5	

1.0 OBJECTIVE:

To lay down a Procedure for Handling of LDPE Granules in FFS section.

2.0 SCOPE:

This SOP is applicable for Handling of LDPE Granules in FFS section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head-Production

5.0 ABBREVIATIONS:

AR No.	Analytical Report Number
Ltd.	Limited
LDPE	Low Density Polyethylene
No.	Number
NLT	Not Less Than
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 HANDLING OF LDPE GRANULES :

- 6.1.1 The LDPE Granules shall be issued from Warehouse in intact Bags.
- 6.1.2 Verify that issued Material quantity is as per BMR (Batch Manufacturing Record).
- 6.1.3 Verify that A.R. No. mentioned on issue slip and mentioned on the issued material is same.
- 6.1.4 Transfer the issued LDPE Granules of One Batch at a time.
- 6.1.5 Shift the all dispensed bags through the lift.
- 6.1.6 Transfer the intact LDPE Granule Bags using Material Transfer Trolley from lift to ampoule area main corridor.
- 6.1.7 Mop the LDPE Granule Bags externally one by one using Wet (70 % IPA solution) lint free duster and place in SS pallets at granule Day store. (record as per Annexure-I)
- 6.1.8 Cut the LDPE bag from a corner with the help of a clean SS scissor.
- 6.1.9 Check the granules visually for any foreign particles



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6.1.10 Transfer LDPE granule with a clean SS scoop in to granule feeding tank and start the hopper loaders for granule supply to FFS m/c. (record as per Annexure-II)

6.1.11 If any bag contains foreign particle, reject the bag & inform to QC / QA & stores for recording and investigation.

6.1.12 Remove the empty bag from granules feeding area.

6.1.13 Any emergency when granule not reached automatically by the hopper loader system, Keep the Bags under UV in provided pass box for Not Less Than 15 Minutes, Open the Door of Pass Box from inside and transfer the Bags to manual granule feeding and empty bag transfer from same pass box.

6.1.14 Once in a month when Machine is not under Operation, Mop the Granule Storage Tank with Lint Free Duster dipped in 70% v/v IPA Solution from inside & outside. (record as per Annexure-III)

7.0 ANNEXURES:

ANNEXURE NO.	TITLE OF ANNEXURE	FORMAT NO.
Annexure-I	Cleaning of outer surface of LDPE granule bags	
Annexure-II	LDPE granule feeding record	
Annexure-III	Cleaning of granule storage tank	

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

