



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

BMR Supersedes No.: 04

Batch No.:

Effective Date: 16/06/2020

Batch Size:



Generic Name	ALLYLESTRENOL TABLETS
Label Claim	Each Film Coated Tablet contains : Allylestrenol 5 mg Excipients q.s. Colour : Titanium Dioxide IP
Mfg. Lic. No.	S-MNB/10/93 & S-MB/10/94
Pharmacopoeia Status	IHS
Product Code	ALL/001
MFR No.	APD/MFR/HT/ALL/001
Mfg. Date	
Exp. Date	
Batch Size	
Shelf Life	36 Months
Presentation	White, Round , Biconvex, Film Coated Tablets having scored on one side
Storage Condition	Store in a cool, dry, dark place.
Issued By QA (Sign & Date)	
Issue Date	
Date of Commencement	
Date of Completion	

	Prepared By	Checked By	Approved By
Signature			
Date	15/06/2020	15/06/2020	16/06/2020
Name	Gulzari Lal	Manjeet Kumar	Kapil Kumar
Designation	Executive	Sr.Executive	Jr.Executive
Department	Production	Production	Quality Assurance
			Manager
			Quality Assurance



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TABLE OF CONTENTS

Sr. No.	Content	Page No.
1.0	General Instruction	4
2.0	Manufacturing Process Flow Chart	5
3.0	Master Formula	6
4.0	Calculation	7
5.0	Dispensing	8
5.1	General Instruction	8
5.2	Line Clearance	8-10
5.3	Environmental Monitoring	10
5.4	RLAF Monitoring	10
5.5	Status Labels of Equipment Cleaning	11
5.6	Dispensing Record	12-14
6.0	Manufacturing Record	15
6.1	Safety Checklist before Operation of Granulation Area	15
6.2	Details of Equipments /Instruments to be used	15
6.3	Equipments preventive maintenance details	16
6.4	Equipments/ Instruments cleaning record	17
6.5	Status labels of equipment's cleaning	18
6.6	Rinse Water Record (Only in case of Product Change Over)	19
6.7	Line clearance for granulation area	20-21
6.8	Dispensed Label to be Paste Here	22
6.9	Dispensed Material Verification	23
6.10	Sifting	24
6.11	Dry Mixing	25
6.12	Record the weight of sifted and sized granules	26
6.13	Lubricants sifting	27
6.14	Blending and Lubrication	27
6.15	Lubricated granules weight	28
6.16	Blend Sample collection	28
6.17	Blend yield Reconciliation	28
6.18	Blend release record	29
7.0	Compression	29
7.1	General Instruction	29
7.2	Safety checklist before operation of compression machine	29
7.3	Line Clearance.	30-31
7.4	Environmental monitoring of Compression Area.	32
7.5	Compression machine tool Verification.	32
7.6	Compression Parameters Start Up & In process.	32
7.7	Tablet parameter and in process checks.	33
7.8	Recording of initial Checks.	34
7.9	Recording of Initial Checks (at the start up in case of the failure of the initial checks)	35
7.10	Compression Operation Details.	36
7.11	In-process Checks Quantity & Frequency.	36
7.12	In process Control Record for Compression.	37-40
7.13	Core Tablets Weight.	41



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD,SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:



Sr. No.	Content	Page No.
7.13.3	Reconciliation of Compressed Tablets.	41
7.13.4	Sampling, Analysis and Release of Tablets.	41
7.13.5	Transfer above compressed tablets to quarantine	42
7.13.6	Issuance of tablets	42
8.0	Coating	42
8.1	Line Clearance for coating Area	42-43
8.2	Environmental Monitoring of Coating Area	43
8.3	Material verification	44
8.4	Sifting	44
8.5	Solution Preparation	44-45
8.6	Coating Procedure	45
8.7	Time Record for Coating	46
8.8	Coated Tablet Appearance checks	46
8.9	Calculation of % Coating Weight Build up	46
8.10	In-Process Specifications	46
8.11	In process Observation	47
8.12	Coated Tablet Weight	47
8.13	Reconciliation of Coated Tablets	48
8.14	Sampling, Analysis and Release of Tablets	48
8.15	Transfer above coated tablets to quarantine	48
8.16	Issuance of tablets for Inspection	48
8.17	Inspection Of Tablets	49-50
8.18	Destruction of Non Recoverable	50
9.0	Accountability	51
10.0	Signature log	51
11.0	Incident / deviation received	51
12.0	Break Down Details	52
13.0	Batch manufacturing history sheet	52
14.0	Check list for batch manufacturing records & release for packing	52-53
15.0	QC Data review Checklist	53
16.0	Abbreviation	53-54
17.0	Document revision History	54



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD,SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

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Effective Date: 16/06/2020

Batch No.:

Batch Size:



1.0 GENERAL INSTRUCTIONS:

- 1.1** Good manufacturing practices shall be followed during the entire process of manufacturing including sampling and dispensing.
- 1.2** All the containers and equipments used for manufacturing shall be properly cleaned as per the relevant SCP.
- 1.3** All the equipments and containers shall have proper status label as per respective SOP.
- 1.4** All the equipments shall be operated as per the relevant SOP's only.
- 1.5** All the measuring equipments and containers shall be calibrated irrespective of the activity and use within the date of calibration as per the calibration schedule
- 1.6** Weights of all the materials shall be cross check by production personnel against dispensing label before taken up for manufacturing.
- 1.7** Overwriting in BMR and all other documents shall be strictly avoided, and if so, shall be as per APD/QAD
- 1.8** All the operations shall be carried out in clean and orderly manner.
- 1.9** Any deviation in process shall be brought to knowledge of QA and prior approval of QA department shall be taken.
- 1.10** Critical parameters including temperature, humidity and pressure differences shall be checked and monitored APD/QAD.
- 1.11** In process controls shall be carried out throughout manufacturing operations as per relevant instructions defined in this BMR and relevant SOP's.
- 1.12** Ensure that all materials like raw materials, in process materials and finished goods shall be placed in respective areas with proper label.
- 1.13** Attach additional sheets wherever required.
- 1.14** No material shall be placed directly on the floor.



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BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

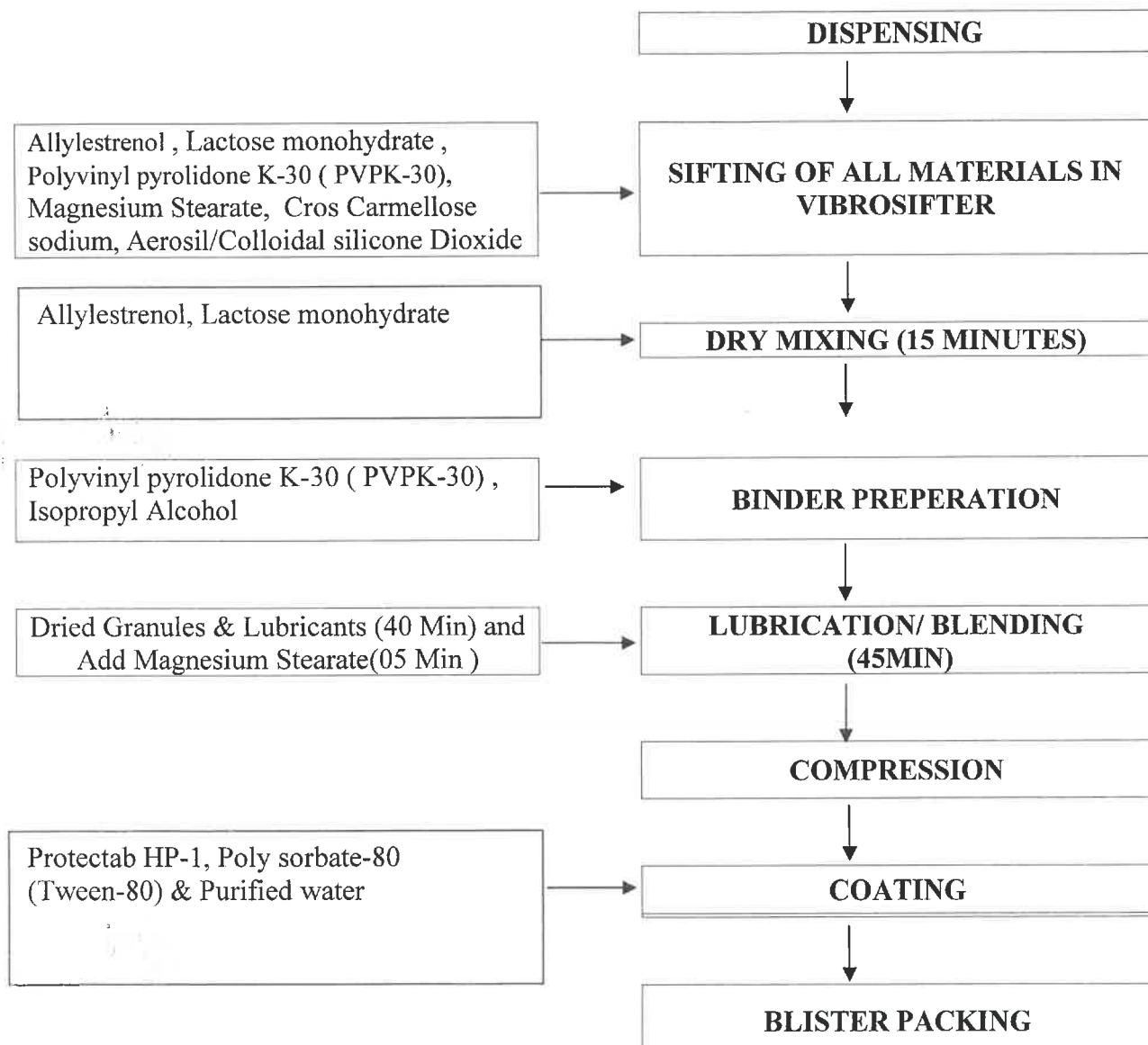
Effective Date: 16/06/2020

Batch No.:

Batch Size:



2.0 MANUFACTURING PROCESS FLOW DIAGRAM:





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BMR Supersedes No.: 04

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Batch No.:

Batch Size:



3.0 MASTER FORMULA:

Item Name	Specification	Item Code	Mg/Tab	Overage %	UOM	Std. Qty. for 1,00,000 Tablets
Allylestrenol	IP	HRMA0001	5.000	2.0	Kg	0.510
Lactose Monohydrate	IP	HRME0034	115.200	----	Kg	11.520
PVP k-30	IP	HRME0051	2.000	----	Kg	0.200
Iso Propyl Alcohol	IP	HRME0081	25.000	----	Kg	2.500
Cross carmellose Sodium	IP	HRME0014	5.000	-----	Kg	0.500
Aerosil (Colloidal Silicon Dioxide)	IP	HRME0002	1.000	-----	Kg	0.100
Magnesium Stearate	IP	HRME0037	1.700	-----	Kg	0.170
Protectab HP-1	IHS	HRME0054	2.600	-----	Kg	0.260
Polysorbate-80 (Tween-80)	IP	HRME0049	0.400	-----	Kg	0.040
Purified Water	IP	HRME0083	23.000	-----	Kg	2.300



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Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:



4.0 CALCULATION:

Ingredient	Batch Qty. (kg)	Assay	API assay on as such basis(A)
(a) Allylestrenol		100 % assay on as such basis	Assay on dried basis x (100-LOD) 100
(b) Lactose Monohydrate		Final weight to be compensated	=

The below calculation is to be used when standard quantity of Allylestrenol is to be dispensed is available from one material A.R no.

Qty. of Allylestrenol is to be dispensed(B) = Std. Qty. X 100 / A = X100/ _____ = _____

Compensated Qty. of Lactose Monohydrate (C) = (a+b) - (B) = _____ Kg

The below table is to be used when standard qty of Allylestrenol is not available from one A.R no.

Materia l A.R. no: _____	Assay on dried basis (c)	LOD	Assay on as such basis(d)= Assay on dried basis X(100- LOD)/100	Actual quantity available(e)	Qty on 100 % assay basis = (e) X (d)/100 (kg)	Remaining qty to be dispensed(g) = Std. Qty – (f)
						(g) = - _____ Kg
						= _____ Kg.
				(e) = _____ Kg	(f) = _____ Kg	

Next material A.R no: _____ Assay on dried basis : _____ LOD: _____

Assay on as such basis: Assay on dried basis x (100-LOD) / 100 = _____

Qty. of Allylestrenol is to be dispensed (D) = (g) x 100/ Assay on as such basis= _____ Kg

Total Qty. Allylestrenol to be dispensed (H) = (e + D) = _____ + _____ = _____

Compensated Qty. Lactose Monohydrate (I) = (a + b) – H= _____ Kg

If assay as such is more than 100% then assay to be consider as 100% for calculation.

*value depends on LOD and Assay, to be calculated.

Done By
Production
Sign & Date:

Checked By
QA
Sign & Date:



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Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

BMR Supersedes No.: 04 **Effective Date:** 16/06/2020

Batch No.: **Batch Size:**



5.0 DISPENSING:

5.1 General Instruction:

- 5.1 To carry out dispensing of Raw material Follow the respective SOP.
- 5.2 Ensure that the relevant documents shall be updated.
- 5.3 Proper line clearance shall be taken before starting the dispensing activity.
- 5.4 All the activities that are related to Equipment Cleaning, Operations, Material Handling and Process Controls, shall be carried out strictly as per respective Standard Operating Procedure.
- 5.5 Check and verify the Item code No., Material, Quantity & A.R. No. of the Material to be dispensed, is as per Material Requisition Slip prior to moving the material in material entry airlock and performing the dispensing activity.
- 5.6 Verify the Raw Material containers for proper close status before and after performing the dispensing activity.
- 5.7 Take raw materials to dispensing area under RLAF.
- 5.8 Start weighing of active ingredients followed by Excipients.
- 5.9 Weigh and dispense all the materials as per dispensing sheet in double polyethylene bags.
- 5.10 Record the material details in dispensing label and affix the label on the dispensed material and same label shall be placed between two polybag duly approve by Store & QA.
- 5.11 After completion of dispensing activity dispensed material shall transfer in respective production area as per respective SOP.

5.2 Line Clearance:

To certify the line clearance Follow the SOP No.: APD/QAD/033.

Date: _____

Time: _____

Previous Product Name: _____

Batch No.: _____

Sr. No.	Check Points	Observation	Checked By Warehouse Sign & Date	Verified By QA Sign & Date
a] Area General Checks:				
1.	Containers/ utensil used for previous batch/product removed from dispensing area	Yes/No		
2.	Containers and vessels in dispensing area shall have cleaned label	Yes/No		
3.	All documents related to the previous batch/ products are removed from dispensing area.	Yes/No		
4.	All previous product/batch remnants removed from area	Yes/No		
5.	Check the Waste bins, it should be clean & empty	Yes/No		
6.	Check gowning of the personnel working in the area, gowning shall be done as per respective area SOP	Yes/No		
7.	Check training records of the personnel working in the area	Yes/No		
b] Area Environmental Control checks:				
8.	Pressure Difference in Dispensing area Limit(NLT 8 Pascal)			



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BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Batch No.: Batch Size:



Sr. No.	Check Points	Observation	Checked By Warehouse Sign & Date	Verified By QA Sign & Date
9.	Relative Humidity in Dispensing area Limit (NMT 55%)			
10.	Temperature of Dispensing area Limit (NMT 25°C)			
11.	Temperature/ humidity log book	Checked/Not checked		
c] Area Cleanliness checks:				
12.	Cleanliness status of floor, corners and walls	Cleaned/ not cleaned		
13.	Area cleanliness record	Checked/not checked		
14.	Area cleaned by			
d] General Checks:				
15.	Cleanliness status of scoops and other accessories	Cleaned/ not cleaned		
16.	Cleanliness status of Balance table.	Cleaned/ not cleaned		
e] Equipment Checks:				
Equipment: Balances (APD/WH/BAL/003)				
17.	Cleanliness status of Balance	Cleaned/ not cleaned		
18.	Daily Weight checking log book of balances	Checked/not checked		
19.	Cleanliness beneath the balance	Cleaned/ not cleaned		
20.	Calibration status of Balance	Calibrated/not calibrated		
Equipment: Balance (APD/WH/BAL/002)				
21.	Cleanliness status of Balance	Cleaned/ not cleaned		
22.	Daily Weight checking log book of balances	Checked/not checked		
23.	Cleanliness beneath the balance	Cleaned/ not cleaned		
24.	Calibration status of Balance	Calibrated/not calibrated		
Equipment: Balance (APD/WH/BAL/012)				
25.	Cleanliness status of Balance	Cleaned/ not cleaned		
26.	Daily Weight checking log book of balances	Checked/not checked		
27.	Cleanliness beneath the balance	Cleaned/ not		



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BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:



Sr. No.	Check Points	Observation	Checked By Warehouse Sign & Date	Verified By QA Sign & Date
		cleaned		
28.	Calibration status of Balance	Calibrated/not calibrated		
29.	Cleanliness status of dispensing booth	Cleaned/ not cleaned		
30.	Cleaning log book of Dispensing record	Checked/not checked		
31.	Pressure Difference across HEPA filter in Dispensing Booth (Limit: 8- 20 mm WC)			
32.	Dispensing booth Cleaned by			

LINE CLEARANCE CERTIFICATE:

Observations of Area, Equipment and Environmental checks are found satisfactory / not satisfactory. Line clearance given / not given to proceed with planned process.

Certified by QA (Sign & Date): _____

Time: _____

5.3 Environmental Monitoring:

Dispensing of Raw Material shall be carried out under following Environmental Conditions & Record in Environment Monitoring Record at the time of start of dispensing, after every Four Hours:

Date	Time	Area Name	Temperature NMT25°C	Relative Humidity NMT 55 %	Differential Pressure NLT 08 Pa	Checked By Store Sign & Date	Verified By QA Sign & Date

Remarks (If any): _____

5.4 RLAf Monitoring:

Date	Time	RLAf Reading I.D. No.:APD/WH/002				Checked By Store Sign & Date	Verified By QA Sign & Date		
		Standard Limit Across		Observation					
		MICROVEE (Pre) Filter	HEPA(Post) Filter	MICROV EE (Pre) Filter	HEPA(Post) Filter				
		08-20 mm wc	15-45 mm wc						
		08-20 mm wc	15-45 mm wc						
		08-20 mm wc	15-45mm wc						
		08-20 mm wc	15-45 mm wc						

Remarks (If any): _____



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BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

BMR Supersedes No.: 04

Effective Date:

16/06/2020

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Batch Size:



5.5 Status Labels of Equipment Cleaning:

Label Attached By Warehouse Sign & Date	Verified By QA Sign & Date



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BMR Supersedes No.: 04

Effective Date: 16/06/2020

Batch No.:

Batch Size:



5.6 Dispensing Record:

Dispensing of Active Pharmaceutical Ingredients

Dispensing Started On: _____

Dispensing Completed On: _____

Item Code	Standard Qty For 1.0 lac Tab. (kg)	Actual Qty For lac Tab. (kg)	UOM	AR No.	Bal. ID No.	Actual weight			Weighed by Store	Ckd By Store Sign & Date	Verified By QA Sign & Date
						Gross Wt.	Tare Wt.	Net Wt.			
Allylestrenol IP											
HRMA0001	0.510										

No. Of Packs/Containers: _____

Material Issued By : _____

Store Officer
(Sign & Date)

Material Received By : _____

Production
(Sign & Date)

Dispensing of Excipients

Dispensing Started On: _____

Dispensing Completed On: _____

Item Code	Standard Qty For 1.0 lac Tab. (kg)	Actual Qty For lac Tab. (kg)	UOM	AR No.	Bal. ID No.	Actual weight			Weighed by Store	Ckd By Store Sign & Date	Verified By QA Sign & Date
						Gross Wt.	Tare Wt.	Net Wt.			
Lactose Monohydrate IP											
HRME0034	11.520										
Lactose Monohydrate IP*											
HRME0034	11.520										

No. Of Packs/Containers: _____

Material Issued By : _____

Store Officer
(Sign & Date)

Material Received By : _____

Production
(Sign & Date)



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FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Effective Date: 16/06/2020

Batch No.:

Batch Size:



Dispensing of Binder

Dispensing Started On: _____

Dispensing Completed On: _____

Item Code	Standard Qty For 1.0 lac Tab. (kg)	Actual Qty For lac Tab. (kg)	UOM	AR No.	Bal. ID No.	Actual weight			Weighed by Store	Ckd By Store Sign & Date	Verified By QA Sign & Date
						Gross Wt.	Tare Wt.	Net Wt.			

PVP k-30 IP

HRME0051	0.200									

Iso Propyl Alcohol IP

HRME0081	2.500									

No. Of Packs/Containers: _____

Material Issued By : _____

Store Officer
(Sign & Date)

Material Received By : _____

Production
(Sign & Date)

Dispensing of Lubricants

Dispensing Started On: _____

Dispensing Completed On: _____

Item Code	Standard Qty For 1.0 lac Tab(kg)	Actual Qty For lac Tab. (kg)	UOM	AR No.	Bal. ID No.	Actual weight			Weighed by Store	Checked By Store Sign & Date	Verified By QA Sign & Date
						Gross Wt.	Tare Wt.	Net Wt.			

Cross carmellose Sodium IP

HRME0014	0.500									

Aerosil (Colloidal Silicon Dioxide) IP

HRME0002	0.100									

Magnesium Stearate IP

HRME0037	0.170									

No. Of Packs/Containers: _____

Material Issued By : _____

Store Officer
(Sign & Date)

Material Received By : _____

Production
(Sign & Date)



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BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Effective Date: 16/06/2020

Batch No.:

Batch Size:



Coating Material

Item Code	Standard Qty For 1.0 lac Tab (kg)	Actual Qty For lac Tab. (kg)	UOM	AR No.	Bal. ID No.	Actual weight			Weighed by Warehouse	Ckd By Warehouse Sign & Date	Verified By QA Sign & Date
						Gross Wt.	Tare Wt.	Net Wt.			

Protactab HP- 1

HRM E0054	0.260										
--------------	-------	--	--	--	--	--	--	--	--	--	--

Polysorbate-80 (Tween -80)

HRM E0049	0.040										
--------------	-------	--	--	--	--	--	--	--	--	--	--

Purified Water

HRME 0083	2.300										
--------------	-------	--	--	--	--	--	--	--	--	--	--

No. Of Packs/Containers: _____

Material Issued By : _____ Material Received By : _____

Warehouse Officer
(Sign & Date)

Production
(Sign & Date)



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FOREST ROAD, SOLAN, H.P. (INDIA)
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BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:



6.0 MANUFACTURING RECORD:

6.1 Safety Checklist before Operation of Granulation Area:

Area: _____

Date: _____

Sr. No.	Check Point	Observation	Checked By Production Sign & Date	Verified By QA Sign & Date
1.	Is any gap between clamp and cover of lighting fixture observed?	Complies/Not Complies		
2.	Is any electrical cable joint observed?	Complies/Not Complies		
3.	Is EMERGENCY STOP switch working (all equipments) can stop instantaneously?	Complies/Not Complies		

Remark (If any): _____

6.2 Details of Equipments / Instruments to be used:

S. No.	Equipment Name	Equipment Id	Capacity	Reference SOP No.
1.	Balance	APD/HT/BAL/001	50 Kg	APD/QAD/033
2.	Vibro Sifter	APD/HT/003	24"	APD/PRD/002
3.	Mass Mixer	APD/HT/001	50 Kg	APD/PRD/038
4.	Multi mill	APD/HT/002	NA	APD/PRD/004
5.	Tray Dryer	APD/HT/004	24 Trays	APD/PRD/037
6.	Double Cone Blender	APD/HT/005	50 Kg	APD/PRD/003
7.	Compression Machine	APD/HT/006	30 Station	APD/PGT/006
8.	Deduster	APD/HT/010	NA	APD/PRD/007
9.	Colloidal mill	APD/HT/015	NA	APD/PRD/014
10.	Coating Pan	APD/HT/016	36"	APD/PRD/010
11.	Spray Gun	APD/HT/021	0.5 Litre	APD/PRD/010
12.	Hardness Tester	APD/HT/011	NA	APD/QAD/079
13.	Disintegration Test Apparatus	APD/HT/013	NA	APD/QAD/076
14.	Friability Apparatus	APD/HT/014	NA	APD/QAD/074
15.	Moisture Analyzer	APD/HT/030	NA	APD/QAD/075



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BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Batch No.: Batch Size:

16/06/2020



6.3 Equipments Preventive Maintenance Details:

S. No.	Equipment Name	Equipment ID	Detail of Preventive Maintenance		Checked By Production Sign & Date	Verified By QA Sign & Date	Remarks (If any)
			Done on	Due on			
1.	Vibro Sifter	APD/HT/003					
2.	Mass Mixer	APD/HT/001					
3.	Multi mill	APD/HT/002					
4.	Tray Dryer	APD/HT/004					
5.	Double Cone Blender	APD/HT/005					
6.	Compression Machine	APD/HT/006					
7.	Deduster	APD/HT/010					
8.	Vernier Caliper	APD/HT/012					
9.	Deduster	APD/HT/010					
10.	Colloidal mill	APD/HT/015					
11.	Coating Pan	APD/HT/016					
12.	Spray Gun	APD/HT/021					
13.	Disintegration Test Apparatus	APD/HT/013					
14.	Friability Apparatus	APD/HT/014					
15.	Moisture Analyzer	APD/HT/030					



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Effective Date: 16/06/2020

Batch No.:

Batch Size:



6.4 Equipments/Instruments Cleaning Record:

S. No.	Machinery/ Equipment	Capacity	Equipments ID No.	Previous Product Name	B. No.	Cleaning Status		Checked By Product on Sign & Date	Verified By QA Sign & Date
						Clean On	Done By		
1.	Balance	50 Kg	APD/HT/BAL/001						
2.	Vibro Sifter	24"	APD/HT/003						
3.	Mass Mixer	50 Kg	APD/HT/001						
4.	Multi mill	NA	APD/HT/002						
5.	Tray Dryer	24 Trays	APD/HT/004						
6.	Double Cone Blender	50 Kg	APD/HT/005						
7.	Compression Machine	30 Station	APD/HT/006						
8.	Deduster	NA	APD/HT/010						
9.	Vernier Caliper	NA	APD/HT/012						
10.	Colloidal mill	NA	APD/HT/015						
11.	Coating Pan	36"	APD/HT/016						
12.	Spray Gun	0.5Ltr.	APD/HT/021						
13.	Hardness Tester	NA	APD/HT/011						
14.	Disintegration Test	NA	APD/HT/013						
15.	Friability Apparatus	NA	APD/HT/014						
16.	Moisture Analyzer	NA	APD/HT/030						



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

BMR Supersedes No.: 04

Batch No.: **Effective Date:** 16/06/2020

Batch Size:



6.5 Status Labels of Equipment Cleaning:

Label Attached By:
Production
Sign & Date

Verified By:
QA
Sign & Date



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: **Batch Size:**



6.6 Rinse Water Record (Only in case of Product Change Over):

Sr. No.	Equipment Name	Previous Product Name	Batch No.	Cleaning Status (OK/Not OK)	Rinse Water A.R No.	Attached/Not Attached	Checked By	
							Production Sign & Date	QA Sign & Date
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								

*Attach the report of Rinse Water Analysis



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

BMR Supersedes No.: 04

Effective Date: 16/06/2020

Batch No.:

Batch Size:



6.7 Line Clearance for Granulation area:

Before proceeding to the line clearance, ensure that BMR and other related is updated till last stage of processing. To certify the line clearance Follow the SOP No.: APD/QAD/033.

Date: _____

Time: _____

Previous Product Name: _____

Batch No.: _____

Sr. No.	Check Points	Observation	Checked By Production Sign & Date	Verified By QA Sign & Date
a] Area General Checks:				
1.	Containers / utensil used for previous batch/product removed from area	Yes/No		
2.	Check the gowning of the working personnel's	Yes/No		
3.	Check the training of the working personnel's	Yes/No		
4.	Verify Cleaned status label on all equipments for the batch/ product processing	Yes/No		
5.	All documents related to the previous batch / product is removed from area.	Yes/No		
6.	All previous product/batch remnants removed from area	Yes/No		
7.	Check the Waste bins, it should be clean & Empty	Yes/No		
b] Area Environmental Control checks:				
8.	Pressure Difference in Granulation area (Limit NLT 08 PASCAL)			
9.	Relative Humidity in Granulation area (Limit NMT 55%)			
10.	Temperature in Granulation area (Limit 25°C)			
11.	Temperature/Relative humidity log book	Checked / Not checked		
c] Area Cleanliness checks:				
12.	Cleanliness status of floor, corners and walls	Cleaned / Not Cleaned		
13.	Area cleanliness record	Cleaned / Not cleaned		
14.	Area cleaned by			
d] Equipment Checks:				
Equipment: Vibro sifter (APD/HT/001) & Sieves				
15.	Cleanliness status of gasket and clamp	Cleaned/ Not cleaned		



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Batch No.: Batch Size:



Sr. No.	Check Points	Observation	Checked By Production Sign & Date	Verified By QA Sign & Date
16.	Cleanliness status of discharge chute	Cleaned/ Not cleaned		
17.	Cleanliness status of Sieve	Cleaned/ Not cleaned		
18.	Integrity of Sieve	Ok/Not Ok		

Equipment: Mass Mixer (APD/HT/001)

19.	Cleanliness of Shaft and blade	Cleaned/ Not cleaned		
20.	Cleanliness of lid	Cleaned/ Not cleaned		
21.	Cleanliness of inner bowl surface	Cleaned/ Not cleaned		

Equipment No: Multi Mill (APD/HT/002)

22.	Blade assembly cleanliness	Clean / Not clean		
23.	Integrity of screen	OK/Not OK		
24.	Feed hopper assembly and discharge hopper cleanliness	Clean/ Not clean		

Equipment: Double Cone Blender 50 KG (APD/HT/004)

25.	Cleanliness status of Pillar Blender	Cleaned/ not cleaned		
-----	--------------------------------------	-------------------------	--	--

LINE CLEARANCE CERTIFICATE:

Observations of Area, Equipment and Environmental checks are found satisfactory/not satisfactory. Line clearance given / not given to proceed with planned process.

Certified by QA (Sign & Date): _____

Time: _____



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD,SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Batch No.: Batch Size:

16/06/2020



6.8 Dispensed Label to be Paste Here:

Label Attached By:
Production
Sign & Date

Verified By:
QA
Sign & Date



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:05**

BMR Supersedes No.: 04

Batch No.: **Batch Size:**



6.9 Dispensed Material Verification

Sr. No.	Item code	Material	Spec ifica tion	AR No.	Gross Weight (kg)	Total Quantity (kg)	Checked By Production Sign & Date	Verified By QA Sign & Date
DRY MIXING								
1.	HRMA0001	Allylestrenol	IP					
2.	HRME0034	Lactose Monohydrate	IP					
3.	HRME0051	PVP k-30	IP					
4.	HRME0081	Iso Propyl Alcohol	IP					
5.	HRME0014	Croscarmellose Sodium	IP					
6.	HRME0002	Aerosil (Colloidal Silicon Dioxide)	IP					
7.	HRME0037	Magnesium Stearate	IP					

Material Verified By: _____

Production
(Sign & Date)

Material Verified By: _____

QA
(Sign & Date)



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

BMR Supersedes No.: 04 **Effective Date:** 16/06/2020

Batch No.: **Batch Size:**



6.10 Sifting:

6.10.1 Masks and gloves should be used during sifting.

6.10.2 Check for the line clearance, Cleanliness status of the area and equipment.

6.10.3 Check and record the Temperature, Humidity and pressure difference.

Frequency: At the start of Operation and every four hours thereafter and end of the process.

Date	Time	Area Name	Temperature (NMT 25°C)	Relative Humidity NMT 55%	Differential Pressure NLT 8 Pa	Checked By Production Sign & Date	Verified By QA Sign & Date

Remarks (If Any):

6.10.4 Transfer the dispensed material to manufacturing area from day store area for verification.

6.10.5 Check the sieve integrity before and after sifting as per SOP No.: APD/PRD/006

6.10.6 Operate the Sifter as per the SOP APD/PRD/ 002 for sifting.

Date of Operation: _____

Start Time: _____

End Time: _____

Sr. No.	Material Name	Specification	Total Container wise Qty. Gross wt. (in kg)	Total Net Qty. In Kg	Sieve Size	Sieve Integrity Before	Sieve Integrity After	Sifting Time From	Sifting Time To	Done By Production Sign & Date	Checked By QA Sign & Date
1.	Allylestrenol	IP		60#							
2.	Lactose Monohydrate	IP		40 #							

6.11 Binder Preparation

Date of Operation: _____ **Start Time:** _____ **End Time:** _____

6.11.1 Masks and gloves should be used during operation.

6.11.2 Check for the line clearance, cleanliness of the area and equipment.

6.11.3 Operate the paste preparation kettle as per the SOP APD/PGT/026

6.11.4 Take Iso Propyl Alcohol in a Paste Kettle.

6.11.5 Add polyvinyl pyrrolidone K-30 (PVPK-30) with continuous stirring.

S. No.	Item Name	Quantity	Added By	Checked By Production Sign & Date
1.	Polyvinyl pyrrolidone K-30 (PVPK-30)			
2.	Iso Propyl Alcohol			

Appearance of Binder:-

Checked By:



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

BMR Supersedes No.: 04

Effective Date: 16/06/2020

Batch No.:

Batch Size:



6.12 Dry Mixing:

Date of Operation: _____

6.12.1 Masks and gloves should be used during operation.

6.12.2 Check for the line clearance, cleanliness of the area and equipment.

6.12.3 Operate the Mass Mixer as per the SOP APD/PRD/038 for dry mixing.

S. No.	Item Name	Quantity kg	Added into Mass Mixer By	Checked By Production Sign& Date
1.	Allylestrenol			
2.	Lactose Monohydrate			

6.12.4 Mix the materials in Mass Mixer for 30 min.

Date	Time Start	Time End	Done By	Checked By Prod. Sign& Date

6.13 Wet Granulation:

Date of Operation: _____

6.13.1 Masks and hand gloves should be used during operation.

6.13.2 Check for the line clearance, cleanliness of the area and equipment.

6.13.3 Check and record the Temperature and Humidity as per SOP APD/QAD/037.

6.13.4 Operate the Mass mixer as per the SOP APD/PRD/038 for wet granulation as per following parameter.

6.13.5 Add the binder solution to Mass mixer and mix it for 10 mins.

6.13.6 After achieve the required granule stop the Mass Mixer.

6.13.7 Parameters for wet granulation:

Parameter	STD Time	Start Time	End Time	Total Time in minute	Done By	Checked By Prod. Sign
Addition of binder solution	Within 10 Minutes					
Granulation	Within 12 Minutes					
Unload wet mass into FBD trolley	2-3 Minutes					

6.14 Drying:

Date of Operation: _____

6.14.1 Masks and gloves should be used during operation.

6.14.2 Check for the line clearance, cleanliness of the area and equipment.

6.14.3 Fix the Trays with wet granules, Switch on the Heater and switch on the drier and dry the granules for 45-60 minutes at an inlet temperature of 50-60°C with an outlet temperature 40±5°C.

6.14.4 Put off the drier, remove the trays of tray dryer and rake the materials.

Date	Status	Time		Duration in mins	Temp (° C)		Done By	Checked By Sign & Date
		On	Off		Inlet	Outlet		
	Drying							



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS			
BMR No.: APD/BMR/HT/ALL/001	Revision No.:05		
BMR Supersedes No.: 04	Effective Date:	16/06/2020	
Batch No.:	Batch Size:		

MASTER COPY
Sign: *[Signature]*
Date: 16/06/2020
(QA/01)

6.15 Sizing of Semi-dried granule : **Date of Operation:** _____

6.15.1 Masks and gloves should be used during operation.

6.15.2 Milled over size granules through 2.5 mm Multi mill screen

Date	Screen Size	Screen No.	Screen Integrity		Start Time	End Time	Total Time Min.	Done By	Checked By Sign & Date
			Before Use	After Use					
	2.5mm								

6.16 Final Drying: **Date of Operation:** _____

6.16.1 Drying the milled granules for 10 minutes at inlet temperature 50-60°C and an outlet temperature 40°C. check the LOD of the granules. If required dry until loss on drying is between 0.2 – 1.8 % w/w.

6.16.2 After regular interval, turn the mass of trays upside down with the help of SS scoop.

Date	Status	Time		Duration in mins	Temp (° C)		Done By	Checked By Sign & Date	LOD %	Done By	Checked By Sign & Date
		On	Off		Inlet	Outlet					
	Drying Final										

6.17 Final Sizing & Sifting :-

6.17.1 Sift final dried granules through sifter using Mesh No.24#.

Date	Sieve Size	Sieve ID No.	Screen Integrity		Start Time	End Time	Total Time Min.	Done By	Checked By Sign & Date
			Before Use	After Use					
	24 #								

6.17.2 Mill the remaining residue through 1.5mm Multimill screen.

Date	Screen Size	Screen No.	Screen Integrity		Start Time	End Time	Total Time Min.	Done By	Checked By Sign & Date
			Before Use	After Use					
	1.5 mm								

6.11 Record the weight of sifted Material :-

S. No.	Gross Weight (In Kg)	Tare Weight (In Kg)	Net Weight (In Kg)	Done By Sign & Date	Checked By Sign & Date
1					
2					
3					
TOTAL NET WEIGHT (KG)					

Theoretical Weight of Sifted Material: - kg

Remarks (IfAny): _____



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: **16/06/2020**

Batch No.: **Batch Size:**



6.12 Lubricants sifting.

Operation Start Time:

Operation End Time:

Sr. No	Material Name	Specification	Total Bag/Container wise Qty. Gross wt. (in kg)	Total Net Qty. In Kg	Sieve Size	Sieve Integrity		Sifting Time		Done By Prod. Sign& Date	Checked By QA Sign& Date
						Before	After	From	To		
1.	Cross Carmellose Sodium	IP			40#						
2.	Magnesium Stearate	IP			40#						
3.	Colloidal silicon dioxide	IP			40#						

6.13 Blending/Lubrication:

- 6.14.1 Operate the Blender as per the SOP No. **APD/PRD/003**.
- 6.14.2 Masks and gloves should be used during operation.
- 6.14.3 Check for the line clearance, cleanliness of the area and equipment.
- 6.14.4 Charge the above mixture of Norethisterone & Lactose granules in blender.
- 6.14.5 Charge the lubrication and lock the blender properly.
- 6.14.6 Mix the blend in blender for 40 min with following parameter.

Date	RPM of Double cone blender		Time Start	Time End	Done By	Checked By Production Date & Sign
	Std	Observed				
	10					

- 6.14.7 Now Stop the blender & Charge the sifted Magnesium Stearate, Mix the blend in blender for 05 min with following parameter.

Date	RPM of Double cone blender		Time Start	Time End	Done By	Checked By Production Date & Sign
	Std	Observed				
	10					

- 6.14.8 After Completion of blending activity transfer the lubricated blend in Double Poly Bag lined HDPE drum/ bin, affix Status and Under Test label as per SOP No.: **APD/QAD/011** and transfer to Granules quarantine area, weigh and record the details.



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:



6.14 Lubricated Granules Weight:

Drum No.	Clean Status OK/Not ok	Gross Wt. (Kg)	Tare Wt. (Kg)	Net Wt. (Kg)	Done By Production	Checked By Production Sign & Date	Remarks (If any)
1.							
2.							
3.							
4.							
Total No. of Container		Total weight					

Theoretical weight of Blend: _____ kg.

Limit: To be ascertained

Remarks (If Any): _____

Physical Parameters for lubricated Granules:-

Parameters	Limits	Unit	Observation	Instrument Code	Checked by(Sign & Date)
L.O.D. of Lubricated		%w/w			

6.15 Blend Sample Collection Record:

Send the sample intimation to QA for sampling.

After sampling, QA shall send the sample along-with intimation to QC for analysis.

Sampling of Lubricated granules shall be performed as per APD/QAD/

Intimation No.	Intimated By Production Date	Sampled By QA Date	Quantity Sampled

6.16 Yield Calculation: (Lubricated Blend)

1.	Theoretical weight of blend	kg.
2.	Actual Weight of blend	Kg
3.	In-process samples A IPQA Samples (if any)kg B QC Sampleskg C Validation Sampleskg	
4.	Total samples: (A + B + C)	kg
5.	Total: (2 + 4)	Kg
6.	Non-Recoverable	
7.	Yield $\{(5/1) \times 100\} = \underline{\hspace{2cm}} \times 100$ (Record the yield)	% Limit: To be ascertain

Remarks (If Any): _____

**Done By Production
(Sign & Date)**

**Checked By Production
(Sign & Date)**

**Verified By QA
(Sign & Date)**



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001	Revision No.:05
------------------------------------	------------------------

BMR Supersedes No.: 04	Effective Date:
-------------------------------	------------------------

Batch No.:	Batch Size:
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6.17 Blend Release Record:

(To be filled by QA Officer /Executive)

Date of Release: _____

Sample Intimation No.: _____

AR No.: _____

Result: **Complies / does not Complies**

Test Report attached/Not Attached

Checked By QA

(Sign & Date) _____

7.0 COMPRESSION:

7.1 General Instruction:

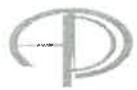
- 7.1.1 Gowning should be as per respective SOP.
- 7.1.2 Check for the line clearance, Cleanliness status of the area and equipment.
- 7.1.3 After receiving release of lubricated granules from Quality Assurance, proceed for the compression.
- 7.1.4 Carry out the Initial Checks of Compression Machine setting and physical parameters of tablets and record.
- 7.1.5 Mask and gloves should be used throughout compression.
- 7.1.6 Counter check weights of total finished granules.
- 7.1.7 Set the punch & dies tools & operate the compression machine, Deduster as per SOP **APD/PRD/007**
- 7.1.8 In case if compression activity is carried out on next day i.e. process is started after shutdown; additional pages for compression activity (Including Safety Checklist, Line clearance, Environmental Monitoring of Compression Area, Compression Machine Tool Verification, Compression Parameters Start Up & In-process, Compression Operation Details).

7.2 Safety Checklist (Before Operation of Compression Machine):

Area: _____ Equipment ID No: _____ Date: _____

Sr. No.	Check Point	Observation	Checked By Production Date& Sign	Verified By QA Date& Sign
1.	Does the Door interlocks (limit switches) working properly?	Complies/Not Complies		
2.	Are all required Personnel Protective Equipments available?	Complies/Not Complies		
3.	Are Electrical cables in good condition and free from joints?	Complies/Not Complies		
4.	Is EMERGENCY STOP switch working (Compression machine) can stop instantaneously?	Complies/Not Complies		

Remarks (If Any):



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:



7.3 Line Clearance:

To certify the line clearance Follow the SOP No.: APD/QAD/034.

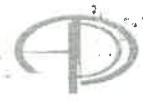
Date: _____

Time: _____

Previous Product Name: _____

Batch No.: _____

Sr. No	Check Points	Observation	Checked By	
			Production	QA
a] Area General Checks:				
1.	Containers/ Utensil materials used for previous batch/product removed from area	Yes/No		
2.	Cleaned status label on all equipments for the batch/product	Yes/No		
3.	All documents related to the previous batch / products are removed from area.	Yes/No		
4.	BMR till last processed stage is updated	Yes/No		
5.	Check the Waste bins; it should be clean & empty.	Yes/No		
b] Area Environmental Control Checks:				
6.	Pressure Difference in Compression area (Limit: NLT8Pascal)			
7.	Relative Humidity in Compression area (Limit: NMT 55%)			
8.	Temperature of Compression area (Limit: NMT 25 °C)			
9.	Temperature/Relative humidity log book	Checked/ Not checked		
c] Area Cleanliness checks:				
10.	Cleanliness status of floor, corners and walls	Cleaned/ Not cleaned		
11.	Area cleanliness record	Cleaned/Not cleaned		
12.	Area cleaned by			
d] Equipment No.: Compression Machine (APD/HT/006)				
13.	Cleanliness status of Feeder assembly	Cleaned/Not cleaned		
14.	Cleanliness status of Hopper assembly	Cleaned/Not cleaned		
15.	Cleanliness status of Turret, hole and scrapper	Cleaned/Not cleaned		
16.	Cleanliness status of roller	Cleaned/Not cleaned		
17.	Cleanliness and No. of the Lower cam track	Ok/Not ok		
e] Equipment No.: Deduster: (APD/HT/010)				
18.	Tablet Path cleanliness	Cleaned/Not		



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

BMR Supersedes No.: 04 **Effective Date:** 16/06/2020

Batch No.: **Batch Size:**



Sr. No.	Check Points	Observation	Checked By	
			Production	QA
		cleaned		
19.	Cleanliness status of Dust collector pipe and assembly	Cleaned/Not cleaned		
20.	Cleanliness of electrical panel	Cleaned/Not cleaned		
f] Punch Tool Checks:				
21.	Punch tool No. and Identity as per BMR	Ok/ Not Ok		
22.	Cleaning log book check for defined Punch tool	Checked/Not checked		
23.	Previous Product: Punch tool No. used			
24.	Cleanliness status of Punches	Cleaned/Not cleaned		
25.	Setting of punches on Compression machine	Ok/Not Ok		
g] Equipment: Balance (BAL:-(APD/HT/BAL/002)				
26.	Cleanliness status of Balance	Cleaned/ not cleaned		
27.	Daily Weight checking log book of balances	Checked/not checked		
28.	Calibration status of Balance	Calibrated/not calibrated		
h] Miscellaneous Equipments:				
29.	Calibration status of Hardness Tester (APD/HT/011)	Calibrated/not calibrated		
30.	Calibration status of Vernier Caliper (APD/HT/012)	Calibrated/not calibrated		
31.	Calibration status of Moisture analyzer balance (APD/HT/030)	Calibrated/not calibrated		
32.	Calibration status of Disintegration Apparatus (APD/HT/013)	Calibrated/not calibrated		
33.	Calibration status of Friability Apparatus (APD/HT/014)	Calibrated/not calibrated		

LINE CLEARANCE CERTIFICATE:

Observations of Area, Equipment and Environmental checks are found satisfactory/ not satisfactory. Line clearance given/ not given to proceed with planned process.

Certified by QA (Sign & Date): _____



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD,SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

BMR Supersedes No.: 04

Batch No.: **Effective Date:** 16/06/2020

Batch Size:



7.4 Environmental Monitoring of Compression Area:

Check and record the Temperature, Humidity and pressure difference as per SOP No.: APD/QAD/007.

Frequency: At the start of operation and thereafter every four hours.

Date	Time	Area Name	Temp. NMT 25°C	Relative Humidity NMT 55%	Differential Pressure NLT8Pascal	Checked By Production Date & Sign	Verified By QA Date & Sign

Remarks (If Any): _____

7.5 Compression Machine Tool Verification:

Date: _____

Time: _____

Particulars	Dies	Upper Punch	Lower Punch	Checked By Production Sign & Date	Verified By QA Sign & Date	Remark (If any)
Punch size	NA	7.10 mm	7.10 mm			
Shape Specification	NA	White, Round. Biconvex	White, Round. Biconvex			
Marking Specification	NA	Scored on one Side	NA			
Quantity of Dies						
Quantity of Punches						

7.6 Compression Parameters Start Up & In-process:

- 7.6.1 Carry out in-process as per SOP No.: APD/QAD/037
- 7.6.2 Rotate hand wheel clockwise for two rotations and weigh the tablets.
- 7.6.3 Set the weight of tablet at 130.00 mg by turning weight dossier anticlockwise for increasing weight and clockwise for decreasing weight. Discard the tablets.
- 7.6.4 Operate machine in auto mode. Check the total weight of 20 tablets.
- 7.6.5 Set weight by turning the Weight dozer anticlockwise for increasing the weight.
- 7.6.6 Set weight by turning the Weight dozer clockwise for decreasing the Weight.
- 7.6.7 Check the weight of 20 tablets & calculate the average weight of tablet.
- 7.6.8 Check the Individual Weight Variation, Diameter, Thickness And Hardness.
- 7.6.9 Set thickness and hardness as per limits given below by turning punch penetration handle clockwise for increasing hardness and reducing thickness and by turning punch penetration handle anti clockwise for decreasing hardness and increasing thickness for each side.
- 7.6.10 Check friability, disintegration time and individual weight variation of tablet. Note down the data as start up checks.



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD,SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:



7.6.11 Compression Machine Setting Parameters: Equipment ID No.: APD/HT/006

M/c Parameters	Acceptance Criteria
Compression M/c	30 Station Single Rotary , (BB tooling)
Upper Punch	7.1 mm Round, Biconvex
Lower Punch	7.1 mm Round, Biconvex
Machine Speed	

7.7 Tablet Parameters and in process checks:

Tablet Parameters	Acceptance Criteria
Average wt of tablet	130 mg±7.5%
Limits of Individual tablet Weight	120.25 mg - 139.75 mg
Thickness	3.2 mm ± 0.2 mm (3.0mm-3.4mm)
Limits of Group Tablets Weight	2.600gm ±2% (2.548gm –2.652 gm)
Disintegration Time	N.M.T. 15 Min.
Hardness (Kg/ cm ²)	NLT 3.0 Kg/cm ²
Friability (%)	N.M.T. 1.0 % w/w
Appearance	White, Round, Biconvex, Scored one Side, Uncoated Tablets

Formula for Calculating Friability:

$$\text{Friability} = \frac{(\text{Initial weight} - \text{Weight after rotation})}{\text{Initial weight}} \times 100$$



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Batch No.: Batch Size:



7.8 Recording of Initial Checks (at the start up)

Parameters	Limits	Observations			
		Production		IPQA	
	Date & Time	NA	LHS	RHS	LHS
Machine Speed	From.....to				
Physical Appearance	White, Round, Biconvex, Scored one Side, Uncoated Tablets				
Deduster	OK / Not OK				
Group Weight of 20 units	2.600gm $\pm 2\%$ (2.548–2.652 gm)				
Individual weight of 30 units	130 mg $\pm 7.5\%$ (120.25mg–139.75 mg)				
Thickness of 10 units	3.2 mm ± 0.2 mm (3.0mm-3.4mm)				
Hardness of 10 units	NLT 3.0 Kg/cm ²				
Friability =Initial Wt.- Final Wt.X100 Initial Wt (NMT 1.0% w/w)					
Disintegration Time	NMT 15 min				
Officer/Executive Sign & Date					



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:05**

BMR Supersedes No.: 04

Batch No.: **Batch Size:**



7.9 Recording of Initial Checks (at the start up in case of the failure of the initial checks):

Parameters	Limits	Observations			
		Production		IPQA	
	Date & Time	NA	LHS	RHS	LHS
Machine Speed	From.....to				
Physical Appearance	White, Round, Biconvex, Scored one Side, Uncoated Tablets				
Deduster	OK / Not OK				
Group Weight of 20 units	2.600gm ±2% (2.548–2.652 gm)				
Individual weight of 30 units	130 mg±7.5% (120.25mg – 139.75 mg)				
Thickness of 10 units	3.2 mm ± 0.2 mm (3.0mm-3.4mm)				
Hardness of 10 units	NLT 3.0 Kg/cm ²				
Friability =Initial Wt.- Final Wt.X100 Initial Wt (NMT 1.0% w/w)					
Disintegration Time	NMT 15 min				
Officer/Executive Sign & Date					



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD,SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD



Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Effective Date: 16/06/2020

Batch No.:

Batch Size:

7.10 Compression Operation Details:

Date	Compression Started at	Compression Completed at	Operated By	Checked By Production Sign & Date
Total Time:				

7.11 In-process Checks Quantity & Frequency:

Parameters	Frequency
Appearance of units of one round	
Individual Weight Variation of 30 units	Production: Every One hour
Group Wt. of 20 units	
Thickness of 10 units	QA: Every Two hours
Hardness of 10 units	
Friability: 50 units	Production: Every two hour
Disintegration Time of 6 units	QA: Every Four hours

Quantity to be taken for in-process check: _____ Units (Each Side)



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD



Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:

7.12 In process Control Record for Compression:

Parameters	Limits	Observations			
	Date				
	Start Time				
	NA	LHS	RHS	LHS	RHS
Machine Speed	From.....to				
Physical Appearance	White, Round, Biconvex, Scored one Side, Uncoated Tablets				
Deduster	OK / Not OK				
Group Weight of 20 units	2.600gm ±2% (2.548–2.652 gm)				
Individual weight of 30 units	130 mg±7.5% (120.25mg– 139.75 mg)				
Thickness of 10 units	3.2mm ± 0.2 mm (3.0mm-3.4mm)				
Hardness of 10 units	NLT 3.0 Kg/cm ²				
Friability =Initial Wt.- Final Wt.X100	Initial Wt (NMT 1.0% w/w)				
Disintegration Time	NMT 15 min				
Checked By Production/QA Sign and Date					

Remark (If any): _____



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:



7.12 In process Control Record for Compression:

Parameters	Limits	Observations							
	Date								
	Start Time								
	NA	LHS	RHS	LHS	RHS				
Machine Speed	From.....to								
Physical Appearance	White, Round, Biconvex, Scored one Side, Uncoated Tablets								
Deduster	OK / Not OK								
Group Weight of 20 units	2.600gm ±2% (2.548–2.652 gm)								
Individual weight of 30 units	130 mg±7.5% (120.25mg – 139.75 mg)								
Thickness of 10 units	3.2mm ± 0.2 mm (3.0mm-3.4mm)								
Hardness of 10 units	NMT 3.0 kg/cm ²								
Friability =Initial Wt.- Final Wt.X100									
Initial Wt (NMT 1.0% w/w)									
Disintegration Time	NMT 15 min								
Checked By Prod./QA Sign and Date									
Remark (If any): _____									



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:05**

BMR Supersedes No.: 04

Batch No.: **Batch Size:**



7.12 In process Control Record for Compression:

Parameters	Limits		Observations			
	Date					
	Start Time					
	NA	LHS	RHS	LHS	RHS	
Machine Speed	From.....to					
Physical Appearance	White, Round, Biconvex, Scored one Side, Uncoated Tablets					
Deduster	OK / Not OK					
Group Weight of 20 units	2.600gm ±2% (2.548-2.652 gm)					
Individual weight of 30 units	130 mg±7.5% (120.25mg – 139.75 mg)					
Thickness of 10 units	3.2mm ± 0.2 mm (3.0mm-3.4mm)					
Hardness of 10 units	NLT 3.0 Kg/cm ²					
Friability =Initial Wt.- Final Wt.X100 Initial Wt (NMT 1.0% w/w)						
Disintegration Time	NMT 15 min					
Checked By Prod./QA Sign and Date						

Remark (If any): _____



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: **Batch Size:**



7.12 In process Control Record for Compression:

Parameters	Limits		Observations						
	Date								
	Start Time								
	NA	LHS	RHS	LHS	RHS				
Machine Speed	From.....to								
Physical Appearance	White, Round, Biconvex, Scored one Side, Uncoated Tablets								
Deduster	OK / Not OK								
Group Weight of 20 units	2.600gm ±2% (2.548–2.652 gm)								
Individual weight of 30 units	130 mg±7.5% (120.25mg – 139.75 mg)								
Thickness of 10 units	3.2mm ± 0.2 mm (3.0mm-3.4mm)								
Hardness of 10 units	NLT 3.0 Kg/cm ²								
Friability =Initial Wt.- Final Wt.X100									
Initial Wt (NMT 1.0% w/w)									
Disintegration Time	NMT 15 min								
Checked By Prod./QA Sign and Date									
Remark (If any): _____									



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:



7.13 Core Tablets Weight:

7.13.1 Verify the Balance Calibration Status prior to weighing:

Balance ID	Capacity	Calibration Status (Ok/ Not Ok)	Checked By QA Sign & Date	Verified By QA Sign & Date

7.13.2 Weighing Record:

Container No.	Clean status Ok/Not Ok	Gross Wt. (Kg)	Tare Wt. (Kg)	Net Wt. (Kg)	Remarks (If any)
1.					
2.					
3.					
4.					
Total No. of Container		Total weight			

Theoretical weight of compressed Tablet: _____ kg.

Limit: To be ascertained

Done By Production: _____ Checked By Q.A.
(Sign & Date) _____ (Sign & Date) _____

7.13.3 Reconciliation of Compressed Tablets:

Sr. No.	Calculation Points	Observed Values	Checked By Production Sign & Date	Verified By QA Sign & Date
1.	Theoretical Batch size (Kg) (A)			
2.	Weight of Compressed Tablets (Kg) (B)			
3.	In process Sample (a)			
4.	QC Sample (b)			
5.	Validation Sample (c)			
6.	Total Sample {(a)+(b)+(c)=(C)}			
7.	Actual Yield [(B+C/A) x100]			
8.	Non Recoverable (Kg)			

7.13.4 Sampling, Analysis and Release of Tablets

Send the intimation slip to QA Dept. to draw the sample of Tablets for analysis.

Sampling, Analysis Details.

Intimated By Production Sign & Date	Intimation Received By QA Sign & Date	Sampled By QA Sign, Date & Time	Quantity Sampled

The compressed tablets are Released/ Not Released for Inspection/ Packing.

QA Sign & Date: _____

Time: _____

Attach the Report from QC: _____

A.R. No: _____



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:



7.13.5 Transfer compressed tablets to quarantine.

Date of Transfer	Qty. Transferred (in kg)	Transferred By Sign & Date	Verified By QA Sign & Date

7.13.6 Issuance of tablets:

Date of Transfer	Date of Receiving	Qty. Received in kg	Received By Sign & Date	Verified By QA Sign & Date

8.0 Coating :

8.1 Line Clearance for coating Area:

To certify the line clearance Follow the SOP No.: APD/QAD/034 .

Date: _____

Time: _____

Previous Product Name: _____

Batch No.: _____

S. No.	Check Points	Observation	Checked By	
			Production Sign & Date	QA Sign & Date

a] Area General Checks:

1.	Containers/ Utensil materials used for previous batch/product removed from area	Yes/No		
2.	Cleaned status label on all equipments for the batch/product	Yes/No		
3.	All documents related to the previous batch /Product are removed from area.	Yes/No		
4.	BMR till last processed stage is updated	Yes/No		
5.	All previous product/batch remnants removed from area	Yes/No		
6.	Check the Waste bins, it should be clean & empty	Yes/No		
7.	Check gowning of the personnel working in the area	Yes/No		
8.	Check training record of the personnel working in the area	Yes/No		

b] Area Environmental Control checks:

9.	Pressure Difference in Dispensing area (Limit: NLT 08 Pascal)			
10.	Relative Humidity in Dispensing area (Limit: NMT 55%)			



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: **16/06/2020**

Batch No.: **Batch Size:**



S. No.	Check Points	Observation	Checked By	
			Production Sign & Date	QA Sign & Date
11.	Temperature of Dispensing area (Limit: NMT 25°C)			
12.	Temperature/Relative humidity log book	Checked/ Not checked		
c] Area Cleanliness checks:				
13.	Cleanliness status of floor, corners and walls	Checked/ Not checked		
14.	Area cleanliness record	Checked/ Not checked		
15.	Area cleaned by			
d] Equipment No: Manual Coating (APD/GT/009)				
16.	Check spray gun, dosing delivery line for cleanliness	Checked/ Not checked		
17.	Solution tank and stirrer cleanliness	Checked/ Not checked		
18.	Check pan and below baffles for the cleanliness	Checked/Not checked		

LINE CLEARANCE CERTIFICATE:

Observations of Area, Equipment and Environmental checks are found satisfactory/not satisfactory.

Line clearance given/not given to proceed with planned process.

Certified by QA (Sign & Date): _____

Time: _____

8.2 Environmental Monitoring of Coating Area:

Check and record the Temperature, Humidity and pressure difference as per SOP No.: APD/QAD/

Frequency: At the start of operation and thereafter every four hours.

Area Name:

Date	Time	Temperature NMT 25°C	Relative Humidity NMT 55%	Differential Pressure NLT 08 Pascal	Checked By Production Date& Sign	Verified By QA Date& Sign

Remarks (If Any): _____



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD



Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:05**

BMR Supersedes No.: 04

Batch No.: **Batch Size:**

8.3 Material verification :

Transfer the dispensed material to manufacturing area from day store area for verification.

Start Time: _____

End Time: _____

S. No.	Material Name	Specification	Total Bag/ Container wise Qty. Gross wt. (in kg)	Total Net Qty. In Kg	Checked By Production Sign& Date	Verified By QA Sign& Date
1.	Protectab HP-1	IHS				
2.	Tween-80					
3.	Purified Water					

8.4 Sifting :-

8.4.1 Transfer the dispensed material to manufacturing area from day store area for verification.

8.4.2 Check the sieve integrity before and after sifting as per SOP No.: APD/PRD/002

8.4.3 Operate the Sifter as per the SOP APD/PRD/002 for sifting.

Date of Operation: _____

Start Time: _____

End Time: _____

8.5 Solution Preparation :-

Date of Operation: _____

Start Time: _____

End Time: _____

8.5.1 Take _____ kg Purified Water in S.S. Vessel/Container.

8.5.2 Add Sifted Protectab HP-1 & Tween-80 into above SS Vessel/Container with constant stirring.
Mix well for 15 min.

8.5.3 Rinse it with of Purified Water.



**ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD,SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD**

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 | Revision No.:05

BMR Supersedes No.: 04

Effective Date: 16/06/2020

Batch No.:

Batch Size:

S. No.	Item Name	Quantity	Added into SS Vessel/Container By	Checked By Production Sign & Date
1.	Protectab HP-1			
2.	Tween-80			
3.	Purified water			

8.5.4 Pass the above solution from colloidal mill.

Date	Time Start	Time End	Done By	Checked By Prod. Sign& Date

8.5.5 Store above solution in air tight container with proper status label.

8.6 Coating Procedure :

- 8.6.1 Check QC release for compressed tablets.
 - 8.6.2 Counter check weight of total core tablets.
 - 8.6.3 Operate Coating Pan as per SOP: APD/PRD/010.
 - 8.6.4 Compressed tablets are loaded into coating machine pan and warmed at 35°C, While warming the bed do not continuously roll the tablet only jog for 15 minutes at every 3 minute interval.
 - 8.6.5 Atomizing air pressure should not less than 5 bar.
 - 8.6.6 Coating solution spraying assembly is then fixed on mouth of coating pan as per SOP.
 - 8.6.7 Care should be taken while coating to avoid sticking of tablet and choking of nozzle of spray.
 - 8.6.8 Unload the coated tablets at the end of coating in drum with double polythene bag, label and weight each drum. Shift drums to Quarantine for Inspection and Primary Packing.
 - 8.6.9 Check the Parameter at the time of start and then follow the given frequency.



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001

Revision No.: 05

BMR Supersedes No.: 04

Effective Date: 16/06/2020

Batch No.:

Batch Size:



8.7 Time Record for Coating:

Date:

Loading		Jogging		Warming		Spraying		Cooling & Drying		Unloading of Tablets		Total Coating Time	Operator	Checked By Production Sign & Date
From	To	From	To	From	To	From	To	From	To	From	To			

8.8 Coated Tablet Appearance checks:

Appearance	Percentage of coating weight builds up	Appearance (OK / Not OK)	Checked By Production Sign & Date	Verified By QA Sign & Date
White, Round, Biconvex, Film Coated tablets having scored on one side.	[Avg. wt. of coated tablet – Avg. wt. of core tablets] / Avg. wt. of core tablets.			

8.9 Calculation of % Coating Weight Build up:

Avg. wt. of core 100 Tablets	Avg. wt. of 100 Coated tablet	% Of Coating Wt. Build up (Limit: 1.0 to 3.0 % w/w)	Checked By Production Sign & Date	Verified By QA Sign & Date

8.10 In-Process Specifications:

Sr. No.	Tests	Specifications	Limits	Frequency	Sample Qty.
1.	Description	White, Round, Biconvex, Film Coated tablets having scored on one side.	White, Round, Biconvex, Film Coated tablets having scored on one side.	At the end of coating	NA
2.	Theoretical Weight of 20 tabs.	To comply	2.660gm ± 2.0% (2.607gm to 2.713gm)	At the end of coating	20 tabs
3.	Uniformity of wt.	To comply	133.00mg ± 7.5% (123.025mg to 142.975 mg)	At the end of coating	20 tabs
4.	Thickness	To comply	3.25±0.2mm (3.05mm - 3.45mm)	At the end of coating	10 tabs
5.	Disintegration time	To comply	NMT 30 min	At the end of coating	6 tabs



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD,SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

BMR Supersedes No.: 04

Effective Date: 16/06/2020

Batch No.:

Batch Size:



8.11 In process Observation:

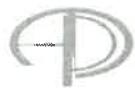
Parameter	Observation By	
	Production	QA
Description		
Theoretical Weight of 20 tabs.		
Uniformity of wt		
Diameter (mm)		
Thickness (mm)		
DT (mins)		

8.12 Coated Tablet Weight:

Container No.	Clean status OK/Not OK	Gross Wt. (Kg)	Tare Wt. (Kg)	Net Wt. (Kg)	Remarks with Sign & Date (If any)
Total No. of Container:		Total Weight			

**Done By Production
Sign & Date**

**Checked By Production
Sign & Date**



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Effective Date: 18/06/2020

Batch No.:

Batch Size:



8.13 Reconciliation of Coated Tablets:

S. No.	Calculation Points	Observed Values	Checked By Production Sign & Date	Verified By QA Sign & Date
1.	Weight of Coated Tablets (Kg) (A)			
2.	Theoretical Batch size (Kg) (B)			
3.	In- Process Sample			
4.	QC Sample			
5.	Validation Sample			
6.	Total Sample (C)			
7.	Actual Yield [(A+ C / B) x100]			
8.	Non Recoverable (Kg)			

8.14 Sampling, Analysis and Release of Tablets:

Send the intimation slip to QA Dept. to draw the sample of Tablets for analysis as per SOP No.: APD/QAD/028

Sampling, Analysis Details

Intimated By Production Sign & Date	Intimation Received By QA Sign & Date	Sampled By QA QA Sign & Date	Quantity Sampled

The coated tablets are **Released/ Not Released** for Inspection/ Packing.

QA Sign & Date: _____

Time: _____

Attach the Report from QC: _____

A.R. No: _____

8.15 Transfer above coated tablets to quarantine

Date of Transfer	Qty. Transferred (in kg)	Transferred By Sign & Date	Checked By QA Sign & Date

8.16 Issuance of tablets for Inspection :

Date of Transfer	Date of Receiving	Qty. Received in kg	Received By Sign & Date	Verified By QA Sign & Date



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD,SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 **Revision No.:** 05

BMR Supersedes No.: 04

Batch No.:

16/06/2020

8.17 Inspection Of Tablets

8.17.1 Line Clearance

Area :..... Line clearance checked at on.....

Previous Product: B. No.

If the previous product same ensure that the powder of earlier batch is completely removed

S. No.	Particulars	Remark (Yes/No)	Done By	Checked By Prod.	Verified By QA
1.	Cleanliness of Area				
2.	Cleanliness of Inspection belt				
3.	Status Label of previous product				
4.	Container of previous product				
5.	Tablet of previous product				

Temperature of area (NMT 25°C)	°C
RH of area (NMT 55%)	%

Checked By Production Sign/Date..... Verified By QA Sign/Date

8.17.2 Tablet Verification:

Date	Time		Weight of tablets taken for Checking (kg)	Weight of good Tablets (kg)	Weight of recoverable residues (kg)	Weight of non-recoverable residues (kg)	Done by	Ckd. by
	From	To						

8.17.3 Weight Verification:

Date	Container No.	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Checked by	
					Prod.	QA
Total weight						





ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Batch No.: Batch Size:



8.17.4 Finished Tablet Release:

Finished Tablet Release report attached here.

Report No.

Checked By Production Sign/Date..... Verified By QA Sign/Date

8.17.5 Yield Reconciliation of Inspected tablet :

Batch size (A)	:	Kg	Tablets
Tablets transferred for packing (B)	:	Kg	Tablets
Recoverable residues (C)	:	Kg	Tablets
Non-recoverable residues (D)	:	Kg	Tablets
Sample to QA analysis (E)	:		Tablets
QC Sample (F)	:		Tablets
Total (G) = (B + C + E + F)	:	Kg	Tablets
% Yield.	:	G X 100 A	%

Limit: NLT 95.0%,

If yield is not within the limit, Justify:

Checked By Production Sign/Date..... Verified By QA Sign/Date

8.18 Destruction of Non Recoverable: Carry out Destruction as per SOP No.: APD/PRD/026.

Stage	Non Recoverable Qty.(kg)	Qty. Destroyed (kg)	Destroyed By Sign & Date
Blending/Lubrication			
Compression			
Coating			
Inspection			

Destroyed in presence of QA

Sign & Date: _____



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD, SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04 Effective Date: 16/06/2020

Batch No.: Batch Size:



9.0 ACCOUNTABILITY:

Sr. No.	Particulars	In Kg	In No.
1.	Theoretical batch quantity		
2.	Total quantity transferred to packing department		
3.	Blending loss		
4.	Compression loss		
5.	Coating loss		
6.	In process Sample		
7.	Analysis Sample		
8.	Validation sample		

$$\text{Accountability} = \frac{(2+3 + 4+ 5 + 6+7+8)}{1} \times 100$$

$$) \times 100$$

= -----% (To be ascertained)

**Officer/ Executive Prod.
Sign and Date**

**Head Production
Sign and Date**

**Verified By QA
Sign and Date**

10.0 SIGNATURE LOG:

Sr. No.	Name of the Employee	Employee Code	Department	Specimen Signature
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

11.0 INCIDENT/DEVIATION RECEIVED (If Any):

Incident No.:

Deviation No.:

Status:

Checked By QA:

Sign & Date:



ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD,SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Product Name: ALLYLESTRENOL TABLETS

BMR No.: APD/BMR/HT/ALL/001 Revision No.:05

BMR Supersedes No.: 04

Effective Date: 16/06/2020

Batch No.:

Batch Size:



15.0 BREAK DOWN DETAILS:

Date	From	To	Nature of Break Down	Area	Stage	Break Down Time	Rectification Time

16.0 BACTH MANUFACTURING HISTORY SHEET:

S. No.	Stage	Start Date	End Date	Checked By Production Sign & Date	Verified By QA Sign & Date
1.	Dispensing				
2.	Manufacturing				
3.	Compression				
4.	Inspection				

17. CHECK LIST FOR BATCH MANUFACTURING RECORDS & RELEASE FOR PACKING:

Sr. No.	Check Points	Status
1.	All the pages are available and comply with index.	Yes / No
2.	Batch number available in all pages.	Yes / No
3.	Manufacturing and expiry date is correctly quoted.	Yes / No
4.	Dispensing carried out on calibrated balance.	Yes / No
5.	Line Clarence is taken prior to all dispensing, Blending Area, Compression area activity.	Yes / No
6.	Dispensing is carried out as per Bill of materials.	Yes / No
7.	The entire dispensed label is properly affixed.	Yes / No
8.	Environmental condition complies during all the manufacturing steps.	Yes / No
9.	No overwriting are observed all wrong entries are having been strike out and signed.	Yes / No
10.	Actual equipments are used as specified.	Yes / No
11.	Batch dispensing is carried out after QA approval.	Yes / No
12.	Batch manufacturing is carried out after QA approval.	Yes / No
13.	Batch compression is carried out after QA approval.	Yes / No
14.	QC approval is available on test request form	Yes / No
15.	Yield and reconciliation of all stage is within acceptance limit.	Yes / No
16.	All the in process check result comply within the acceptance limit	Yes / No
17.	All the blank space is filled correctly without pending entries.	Yes / No
18.	Batch reconciliation is completed and complies within the limit (In case it is outside limit justification is available)	Yes / No
19.	If there is any deviation during the in process, it is recorded in process History sheet and deviation is raised and approved.	Yes / No
20.	Status Labels of Machinery	Yes / No
21.	TR of wash water, blend and TR of compressed tablets attached.	Yes / No
22.	RM excess issue order (if applicable)	Yes / No



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23.	Deviation and its Justification	Yes / No
24.	Signature of Authorized Persons	Yes / No
25.	Legibility of contents	Yes / No

BMR Checked By:
Production (Sign & Date)

BMR Reviewed By:
QA (Sign & Date)

18. QC Data review Checklist:

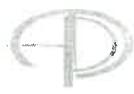
Sr.	Check points	Status
1.	Analytical report complete and approved	Yes / No
2.	Records are readable, unequivocal & correct	Yes / No
3.	Test according to current authorized specification and standard test procedure	Yes / No
4.	Test results are according to approved specification	Yes / No
5.	All raw data along with signed copy of audit Trail	Yes / No

Reviewed By QA/QC

Sign & Date

19. ABBREVIATION:

%	: Percentage
#	: Mesh
°C	: Degree Centigrade
&	: And
Approx.	: Approximately
A.R.	: Analytical Report
Avg.	: Average
B. No.	: Batch Number
Bal.	: Balance
BMR	: Batch Manufacturing Record
Ckd.	: Checked
Dt.	: Date
Exp.	: Expiry
Gm/g	: Gram
GMP	: Good Manufacturing Practice
IP	: Indian Pharmacopoeia
kg	: kilogram
L	: Liter
L.A.	: Labeled Amount
L.C.	: Label Claim
LOD	: Loss on Drying
Mfg.	: Manufacturing
mg	: Milligram
min	: Minutes
Kg/cm ²	: Kilogram per centimeter square
mm	: Millimeter
NA	: Not Applicable
NLT	: Not Less Than
NMT	: Not More Than



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Batch Size:



No. / Nos.	: Number / Numbers
Prod.	: Production
QA	: Quality Assurance
QC	: Quality Control
Qty.	: Quantity
q.s.	: Quantity Sufficient
Ref.	: Reference
RH	: Relative Humidity
RMG	: Rapid Mixer Granulator
RPM	: Rotation Per Minute
R.O.	: Role on
Sr. No.	: Serial Number
SOP	: Standard Operating Procedure
S.S	: Stainless Steel
TAB	: Tablet
Temp.	: Temperature
Wt.	: Weight
w/w	: Weight by Weight
±	: Pluses and Minus
DT	: Disintegration Test
TR	: Test Report

20. DOCUMENT REVISION HISTORY:

Revision No.	Effective Date	CCF No.	Details of Revision	Reason For Revision
00	01 APR 2015	NA	New BMR	New BMR
01	08 JULY 2016	APD/CC/1506	Separate SOP for Preparation of BMR and BPR is Incorporated.	Separate SOP for Preparation of BMR and BPR is Incorporated
02	08 JULY 2018	NA	Periodic Review	Periodic Review
03	24 MAR 2019	APD/CC/1919	Re formulation of BMR as per SOP No APD/QAD/023	System up-gradation
04	04 MAY 2020	APD/PRD/20-014	Removal of Doshion P 544 D and Additional of Sodium Lauryl Sulphate	Change in formulation
05	16 JUNE 2020	APD/PRD/20-023	Change in formulation	Change in formulation