Pharmaceutical Guidelines
Delhi, India
Batch Manufacturing Record

Product	: Atorvastatin Tablets IP 40 mg	**B.M.R. No.**	XX/XXX/000
		B.M.R Revision No./ Date	00/ddmmyyyy
Batch Size	: 2,00,000 Tablets	**Ref. M.F.R. No**	XX/XXX/000
Batch No.	: XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Batch Quantity	: 35.00 kg.	**COMPOSITION:** **Each Film Coated Tablet contains:** Atorvastatin Calcium IP Equivalent to Atorvastatin ------ 40 mg Color :Titanium Dioxide IP
Reworking Added (If any)	:	
Theoretical Yield	:	
Mfg. Date:		Exp. Date:
Document issued by: Date:		Document Received by: Date:
This Document Supersedes	: None	
Reason for Change	: New	
Mfg. Licence No.	: XXXX/XX/XXXX	Material code No. - XXXXXXXX
Shelf Life	: 36 Months or expiry of active ingredient whichever is less.	
Storage Condition	: Store in cool, dry & dark place.	
Marketed by	: XYZ Pharmaceuticals Ltd.	
Serial No.	:	

	Granulation	Compression	Coating
Date of Commencement:			
Date of Completion:			
Area Used:			
Previous Product Processed:			
Batch No:			
Checked by Pharmacist: Date:			

This batch has/has not been completed according to the instructions given in M.F.R. No. XX/XXX/00.
Deviation sheet attached: Y/N

Actual Yield:_____Tablets Reworking Generated:_____Kg. Total Yield: _____%	Date of Packing: Quantity:
Final BMR Checked By: Date:	Final BMR Checked By: Date:

Prepared By	**Checked By**	**Reviewed By**	**Approved By**
Quality Assurance	**Production**	**Production Head**	**QA & QC Head**
Date:	**Date:**	**Date:**	**Date:**

Product	**:** Atorvastatin Tablets IP 40 mg	**B.M.R. No.**	XX/XXX/000
		B.M.R Revision No./ Date	00/ddmmyyyy
Batch Size	**:** 2,00,000 Tablets	**Ref. M.F.R. No**	XX/XXX/000
Batch No.	**:** XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

General Instruction for Manufacturing

Precautions for Safety:

- Safety precautions to be taken against explosions in Fluidized Bed Drier & while grinding.
- Protect the respiratory organs from active substance.
- Store the granules & tablets in well closed containers lined with double polythene bags.
- Follow personal hygienic requirements.

Notes:

1. Manufacturing is to be carried out as per requirements of current GMP.
2. Use clean and dry S.S. Equipments at all stages of manufacturing.
3. Carry out sifting and milling operations near dust extraction.
4. All equipments and machineries must be adequately guarded and earthed. The operators must use proper safety equipments like hand gloves, nose masks, ear muffs, etc. during all operations.
5. Ensure that general cleaning & utensils cleaning are carried out as per respective S.C.P. & checked for cleanliness before use.
6. Ensure that RMG, Octagonal Blender, Multi mill, Vibratory sifter, S.S. Sieves, S.S., FBD, Screens, Compression machine coating pan & tools and accessories etc. are cleaned as per respective S.C.P.
7. Before weighing operations, check cleanliness of balances as per S.C.P.
8. Batch size may be varied, depending upon the requirement. Prior permission of QC/QA should be obtained except in case of batches in which reworking is added.
9. All the ingredients must have been passed by Q.C. Dept., prior to use and must be within retest date.
10. Destroy all rejected material & tablets by putting in a container of water after recording the weights.

Cleaning Record of Machinery & Equipment

Sr. No.	Machinery / Equipment	Capacity	Equipment No.	Previous Product & B. No.	Cleaned		Chd. By	Re-chd. by
					On	by		
1.	Balance.	350 kg						
2.	Sifter	36”						
3.	RMG	250 Lts.	-					
4.	Seives	-						
5.	Multimill	-						
6.	Fluidised Bed Dryer	100 Kg.						
7.	Octagonal Blender	250 Ltrs.						
8.	Vessels & Spatulas	-						
9.	Compression machine	55 station						
10.	Coating Pan	42’						
11.	Tools and other Accessories	-						

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Batch No.	: XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Bill of Raw Materials & Weighing Record

Sr No	Ingredients	Qty /Tab (mg)	Qty for batch (kg)	A. R. No./ Date	Bal. No.	Gross Wt. (kg.)	Tare Wt (kg.)	Net Wt (kg.)	Wtd By	Chkd. By
1.	Atorvastatin Calcium IP Trihydrate (Eq. to Atorvastatin) Mfg. Date: Exp. Date:									
2.	Microcrystalline Cellulose IP PH-101									
3.	Lactose Monohydrate IP									
4.	Calcium Carbonate IP									
5.	Povidone IP (PVP k-30)									
6.	Polysorbate 80 IP									
7.	Isopropyl alcohol IP									
8.	Colloidal Silicon Dioxide IP									
9.	Croscarmellose sodium IP									
10.	Magnesium Stearate IP									
Compression Weight		**: 165 mg / tablet**								

Calculation:

Quantity will vary depending upon Assay limit.

Mol. Wt. of

$$\text{Atorvastatin Calcium IP Trihydrate} = \text{L.C. in mg.} \times \frac{100}{\text{Assay on as is basis}} \times \frac{\text{B. Size in Tab.}}{1000 \times 1000} \times \frac{\text{Atorvastatin Calcium IP}}{\text{Mol. Wt. of Atorvastatin}}$$

$$= \frac{40}{1} \times \frac{100}{\text{Assay on as is basis}} \times \frac{2,00,000}{1000 \times 1000} \times \frac{1155.36}{1117.28}$$

= ---------- = Kg.

Requisition given by :		Date :
Area Cleanliness checked by :	Production Pharmacist :	Date :
	Stores Supervisor :	Date :
Previous Product Processed :		B. No. :
Material required on :		Issued on :
Calculation Checked By :		
Production :		Date :
Q.A. :		Date :

Bill of Raw Materials & Weighing Record

Sr. No.	Ingredients	Qty for Batch (kg.)	A. R. No / Date	Bal. No.	Gross W t. (kg.)	Tare Wt. (kg.)	Net Wt. (kg.)	Wd By	Chd. By
Coating									
1.	Hydroxy Propyl Methyl Cellulose IP 5cps								
2.	Polyethylene glycol 6000 IP								
3.	Titanium dioxide IP								
4.	Purified Talc IP								
5.	Isopropyl Alcohol IP								
6.	Methylene chloride IP								

Requisition given by :		Date :
Area Cleanliness checked by :	Production Pharmacist :	Date :
	Stores Supervisor :	Date :
Previous Product Processed :		B. No. :
Material required on :		Issued on :
Calculation Checked By :		
Production :		Date :
Q.A. :		Date :

	Pharmaceutical Guidelines Delhi, India Batch Manufacturing Record		
Product	: Atorvastatin Tablets IP 40 mg	**B.M.R. No.**	XX/XXX/000
		B.M.R Revision No./ Date	00/ddmmyyyy
Batch Size	: 2,00,000 Tablets	**Ref. M.F.R. No**	XX/XXX/000
Batch No.	: XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Process Sheet

Sr. No.	Operation	Date & Time of Operation		Operation	
		From	To	Done by	Chd. BY
	Granulation Area ID No. : Previous product processed: It's B. No. : Area clearance checked by Production: Area clearance checked by QA:				
1.0	**Sifting:** Refer SOP NO: XX/XX/000 Check the integrity of the sieve before & after sifting of individual material. Sift the material as per sequence & specified mesh sieves given. Check for residue if any for each ingredient & replace the material retained over sieve with fresh material & record the wt.				
1.1	Sift through 40 mesh; Atorvastatin calcium IP Trihydrate …….. Kg Microcrystalline Cellulose IP (PH-101)…….. Kg Lactose Monohydrate IP …….. Kg Calcium Carbonate IP …….. Kg				
2.0 2.1	**Preparation of Granulating Solution** Add Povidone IP …….. kg Polysorbate 80 IP …….. kg In Isopropyl alcohol IP…….. kg Under continuous stirring & filter through 100# nylon cloth.				

Process Sheet

Sr. No.	Operation	Date &Time of Operation		Operation	
		From	To	Done by	Chd. by
3.0 3.1 3.2 3.3 3.4	**Mixing And Granulation:** Refer SOP NO: XXX/XX/000 Transfer from stage 1.1 into a clean RMG Mixer, i.e. Atorvastatin calcium IP Trihydrate…….. Kg., Microcrystalline Cellulose IP (PH-101)…….. Kg., Lactose Monohydrate IP ……Kg. Calcium Carbonate IP ……..Kg. Mix for 10 minutes at slow speed for homogeneity. Add granulating solution of stage 2.1, in a thin stream into mixer, while mixing at slow speed within 4 min. Then mix for 3 min. on fast speed. Scrap and mix for 1 min. with agitator and chopper "ON" to get suitable consistency of granulation. Continue the mixing further on slow speed. If necessary add extra Isopropyl alcohol IP to get suitable consistency of granules. Note down the wt. of extra Isopropyl alcohol IP added. Transfer the Granules to FBD bowl through the discharge port. Keep the agitator at slow speed & chopper in OFF position during transferring the wet mass Extra Purified Water IP added:				

Product	**:** Atorvastatin Tablets IP 40 mg	**B.M.R. No.**	XX/XXX/000
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Batch No.	**:** XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Process Sheet

Sr. No.	Operation	Date &Time of Operation From	To	Operation Done by	Chd. By
4.0	**Drying:(Semi –Drying)** Refer SOP No.: XXX/XX/000 Dry the wet mass of step 3.5, in FBD at ambient temperature for 10 min. Inlet Damper:……..% (80-100%) Exhaust Damper:……% (40-50%)				
5.0	**Wet Mass Milling:** Refer SOP No : XXX/XX/000 Check the integrity of the sieve before & after sifting of individual material. Pass the semidry mass at stage 4.0 through multimill using 8 mm screen medium speed knives forward direction.	:			
6.0	**Drying:** Refer SOP NO : XXX/XX/000 Dry the wet mass at stage 5.0 in a FBD at ambient temperature for 20 minutes & then at 50 ± 5°C. Rake over intermittently so that all the material in contact with the screen is turned. The drying is adequate when the LOD reaches 2.5 %. Limit: 2.0 – 3.5 % at 105 °C Inlet Damper:……..% (80 - 100%) Exhaust Damper:……% (25 - 35%) Inlet temperature :……(50-55°C) Outlet temperature :……..(30-35°C) Total time taken for drying:……..				
7.0	**Sizing & Sifting:**Refer SOP No. XXX/XX/000 Check the intactness of sieve before use Pass the dried granules through 20# sieve. Grind the coarse material through multimill using 1.5 mm screen with knives forward direction with knives forward direction. Redry if required and repeat stage 6.0 Note & record yield of dried granules Std. Yield: 99.50%, Permissible Yield:99.00 – 100.00 %				

Process Sheet

Sr. No.	Operation	Date &Time of Operation From	To	Operation Done by	Chd By
8.0	**Reworking:** Refer SOP NO: XXX/XX/000				

Batch No.	Mfg. Date	Exp. Date	Quantity

The total qty. of reworking added should not exceed 3% of the batch qty. The reworking to be added should be crushed through 2 mm screen using multimil, knives forward at medium speed & sift through 20#. Add the reworking to the bulk of blending. Reworking generated should be used within 3 month of its generation.

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Batch No.	: XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

9.0	**Lubrication:** Refer SOP NO. XXX/XX/000				
9.1	Transfer granules of stage 7.0 & reworking of stage 8.0 if any to the Octagonal Blender by sandwich method & mix for 5 min.				
9.2	Sift through 40# mesh – Croscarmellose Sodium IP…….. Kg Colloidal Silicon Dioxide IP…….. Kg				
9.3	Transfer the lubricants of stage 9.2 to blend of 9.1 by sandwich method & Mix for 10 minutes.				
9.4	Sift through 60# mesh; Magnesium Stearate IP…… Kg & transfer to stage 9.3 and Mix for 3 minutes.				
9.5	Collect the lubricated granules in double polyethene bag & record wt. Theoretical weight = ……. kg + weight of reworking = ……kg Std. Yield : 99.50% Permissible Yield: 99.00 –100.00 %				
10.0	**Compression:** Refer SOP NO : XXX/XX/000 Compress the lubricated granules into tablets as per given specification.				

Lubricated Granules Output

Balance ID No.:……..

Container	Gross Wt. (Kg.)	Tare Wt. (Kg.)	Net Wt. (Kg.)	Signature
1				
2				
3				
4				
5				
6				
7				
8				
TOTAL				
Signature of Production Pharmacist : _____ Date :				

Line Clearance Record

Tablet Compression Machine – Line Clearance Record				
Previous Product Compressed : Batch No. : Completed On : Time :				
Sr. No.	Description	Remark Yes / No	Checked By (Prod.)	Rechecked By (Q.A.)
1	Label (s) of Previous Product			
2	Tablets/ Granules of Previous Product			
3	Container (s) of Previous Product			
4	Area Cleanliness (Floor, Walls)			
5	Compression Machine is adjusted properly			
6	Batch is approved for Compression by Q.A.			
7	Temp. = °C, Humidity = % RH			
Line Clearance is Satisfactory / not Satisfactory.				
Line Cleared By (Prod.) : Date : Time: Checked By (Q.A.) : Date : Time:				

	Pharmaceutical Guidelines Delhi, India Batch Manufacturing Record		
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		B.M.R Revision No./ Date	00/ddmmyyyy
Batch Size	: 2,00,000 Tablets	**Ref. M.F.R. No**	XX/XXX/000
Batch No.	: XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Compression Record

Container	Net Wt (Kg.)	Signature	Container	Net Wt (Kg.)	Signature
1			5		
2			6		
3			7		
4			8		
			TOTAL		

Machine used		Operator	
Last Product processed : B. No :		Cleanliness check on the Machine & area	
Punches and dies	7.8 mm circular, break line on one side.	Cleanliness check for punches	
Balance check		Lubricant level	
Date		Time started	

Description Compressed Tablets: White coloured, circular, uncoated tablets with Heart shaped embossing on one side.

SR. NO.	OPERATION	L	R	STD	UNITS	SIGNATURE
1	Setting of machine					
2	Checking of complete rotation					
3	Weight adjustment : Per Tablet 20 tablets			165 mg / tablet 3.30 gm ± 2.0 %		
4	Appearance					
5	Hardness			NLT 6	Kg/cm^2	
6	Thickness			3.4 ± 0.2	mm	
7	Disintegration time			NMT15	min	
8	Friability (Wt. of Tabs. corresponding about 6.5 gm. Before Rotations)			NMT 1	%	
9	Machine speed			R.P.M.		
10	Temperature			°C		
11	Humidity			%		

Initial Checks at Complete Rotation

Balance ID No.:

Sr. No	Left			Right		
	Appearance	Individual Wt.	Thickness	Appearance	Individual Wt.	Thickness
		165 mg./Tab.	3.4 ± 0.2 mm		165 mg./Tab.	3.4 ± 0.2 mm
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						

13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						
21.						
22.						
23.						
24.						
25.						
26.						
27.						
28.						
29.						
30.						
31.						
32.						
33.						
34.						
35.						

In Process Control Card

Balance ID No.:

Date of Compression		Shift	I	II	III
M/C Used		Operator			
No. of punches		Punches used			
Theoretical weight of 20 Tablets		Wt. Variation limit	+/- 2% of 20T		

Time	Actual wt. of 20 tablets		Disintegration Time		Hardness		Thickness		Signature Operator	Chd. By
	3.30 gm ± 2.0%		NMT 15 min.		NLT 6Kg./cm^2		3.4 ± 0.2 mm			
	L	R	L	R	L	R	L	R		

	Pharmaceutical Guidelines **Delhi, India** **Batch Manufacturing Record**		
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Batch No.	**:** XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Check & record the weight of 20 tablets every 15 minutes.
Check & record the average hardness of 3 tablets & average thickness of 3 tablets every 30 min.
Check & record the D.T. of 6 Tablets, weight variation & friability of tablets every 2 hours.

Weight Variation Record

Machine ID No.:_____ **Balance ID No:**

Date : **Shift :** **Wt. variation Limit:** ± 7.5 % of Avg. Wt.

Wt. of 20 Tablets ⇒		g	g	g	g	g	g	g	g	g
Avg. wt. of Tab. ⇒		mg	mg	mg	mg	mg	mg	mg	mg	mg
Time ⇒ in hours										
Weight of Individual Tablets in mg. ⇓										
1.										
2.										
3.										
4.										
5.										
6.										
7.										
8.										
9.										
10.										
11.										
12.										
13.										
14.										
15.										
16.										
17.										
18.										
19.										
20.										
Max. Wt.	Allowed									
	Actual									
Min. Wt.	Allowed									
	Actual									

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Batch No.	**:** XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Friability Test									
Wt. of Tabs. Corresponding about 6.5 gm. Before Rotations									
Wt. of Tabs. After 100 Rotations									
% Loss									
Pharmacist Sign.									
Date									

Tablet Output Form

Balance ID No:

Container	Gross wt (Kg.)	Tare wt (Kg.)	Net wt (Kg.)	Sign
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

Total wt in Kg. : No of tablets :
(Actual yield)
Reworking generated: …….. Kg.

Theoretical Yield: …….. Kg. + Reworking added: …….. Kg.

Total Theoretical yield: ……..

Standard yield: 99.00 % Actual Yield: …….. Permissible yield: 98.50 - 99.50 %

Check by Pharmacist: Date :

Inspection (Core Tablets)	
De-dust and inspect the tablets for black spots, foreign particles, chipped or broken tablets. etc.	
A	Record the weight of rejected tablets i.e. black spots, foreign particles, chipped or broken tablets and put in water for destruction. Weight of tablets = …… Kg
B	Chipped and broken tablets of high and low weight, generated during compression, can be used as utilizable residue in next batches. Transfer the inspected tablets to double polyethylene bags inside in suitable airtight containers. Record the weight of inspected tablets. Weight of tablets = …… Kg Intimate Q.A to draw the sample of core tablets for analysis.

	Pharmaceutical Guidelines **Delhi, India** **Batch Manufacturing Record**		
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Batch No.	**:** XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Tablet Inspection and Rejection Record

Area clearance checked by :	Production Pharmacist – Q.A. Chemist -	Date – Date -
Date : Shift : Time - From : To : Previous product processed : B. No. No. :		
Total weight of tablets received for inspection = …… Kg.		
Inspection carried out by : Wt of tablets after inspection = …….. Kg		
Balance Used: _____		

Sr. No.	Gross Wt Kg.	Tare Wt. Kg.	Net Wt Kg.	Sr. No.	Gross Wt Kg.	Tare Wt Kg.	Net Wt Kg.
1.				5.			
2.				6.			
3.				7			
4.				8			

Total Wt: …… Kg.
A) Reusable residue: …….. Kg.
B) Rejects to be destroyed: …… Kg.
Pharmacist : Date:

Rejection & Destruction Record		
	Qty. Destroyed	Method Used
Rejection generated during tablet Compression / Inspection		
Destruction Witnessed By :	Production Pharmacist – Q.A. Chemist -	Date – Date -

Batch Reconciliation Data

Manufacturing	Compression
Date of Manufacturing:	Date of compression:
Standard Batch Size = …….. Kg.	Compression Wt. = …….. mg
Reworking added = …….. Kg.	Actual Yield (A) = …….. Kg.
Theoretical Yield = …….. Kg.	= …….. Tablets
	Reworking generated (B) = …….. Kg.
Actual Yield = …….. Kg.	Theoretical Yield (T) = …….. Kg.
= …….. %	Total Yield (A+B) = …….. Kg.
	% Yield = (A+B) / T x 100 = …….. %
Variance = …….. Kg.	Variance = …….. Kg.
Pharmacist Signature:	Pharmacist Signature
Date :	Date :

To be Filled By Quality Assurance (Uncoated Tablets)	Remarks: **Approved / Not Approved for Coating**
Appearance of the tablet:	
Average weight of the tablet : …….. mg.	
Hardness = …….. kg/cm^2	Analyst :
Disintegration time = …….. min	
Thickness = …….. mm.	Date :
Friability = …….. %	
Date of Manufacturing:	Date of Expiry :

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Batch No.	**:** XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Process Sheet (Coating)

Sr. No.	Operation	Date &Time of Operation		Operation	
		From	To	Done by	Chd.. by
	Area clearance checked by Production: Area clearance checked by QA: Previous product processed: B. No :				
11.0	**Preparation Of Coating Solution**:				
11.1	Under constant mechanical stirring disperse by sprinkling, In Isopropyl Alcohol IP..... kg. Hydroxy Propyl Methyl Cellulose IP (5 Cps)..... Kg. Then add Methylene chloride IP ..... Kg., Polyethylene Glycol 6000 IP ..... Kg. Purified Talc IP.....Kg.				
11.2	Prepare paste of, Titanium Dioxide IP ..... Kg with sufficient quantity of solution prepared at stage 10.1 Transfer this paste to solution remaining at stage 10.1 Under constant mechanical stirring. Stir for 10 minutes to get homogeneous viscous slurry. Filter the solution through 200 # nylon cloth and weigh				
12.0	**Coating** Area clearance checked by: Previous product processed: B. No: Area ID No.:				
12.1	Load the dedusted & inspected core tablets into a clean, dry S.S. coating pan.				
12.2	**ADJUST** : RPM of coating pan : 1- 5 RPM Temperature of hot air blower: 45 - 55° C. Air pressure : 2 – 4 Kg./cm^2 Peristaltic pump :15 to 35 RPM	.....RPM ..... ° C .....Kg./cm^2 ..... RPM			
12.3	Apply the film coating solution to the tablets using a clean spray gun assembly.				
12.4	After completion of coating rotate the pan for drying the tablets in pan for 10 minutes at 40°C.	Time From: To: Temp..... ^{0}C			
12.5	At the end of coating, record weight of 100 tablets. Collect the tablets in double polyethylene bags.	Wt.:.....gm.			
12.6	Intimate Q.A. Department to collect the representative sample for testing.				
12.7	Check & record net weight of coated tablet Keep the batch tightly closed with proper labels.	Wt.:.....Kg			
12.8	Before taking tablets for packing, Inspect the tablets for spotted appearance, black specs, Broken & chipped tablet. Seggregate the rejection as reusable and to be destroyed, separately & note down the wts. accordingly & store the tablets in double Polythene bags.				
12.9	Intimate Q.A. to collect the sample for Analysis & release for Packing.				

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Batch No.	**:** XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Coated Tablet Check

Appearance :		
Weight. of 100 tablets :	…… gm.	
	Standard	**Observed**
Average weight :	168 mg./ Tab ± 5.0% w/w	
Disintegration Time :	NMT 15 minutes.	
Thickness :	3.5 mm ± 0.2 mm	
Pharmacist check & Date :		

Tablet Output Form (Coated)

Balance ID No.:

Container No.	Gross wt. Kg.	Tare wt. Kg.	Net wt. Kg.	Sign.
1				
2				
3				
4				
5				
6				
7				
8				

Total wt in Kg: …… No of tablets: ……..
(Actual yield)
Theoretical Yield : …….. kg + Reworking added : …….. kg
Total Theoretical Yield: ……
Standard Yield: 99.00 % Actual Yield: …….. Permissible Yield : 98.50 to 99.50 %
Pharmacist check : Date :

Inspection (Coated Tablets)	
Inspect the tablets for black spots, foreign particles, chipped or broken tablets. etc.	
A	Record the weight of rejected tablets i.e. black spots, foreign particles, chipped or broken tablets and put in water for destruction. Weight of tablets = …… Kg
B	Chipped and broken tablets, generated during coating, can be used as utilisable residue in next batches. Transfer the inspected tablets to double polyethylene bags inside in suitable airtight containers. Record the weight of inspected tablets. Weight of tablets = …….. Kg

	Pharmaceutical Guidelines Delhi, India Batch Manufacturing Record		
Product	: Atorvastatin Tablets IP 40 mg	**B.M.R. No.**	XX/XXX/000
		B.M.R Revision No./ Date	00/ddmmyyyy
Batch Size	: 2,00,000 Tablets	**Ref. M.F.R. No**	XX/XXX/000
Batch No.	: XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Tablet Inspection and Rejection Record (Coated)

Area clearance checked by :	Production Pharmacist – Q.A. Chemist -	Date – Date -

Date : Shift : Time - From : To :
Previous product processed :
B. No. :

Total weight of tablets received for inspection = …….. Kg.

Inspection carried out by :

Wt. of tablets after inspection: ……..

Balance ID No.:

Container No.	Gross wt. Kg.	Tare wt. Kg.	Net wt. Kg.	Sign.
1				
2				
3				
4				
5				
6				
7				
8				

Total Wt: …….. Kg.

A) Reusable residue: …….. Kg. No of Tablets : ……..

B) Rejects to be destroyed: …….. Kg. No of Tablets : ……..

Pharmacist : Date:

Rejection & Destruction Record

	Qty. Destroyed	Method Used
Rejection generated during tablet Coating / Inspection		
Destruction Witnessed By :	Production Pharmacist – Q.A. Chemist -	Date – Date -

Yield Statement

Sr. No.	STAGE OF OPERATION	INPUT (KG.) A	ACTUAL WT. KG. B	PERCENTAGE (%) B/A X 100	STD. YIELD (%)	PERMISSIBLE YIELD (%)	
						LOWER	**HIGHER**
1.	Dried Granules				99.50	99.00	100.00
2.	Lubricated granules				99.50	99.00	100.00
3.	Compressed tablets				99.00	98.50	99.50
4.	Coated Tablets				99.00	98.50	99.50

Checked by Pharmacist:
Date:

Abbreviations:

SOP : Standard Operating Procedure
BMR : Batch manufacturing record
MFR : Mater Formula Record
B.No. : Batch Number
N.A. : Not Applicable
IP : Indian Pharmacopoeia
No. : Number
Wt. : Weight
Sr. : Serial
mm : millimeter
Mg : Milligrams
Kg : Kilograms
G : grams

History of Change

Sr. No.	Revision No./ Date	This Document supersedes	Reason for Change
1	00/15.05.2015	N.A.	New