BATCH NO.: undefined

BATCH MANUFACTURING RECORD

Product Name: Atorvastatin Calcium Tablets USP 20 mg

BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 1 of 108**

Product Details	
Ref. MFC No.:	MFC/ATOTI/U18-06
Product Code	ATOTIK2 (Coated)
Label claim	Each film coated tablet contains 20 mg of Atorvastatin.
Batch Size	1366650 Tablets
Shelf Life	24 Months
Manufacturing Site	Graviti Pharmaceuticals Pvt. Ltd., Isnapur.
Market / Customer Details	USA

Execution Details			
Manufacturing Date		**Expiry Date**	
Allotted By PR Sign & Date		Checked By QA Sign & Date	

Stage	Process Start Date	Process End Date
Compression		
Coating		
Inspection		

Issuance Pages	No. of Pages	Issued by (Sign & Date)
	Initial:	
	Additional:	
	Additional:	
	Total No. of Pages:	

Reviewed by (Sign & Date)		
	Production	
	Quality Assurance	

Hold Time:
Dispensed materials NMT 30 days. Coating solution NMT 24 hours. Compressed tablets NMT 15 days. Coated tablets NMT 30 days.
The maximum hold time from the date of manufacturing to the packaging should not exceed more than 60 days.

Department	**PREPARED BY**	**REVIEWED AND APPROVED BY**		**AUTHORIZED BY**
	PR	**PR**	**QA**	**Head Quality / Designee**
Name	Irfan Pasha	P. Vijay	D. Dastagiri	K. Venugopal
Designation	Assistant Manager	Asst. Manager	Asst. Manager	Manager
Sign & Date	04-JUN-24	05-JUN-24	05-JUN-24	05-JUN-24

1.0 Index

2.0 List of attachments

S. No.	Attachments	Status		Verified by (Sign & Date)		Remarks
				Production	QA	
1	Raw material dispensing tag	Attached / Not Attached	No. of tags:			
2	Product details label	Attached / Not Attached	No. of labels:			
3	In-process sample analysis report	Attached / Not Attached	No. of reports:			
4	**Others:**					

3.0 General instructions

3.1 Follow the gowning procedure.

3.2 Wear nose mask and hand gloves while handling the material / product.

3.3 Ensure the area and equipment is cleaned before start of the activity.

3.4 Previous product label, batch records, containers, materials and tools should be removed from the area.

3.5 Ensure pressure differential readings are meeting acceptable limits.

3.6 Check and ensure that all weighing balances are calibrated before use.

3.7 Check the materials for name, material codes, appearance (visual check), quantity, AR No. and expiry / retesting date (if any) etc.

3.8 Issue only approved materials.

3.9 Verify the container label before start of the activity.

3.10 Ensure that the product is labeled at all stages of manufacture.

3.11 Follow the respective "Standard Operating Procedures".

3.12 Dispense the materials in dispensing booth.

3.13 Environmental conditions: Room Temperature: 15°C - 25°C, Relative Humidity: 40 % - 60 % RH. Record the room environmental conditions at the beginning, for every two hours ± 10 min and at the end of the activity.

3.14 Store the compressed / coated tablets in HDPE container lined with double lined polyethylene bag, closed tightly.

3.15 Indent the required polyethylene bags for operational use / collection for storage of material / product.

3.16 Take Line Clearance from MQA before starting of the activity as per SOP No. QA036.

3.17 Follow Good Documentation Practices as per SOP No. QA008.

3.18 In case of any PNC's or temporary change controls shall authorize by Quality assurance.

3.19 After verification of recipe by PR personnel and MQA personnel, continue the next activity.

Note:

- ***Affix the in-process print outs and labels in blank pages.***
- ***Continue the compression operation regardless of the Certificate of Analysis (In-process) as per SOP No.: QA028.***

Hold Time:

- ***Dispensed materials hold time should not exceed more than 30 days***
- ***Lubricated blend hold time should not exceed more than 15 days.***
- ***The hold time for compressed tablets to coating should not exceed more than 15 days.***
- ***The hold time for coated tablets to packaging should not exceed more than 30 days.***
- ***Coating solution hold time should not exceed more than 24 hours.***
- ***The maximum hold time from the date of manufacturing to the packaging should not exceed more than 60 days.***

4.0 Dispensing details

4.1 Master formula

Name of the Material	Manufacturer Details	Material Code	Quantity for Batch (Kg)
OPADRY® WHITE (complete film coating system YS-1-7040)	Colorcon	05021000006	10.660 Kg*
Purified Water USP [$] (12% solids)	IH	05041000001	78.173 Kg*

*Given standard quantity of coating material includes 30% excess based on the coating efficiency and to compensate manufacturing process loss.
[$]Not present in the final product and evaporates during process.

BATCH MANUFACTURING RECORD		
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4.2 List of persons involved in the dispensing activity

S. No.	Name of Person	Employee ID	Department	Sign	S. No.	Name of Person	Employee ID	Department	Sign

4.3 Record the temperature, relative humidity and pressure differential of dispensing area

(Frequency: Temperature, relative humidity and pressure differential to be checked at the beginning, at the end of the process and for every two hours ± 10 min during dispensing.**)**

Room No.	Date	Time (Hrs)	Temperature 15°C - 25°C	Relative Humidity 40 % - 60 % RH	Pressure Differential (NLT 1.0mm of WC)	Checked by (Sign & Date)	Room No.	Date	Time (Hrs)	Temperature 15°C - 25°C	Relative Humidity 40 % - 60 % RH	Pressure Differential (NLT 1.0mm of WC)	Checked by (Sign & Date)

4.4 Weighing record

Ware House Balance ID No.: _____ **Production Balance ID No.:** _____

S. No.	Name of the ingredient	Material Code	Quantity to be dispensed (Kg)	Actual Quantity to be dispensed (Kg)	In-house batch No. /A.R. No.	UOM	Container No. (X of Y)	Tare Wt. (A)	Gross Wt. (B)	Net Wt. (B-A)	Warehouse		Production	
											Weighed by WH (Sign & Date)	Checked by PR (Sign & Date)	Gross Wt.	Verified by PR (Sign & Date)
1.	OPADRY® WHITE (complete film coating system YS-1-7040)	05021000006	10.660										Yes / No / NA	

Observed gross weight should be with in ±0.10 % of labelled gross weight or minimum readability whichever is greater. Put encircle on 'Yes' for complies; 'No' for does not complies; NA- Not applicable.

BATCH MANUFACTURING RECORD		
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5.0 Transfer of blend

5.1 **Label details:** Refer batch manufacturing record of previous stage to record below details.

Product Name: Common blend for Atorvastatin Calcium Tablets USP 10mg, 20 mg, 40 mg and 80 mg	**Batch No.:** _____	**Issued Quantity for Compression (Kg):** _____
Hold Time Valid up to (NMT 15 Days): _____	**Next Stage:** Compression	

5.2 Verify label details on container labels against the details as per in step no. 5.1.

Container No.	Label details	Container No.	Label details
	□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies
Checked by PR **Sign & Date**		**Verified by QA** **Sign & Date:**	

Put "✓" mark as applicable.

Note: If any non-compliance is observed, inform the superior immediately.

6.0 Manufacturing process

6.1 Compression process

6.1.1 List of the equipment

Name of the Equipment	Model	Capacity/Size	Manufacturer's Details	Operating Procedure*	Cleaning Procedure*	Equipment Number	Type of cleaning (A / C)
Compression machine	C300	49 Station / 61 Station	Cadmach	PR092	PR092	PRE064 / PRE084 / PRE085 / PRE192 / PRE0246 / PRE0308 PRE0333	
Combo metal detector and deduster	SS30+ – DD10 / Metal Trap SS30PH	NA	Techno four / Kambert	PR128	PR128		

***Current version shall be followed.**

Checked by PR (Sign & Date):_____ **Verified by QA (Sign & Date):**_____

6.1.2 In-process instruments

Name of the Instrument	Instrument Number	Operation SOP*	Calibration Status
Vernier caliper			□ OK / □ Not OK / □ N/A
Disintegration test apparatus			□ OK / □ Not OK
Hardness tester			□ OK / □ Not OK
Friabilator			□ OK / □ Not OK
Weighing balance			□ OK / □ Not OK

***Current version shall be followed.**

Put "✓" mark as applicable.

Checked by PR (Sign & Date):_____ **Verified by QA (Sign & Date):**_____

6.1.3 List of persons involved in the compression activity

S. No.	Name of Person	Employee ID	Department	Sign	S. No.	Name of Person	Employee ID	Department	Sign

6.1.4 Record the temperature, relative humidity and pressure differential of the compression area:

(Frequency: Temperature, relative humidity and pressure differential to be checked at the beginning, at the end of the process and for every two hours ± 10 min.**)**

Room No.	Date	Time (Hrs)	Temperature 15°C - 25°C	Relative Humidity 40 % - 60 % RH	Pressure Differential (NLT 1.0mm of WC)	Checked by (Sign & Date)		Room No.	Date	Time (Hrs)	Temperature 15°C - 25°C	Relative Humidity 40 % - 60 % RH	Pressure Differential (NLT 1.0mm of WC)	Checked by (Sign & Date)

6.1.5 Manufacturing steps

6.1.5.1 Operate the compression machine as per SOP.

6.1.5.2 Load the blend from in-process container through lifting and positioning device / manual to the hopper of the compression machine.

6.1.5.3 Set the compression machine for the specified parameters as per batch record instructions.

6.1.5.4 Connect the metal detector with dedusting to the compression machine and pass through to collect in double lined polyethylene bags in container.

6.1.5.5 During start up, collect the required number of tablets in one full rotation of the turret + additional 5 stations.

6.1.5.6 Check the tablets for description, individual tablet weight, thickness, friability, hardness, disintegration time and group weight of tablets.

6.1.5.7 Perform the startup checks by production personnel and same shall be verified by QA Personnel. After satisfactory completion of startup checks, QA personnel shall give the clearance to continue the compression activity.

6.1.5.8 If minor sticking/picking (Tiny portion is missing from tablet surface however tablet weight is well within the limit and embossing, if any, is legible) noticed during in-process checks, stop the compression machine. Record the stoppage details in BMR. Clean the corresponding punches. Restart the compression machine and perform the in-process checks to confirm that the product meets the specification.

6.1.5.9 If any change in set parameters (Machine RPM, Feeder RPM, Cylindrical Height, Compaction Force, Individual Rejection Force Limit) in HMI / PLC during compression process immediately perform in-process checks.

6.1.5.10 Next in-process check interval time shall be considered from the last in-process check.

Note: Continue the compression operation regardless of the Certificate of Analysis (In-process) as per SOP No.: QA028.

6.1.6 Tooling settings

Tooling Details	Number of Punches and Dies	Done by (Sign & Date)	Checked by (Sign & Date)	Verified by QA (Sign & Date)
Size: 10.5 X 5.5 mm	N/A			
Upper Punch: "114"				
Lower Punch: Plain				
Dies				
Size of Filling Cam:				

6.1.7 Set the desired parameters as per below

Parameter	Specification	Start Up		In-Process	
		Frequency	No. of tablets required	Frequency	No. of tablets required
Appearance	White to off white oval shaped tablet plain on one side and debossed with "114" on other side.	Initial Production	No. of stations + 5 tablets from each side	**Production:** Initial, end of the batch and every 02 hr. ± 15 minutes.	No. of stations + 5 tablets from each side
Weight of 10 tablets	2.00gm ± 4.0% (1.92 gm – 2.08 gm)		10 Tablets from each side	**Production:** Every 30 minutes ± 5 minutes and if any change in compression set parameter.	10 Tablets from each side
Thickness	3.80 mm - 4.40 mm		No. of stations + 5 tablets from each side	**Production:** Initial, end of the batch, every 02 hr. ± 15 minutes and if any change in compression set parameter.	10 Tablets for each side
Hardness	8.0 Kp - 15.0 Kp				
Uniformity of weight	200.00 mg ± 5.0 % (190 mg – 210 mg)				
Friability	NMT 1.0 % w/w		10 tablets If Individual weight is > 650 mg. Collect the sample equivalent to 6.5 gm If Individual weight is ≤ 650 mg from each side	**Production:** Initial, end of the batch, every 04 hr. ± 15 minutes and if any change in compression set parameter.	10 tablets If Individual weight of tablet is > 650 mg. Collect the sample equivalent to 6.5 gm if individual weight is ≤ 650mg.
Disintegration Time	NMT 15 minutes		06 tablets from each side		06 tablets from each side

Recipe Checked by PR (Sign & Date): _____ **Recipe Verified by QA (Sign & Date):** _____

6.1.8 Setting up of the metal detector

- Connect the tablet-de dusting machine with metal detector to the compression machine in such a way that all compressed tablets are passed through the tablet-de dusting machine with metal detector before being collected in double polyethylene bag lined container.
- Set and check the metal detector functioning using standard blocks.
- **Metal detector check during at start of the batch / shift, at the end of the batch, after any major break down if any, power failure and machine stoppage. (Refer SOP No.: QA027).**
- Acceptance Criteria: Ferrous, Stainless steel & Non-Ferrous shall be detected & rejected. Neutral block shall not be detected.
- In metal detector results write as Pass or Fail. (Record results as Pass if Ferrous, Stainless steel, Non-Ferrous test pieces collected in the rejection box and Neutral block test piece not collected in the rejection box, otherwise recorded as Fail).

Date:														
Time:														
Metal Detector Check	**Pass / Fail**		**Pass / Fail**		**Pass / Fail**		**Pass / Fail**		**Pass / Fail**		**Pass / Fail**		**Pass / Fail**	
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
Ferrous block														
Stainless Steel block														
Non-Ferrous block														
Neutral block														
Performed by PR (Sign & Date)														
Verified by QA (Sign & Date)														

6.1.9 Machine setting: (Start Up)

Step No.	Process	Equipment No.	Date	Start Time	Finish Time	Done by (Sign & Date)
6.1.9.1	Operate the compression machine as per SOP					
6.1.9.2	Set the compression machine as per the listed parameters and perform the startup checks by PR personnel and same shall be verified by QA personnel.					
6.1.9.3	After setting of the machine, collect the required number of tablets and perform checks as per section 6.1.7. Record the startup rejects in following table.					

Container No.	Gross wt. (Kg)	Tare wt. (Kg)	Net wt. (Kg)
		Total Net Wt. (Kg):	

Checked by (Sign & Date): _____ **Verified by (Sign & Date):** _____

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 20 of 108**

Date & Sampling Time		
Side	**RHS**	**LHS**
Appearance: White to off white oval shaped tablet plain on one side and debossed with "114" on other side.	Complies / Not complies	

Physical Inspection of Compressed Tablets: Note: Write number of defective tablets identified in the respective column/row. If a tablet is found to have one or more nonconformities of same categories, then the unit shall be counted as one nonconforming unit.

Category	**Type of defects observed (For Categorization of defects, refer the SOP No.: QA032)**		
Critical*			
Major#			
Minor#			
Others (if any specify)			
Total defects			
Done by (Sign & Date):		**Verified by QA (Sign & Date):**	

*If critical defective tablets observed raise PNC and investigate as per SOP No.: QA046.

If any major and minor defective tablets observed, take necessary actions and continue the activity.

BATCH NO.: undefined

BATCH MANUFACTURING RECORD

Product Name: Atorvastatin Calcium Tablets USP 20 mg

BMR No.: CBMR/ATOTIK2/01-08 | **Effective Date:** 05 JUN 2024 | **Page 21 of 108**

Weight of 10 tablets: (1.92 gm – 2.08 gm) _____ (RHS), _____(LHS) **Print outs attachment: Yes □ / No □**

S.No.	Individual weight (mg) Limit: 190 – 210		Thickness (mm) Limit: 3.80 – 4.40		Hardness (Kp) Limit: 8.0 – 15.0		S.No.	Individual weight (mg) Limit: 190 – 210		Thickness (mm) Limit: 3.80 – 4.40		Hardness (Kp) Limit: 8.0 – 15.0		S.No.	Individual weight (mg) Limit: 190 – 210		Thickness (mm) Limit: 3.80 – 4.40		Hardness (Kp) Limit: 8.0 – 15.0	
	RHS	LHS	RHS	LHS	RHS	LHS		RHS	LHS	RHS	LHS	RHS	LHS		RHS	LHS	RHS	LHS	RHS	LHS	
Affix the in-process print outs																					
1							23							45							
2							24							46							
3							25							47							
4							26							48							
5							27							49							
6							28							50							
7							29							51							
8							30							52							
9							31							53							
10							32							54							
11							33							55							
12							34							56							
13							35							57							
14							36							58							
15							37							59							
16							38							60							
17							39							61							
18							40							62							
19							41							63							
20							42							64							
21							43							65							
22							44							66							

Done by (Sign & Date):	**Verified by QA (Sign & Date):**

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
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Date & Sampling Time		Friability (%) = (W1-W2) X 100 / W1 (Limit: NMT 1.0 % w/w)			Disintegration time (Limit: NMT 15 Min)	Done by (Sign & Date)	Verified by QA (Sign & Date)
		Initial (W1) (gm)	Final (W2) (gm)	% Friability=$\frac{W1-W2X100}{W1}$			
RHS							
LHS							

Affix the in-process print outs

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
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Date & Sampling Time		
Side	**RHS**	**LHS**
Appearance: White to off white oval shaped tablet plain on one side and debossed with "114" on other side.	Complies / Not complies	

Physical Inspection of Compressed Tablets: Note: Write number of defective tablets identified in the respective column/row. If a tablet is found to have one or more nonconformities of same categories, then the unit shall be counted as one nonconforming unit.

Category	**Type of defects observed (For Categorization of defects, refer the SOP No.: QA032)**		
Critical*			
Major#			
Minor#			
Others (if any specify)			
Total defects			

Done by (Sign & Date):	**Verified by QA (Sign & Date):**

*If critical defective tablets observed raise PNC and investigate as per SOP No.: QA046.

If any major and minor defective tablets observed, take necessary actions and continue the activity.

] BATCH NO.: undefined

BATCH MANUFACTURING RECORD

Product Name: Atorvastatin Calcium Tablets USP 20 mg

BMR No.: CBMR/ATOTIK2/01-08 | **Effective Date:** 05 JUN 2024 | **Page 24 of 108**

Weight of 10 tablets: (1.92 gm – 2.08 gm) _____ (RHS), _____(LHS) **Print outs attachment: Yes □ / No □**

S.No.	Individual weight (mg) Limit: 190 – 210		Thickness (mm) Limit: 3.80 – 4.40		Hardness (Kp) Limit: 8.0 – 15.0		S.No.	Individual weight (mg) Limit: 190 – 210		Thickness (mm) Limit: 3.80 – 4.40		Hardness (Kp) Limit: 8.0 – 15.0		S.No.	Individual weight (mg) Limit: 190 – 210		Thickness (mm) Limit: 3.80 – 4.40		Hardness (Kp) Limit: 8.0 – 15.0	
	RHS	LHS	RHS	LHS	RHS	LHS		RHS	LHS	RHS	LHS	RHS	LHS		RHS	LHS	RHS	LHS	RHS	LHS	
Affix the in-process print outs																					
1							23							45							
2							24							46							
3							25							47							
4							26							48							
5							27							49							
6							28							50							
7							29							51							
8							30							52							
9							31							53							
10							32							54							
11							33							55							
12							34							56							
13							35							57							
14							36							58							
15							37							59							
16							38							60							
17							39							61							
18							40							62							
19							41							63							
20							42							64							
21							43							65							
22							44							66							

Done by
(Sign & Date):

Verified by QA
(Sign & Date):

BATCH NO.: undefined

BATCH MANUFACTURING RECORD			
Product Name: Atorvastatin Calcium Tablets USP 20 mg			
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Date & Sampling Time		Friability (%) = (W1-W2) X 100 / W1 (Limit: NMT 1.0 % w/w)			Disintegration time (Limit: NMT 15 Min)	Done by (Sign & Date)	Verified by QA (Sign & Date)
		Initial (W1) (gm)	Final (W2) (gm)	% Friability=$\frac{W1-W2}{W1}$X100			
RHS							
LHS							

Affix the in-process print outs

BATCH NO.: undefined

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Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 26 of 108**

Date & Sampling Time		
Side	**RHS**	**LHS**
Appearance: White to off white oval shaped tablet plain on one side and debossed with "114" on other side.	Complies / Not complies	

Physical Inspection of Compressed Tablets: Note: Write number of defective tablets identified in the respective column/row. If a tablet is found to have one or more nonconformities of same categories, then the unit shall be counted as one nonconforming unit.

Category	**Type of defects observed (For Categorization of defects, refer the SOP No.: QA032)**		
Critical*			
Major#			
Minor#			
Others (if any specify)			
Total defects			
Done by (Sign & Date):		**Verified by QA (Sign & Date):**	

*If critical defective tablets observed raise PNC and investigate as per SOP No.: QA046.

If any major and minor defective tablets observed, take necessary actions and continue the activity.

BATCH NO.: undefined

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Product Name: Atorvastatin Calcium Tablets USP 20 mg

BMR No.: CBMR/ATOTIK2/01-08 | **Effective Date:** 05 JUN 2024 | **Page 27 of 108**

Weight of 10 tablets: (1.92 gm – 2.08 gm) _____ (RHS), _____(LHS) **Print outs attachment: Yes □ / No □**

S.No.	Individual weight (mg) Limit: 190 – 210		Thickness (mm) Limit: 3.80 – 4.40		Hardness (Kp) Limit: 8.0 – 15.0		S.No.	Individual weight (mg) Limit: 190 – 210		Thickness (mm) Limit: 3.80 – 4.40		Hardness (Kp) Limit: 8.0 – 15.0		S.No.	Individual weight (mg) Limit: 190 – 210		Thickness (mm) Limit: 3.80 – 4.40		Hardness (Kp) Limit: 8.0 – 15.0	
	RHS	LHS	RHS	LHS	RHS	LHS		RHS	LHS	RHS	LHS	RHS	LHS		RHS	LHS	RHS	LHS	RHS	LHS
Affix the in-process print outs																					
1							23							45							
2							24							46							
3							25							47							
4							26							48							
5							27							49							
6							28							50							
7							29							51							
8							30							52							
9							31							53							
10							32							54							
11							33							55							
12							34							56							
13							35							57							
14							36							58							
15							37							59							
16							38							60							
17							39							61							
18							40							62							
19							41							63							
20							42							64							
21							43							65							
22							44							66							

Done by
(Sign & Date):

Verified by QA
(Sign & Date):

BATCH NO.: undefined

BATCH MANUFACTURING RECORD							
Product Name: Atorvastatin Calcium Tablets USP 20 mg							
BMR No.: CBMR/ATOTIK2/01-08				**Effective Date:** 05 JUN 2024			**Page 28 of 108**

Date & Sampling Time		Friability (%) = (W1-W2) X 100 / W1 (Limit: NMT 1.0 % w/w)			Disintegration time (Limit: NMT 15 Min)	Done by (Sign & Date)	Verified by QA (Sign & Date)
		Initial (W1) (gm)	Final (W2) (gm)	% Friability=$\frac{W1-W2X100}{W1}$			
RHS							
LHS							

Affix the in-process print outs

6.1.9.4 **Challenge test**

Start of the batch

Is this the first batch after Type 'C'. □ **Yes** / □ **No.**

- If Yes, perform challenge test.
- If No, no need to perform challenge test.

Test	Frequency	Results	Observation	Done by (Sign & Date)	Checked by (Sign & Date)	Verified by QA (Sign & Date)
Record actual fill depth **RHS**_____**mm, LHS**_____**mm** after achieving thickness, hardness & weight.						
Increase compaction force by increasing the fill depth (by increasing the set fill depth)	**Start of the batch** Date & Time:	The Tablets shall be rejected by the machine	**Rejected** Yes / No			
Decrease compaction force by decreasing the fill depth (by decreasing the set fill depth)			**Rejected** Yes / No			
Restart the machine after stoppage		Two rounds tablets shall be rejected	**Rejected** Yes / No			

6.1.10 Start the compression machine if pre-start checks found satisfactory and perform the in-process checks as per sop "in-process checks during manufacturing and packing" (SOP No. QA027*). ***Current version shall be followed**

6.1.11 Compression process activity

Note: Record the stoppage details, which are not reflecting in machine soft data (Alarm report), in following table.

Examples for stoppage details (to be recorded in BMR): Bio break, meals break, Meetings etc. Also record all the stoppages attributed to the generation of defective product (Sticking, picking, capping, broken tablets, OOS tablet noticed during in-process checks, etc).

Date	Machine Speed (RPM) Limit: 15 – 45	Operation Time		Done by (Sign & Date)	Checked by (Sign & Date)	Stoppage Details			Done by (Sign & Date)	Checked by (Sign & Date)
		From	To			From	To	Reason for stoppage		

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 31 of 108**

Date	Machine Speed (RPM) Limit: 15 – 45	Operation Time		Done by (Sign & Date)	Checked by (Sign & Date)	Stoppage Details			Done by (Sign & Date)	Checked by (Sign & Date)
		From	To			From	To	Reason for stoppage		

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 32 of 108**

INPROCESS CHECKS RECORD

For below parameters, the in-process checks shall be performed as: Initial, every 30 min ± 5min and end of the batch and if any change in compression set parameter by PR

Date & Sampling Time								
Machine Speed RPM: 15 – 45								
	Affix the in-process print out		***Affix the in-process print out***		***Affix the in-process print out***		***Affix the in-process print out***	
Side	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
Container No.								
Weight of 10 tablets 2.00 gm ± 4.0% (1.92 gm – 2.08 gm)								
Average weight 200 mg ± 4.0% (192 mg – 208 mg)								
Done by (Sign & Date)								
Verified by QA (Sign & Date)								

] BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 33 of 108**

INPROCESS CHECKS RECORD

For below parameters, the in-process checks shall be performed as: Initial, every 30 min ± 5min and end of the batch and if any change in compression set parameter by PR

Date & Sampling Time								
Machine Speed RPM: 15 – 45								
	Affix the in-process print out		***Affix the in-process print out***		***Affix the in-process print out***		***Affix the in-process print out***	
Side	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
Container No.								
Weight of 10 tablets 2.00 gm ± 4.0% (1.92 gm – 2.08 gm)								
Average weight 200 mg ± 4.0% (192 mg – 208 mg)								
Done by (Sign & Date)								
Verified by QA (Sign & Date)								

] **BATCH NO.:** undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 34 of 108**

INPROCESS CHECKS RECORD

For below parameters, the in-process checks shall be performed as: Initial, every 30 min ± 5min and end of the batch and if any change in compression set parameter by PR

Date & Sampling Time								
Machine Speed RPM: 15 – 45								
	Affix the in-process print out		***Affix the in-process print out***		***Affix the in-process print out***		***Affix the in-process print out***	
Side	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
Container No.								
Weight of 10 tablets 2.00 gm ± 4.0% (1.92 gm – 2.08 gm)								
Average weight 200 mg ± 4.0% (192 mg – 208 mg)								
Done by (Sign & Date)								
Verified by QA (Sign & Date)								

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 35 of 108**

INPROCESS CHECKS RECORD

For below parameters, the in-process checks shall be performed as: Initial, every 30 min ± 5min and end of the batch and if any change in compression set parameter by PR

Date & Sampling Time								
Machine Speed RPM: 15 – 45								
	Affix the in-process print out		***Affix the in-process print out***		***Affix the in-process print out***		***Affix the in-process print out***	
Side	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
Container No.								
Weight of 10 tablets 2.00 gm ± 4.0% (1.92 gm – 2.08 gm)								
Average weight 200 mg ± 4.0% (192 mg – 208 mg)								
Done by (Sign & Date)								
Verified by QA (Sign & Date)								

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 36 of 108**

INPROCESS CHECKS RECORD

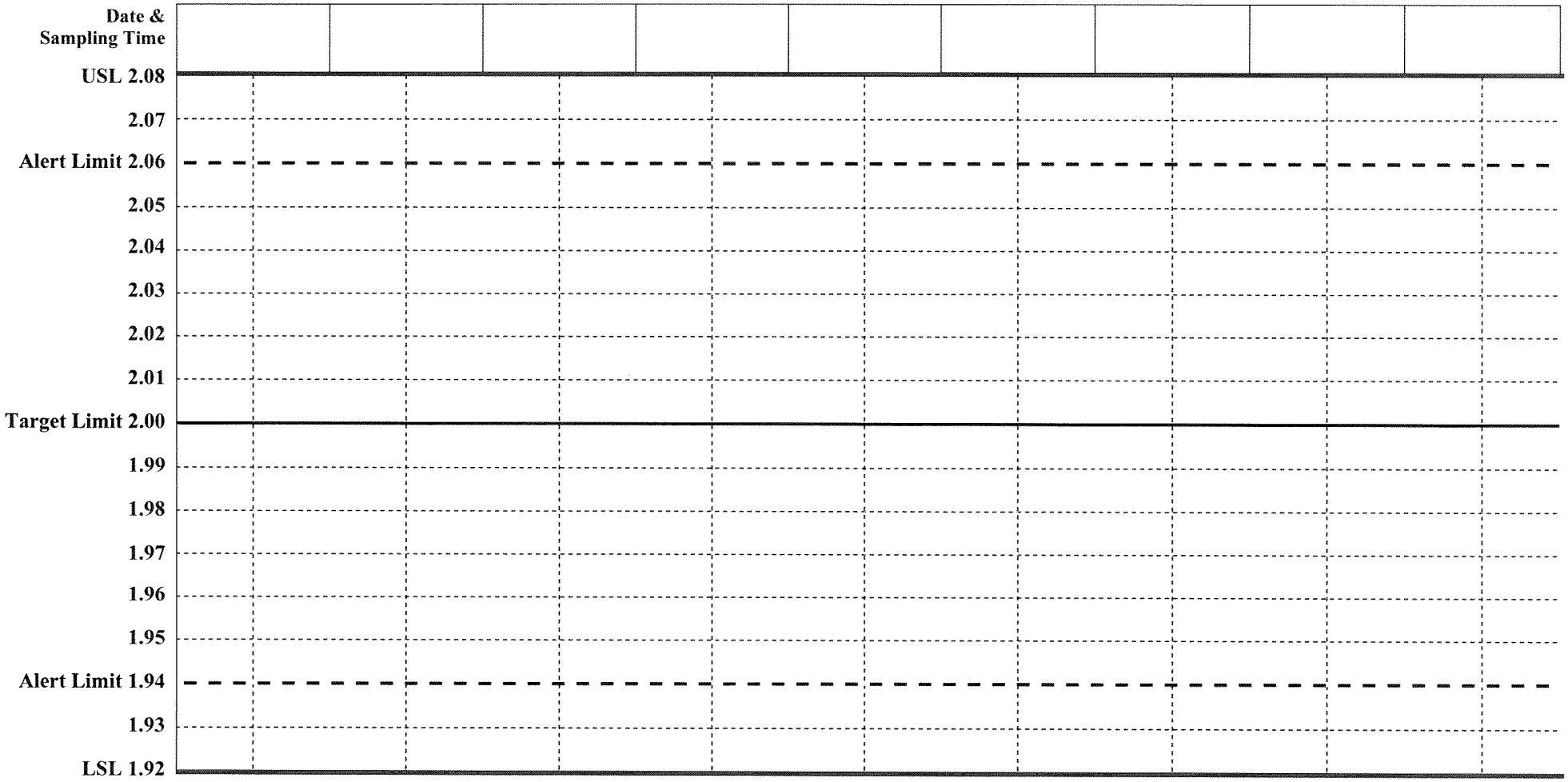
For below parameters, the in-process checks shall be performed as: Initial, every 30 min ± 5min and end of the batch and if any change in compression set parameter by PR

Date & Sampling Time								
Machine Speed RPM: 15 – 45								
	Affix the in-process print out		***Affix the in-process print out***		***Affix the in-process print out***		***Affix the in-process print out***	
Side	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
Container No.								
Weight of 10 tablets 2.00 gm ± 4.0% (1.92 gm – 2.08 gm)								
Average weight 200 mg ± 4.0% (192 mg – 208 mg)								
Done by (Sign & Date)								
Verified by QA (Sign & Date)								

] BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 37 of 108**

AVERAGE WEIGHT CHART

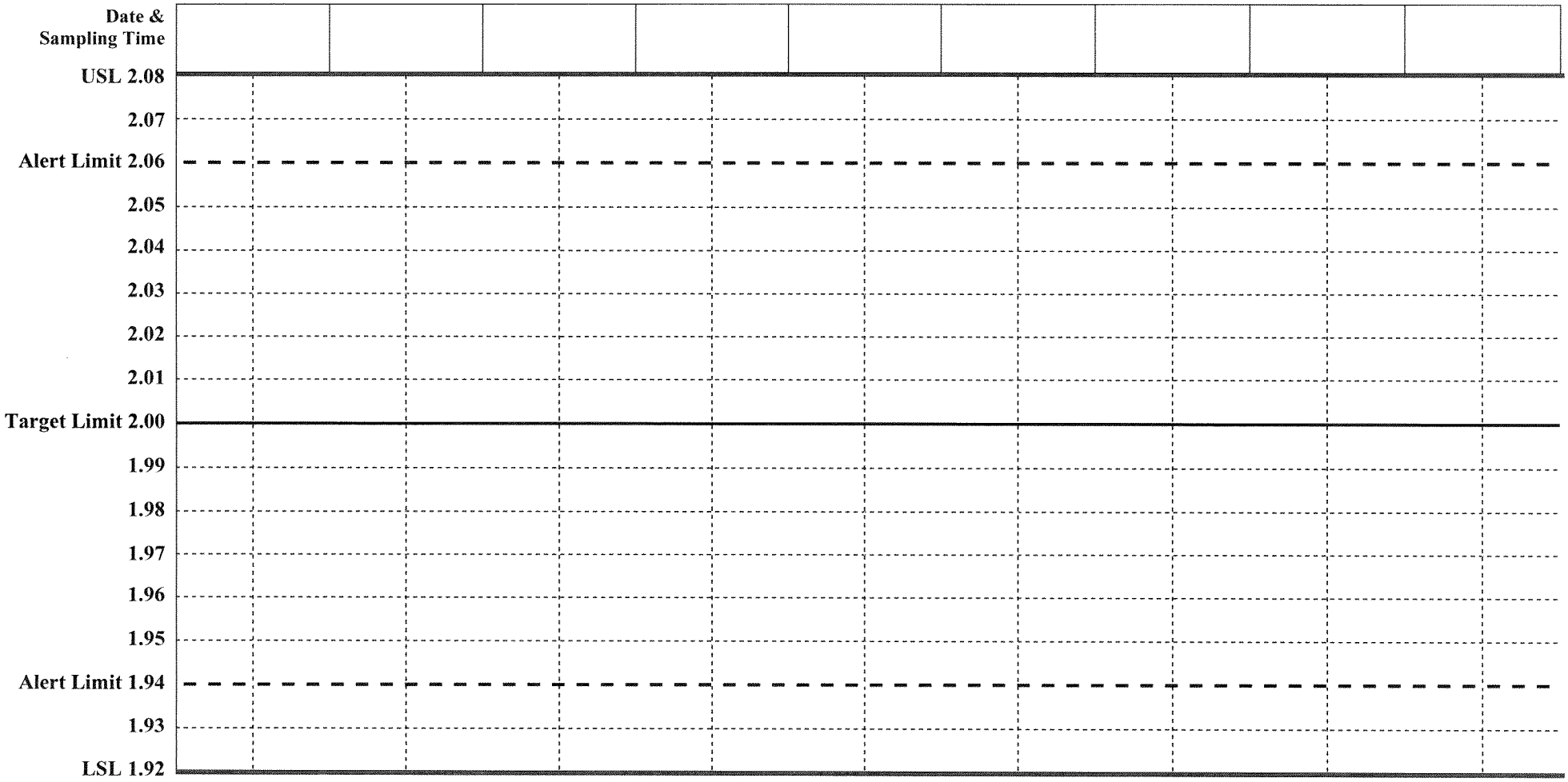


R.H.S: * ------ & L.H.S: ● ——

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 38 of 108**

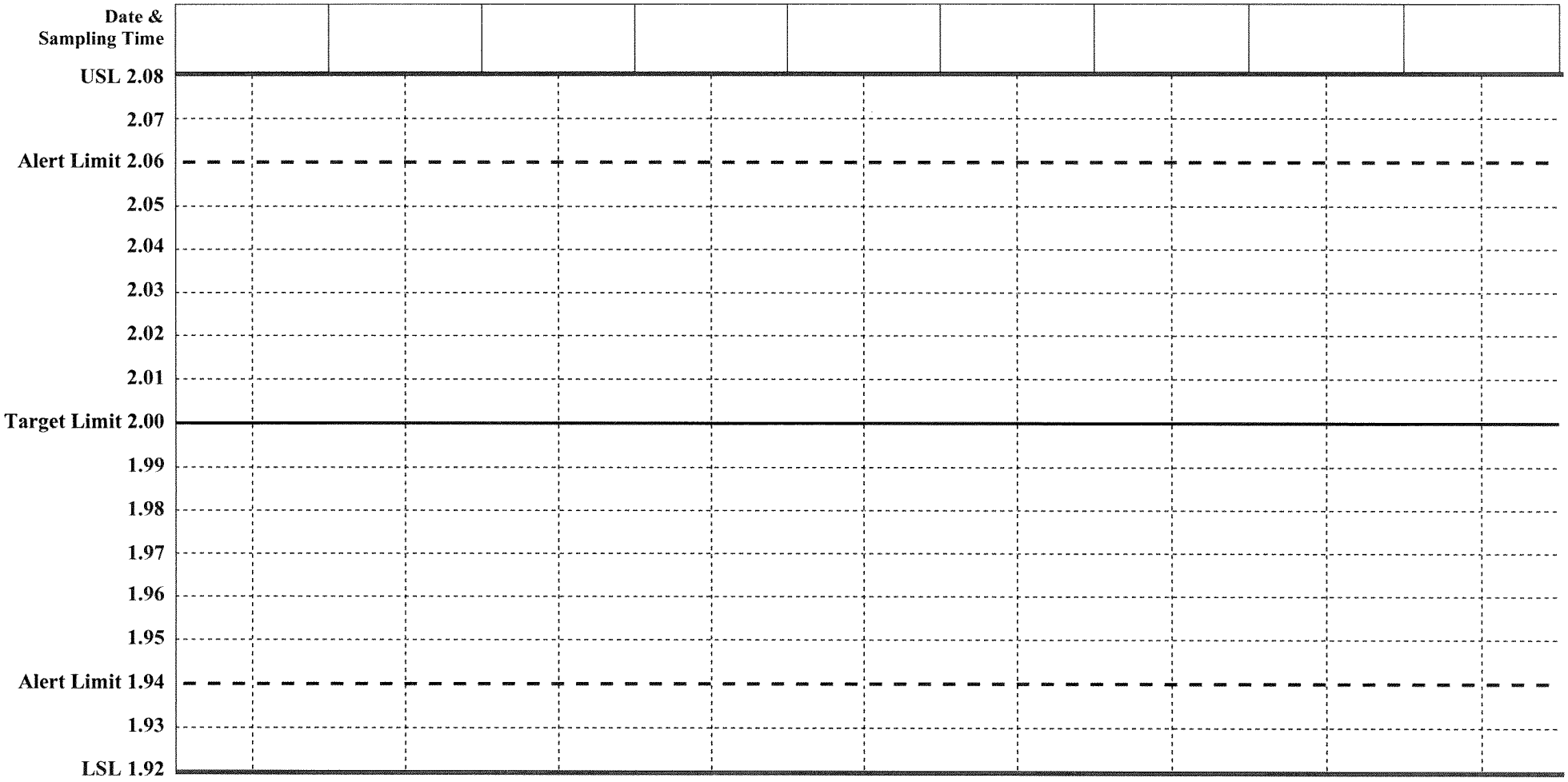
AVERAGE WEIGHT CHART



R.H.S: * ------ & L.H.S: ● ——

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 39 of 108**

AVERAGE WEIGHT CHART



R.H.S: * ------ & L.H.S: ● ——

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 40 of 108**

INPROCESS CHECKS RECORD

For below parameters, the in-process checks shall be performed as: Initial, end of the batch and every 2 hr. ± 15min by PR

Date & Sampling Time												
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
Container No.												
Appearance: White to off white oval shaped tablet plain on one side and debossed with "114" on other side.	Complies / Not complies		Complies / Not complies		Complies / Not complies		Complies / Not complies		Complies / Not complies		Complies / Not complies	
Physical Inspection of Compressed Tablets Note: Write number of defective tablets identified in the respective column/row. If a tablet is found to have one or more nonconformities of same categories, then the unit shall be counted as one nonconforming unit.												
Category	**Type of defects observed (For Categorization of defects, refer the SOP QA032)**											
Critical*												
Major#												
Minor#												
Others (if any specify)												
Total defects												
Done by (Sign & Date)												
Verified by QA (Sign & Date)												

*If critical defective tablets observed raise PNC and investigate as per SOP No.: QA046. # If any major and minor defective tablets observed, take necessary actions and continue the activity.

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 41 of 108**

INPROCESS CHECKS RECORD

For below parameters, the in-process checks shall be performed as: Initial, end of the batch and every 2 hr. ± 15min by PR

Date & Sampling Time												
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
Container No.												
Appearance: White to off white oval shaped tablet plain on one side and debossed with "114" on other side.	Complies / Not complies		Complies / Not complies		Complies / Not complies		Complies / Not complies		Complies / Not complies		Complies / Not complies	
Physical Inspection of Compressed Tablets Note: Write number of defective tablets identified in the respective column/row. If a tablet is found to have one or more nonconformities of same categories, then the unit shall be counted as one nonconforming unit.												
Category	**Type of defects observed (For Categorization of defects, refer the SOP QA032)**											
Critical*												
Major#												
Minor#												
Others (if any specify)												
Total defects												
Done by (Sign & Date)												
Verified by QA (Sign & Date)												

*If critical defective tablets observed raise PNC and investigate as per SOP No.: QA046. # If any major and minor defective tablets observed, take necessary actions and continue the activity.

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 42 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 2 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time:					**Print outs attachment: Yes □ / No □**	
Tablets No.	**Individual weight (mg) Limit: 190 – 210**		**Thickness (mm) Limit: 3.80 – 4.40**		**Hardness (Kp) Limit: 8.0 – 15.0**	
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
	Affix the in-process print out		*Affix the in-process print out*			
1						
2						
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7						
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10						
Min.						
Max.						
Done by (Sign & Date):						
Verified by QA (Sign & Date):						

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 43 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 2 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time:					**Print outs attachment: Yes □ / No □**	
Tablets No.	**Individual weight (mg) Limit: 190 – 210**		**Thickness (mm) Limit: 3.80 – 4.40**		**Hardness (Kp) Limit: 8.0 – 15.0**	
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
	Affix the in-process print out		***Affix the in-process print out***			
1						
2						
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6						
7						
8						
9						
10						
Min.						
Max.						
Done by (Sign & Date):						
Verified by QA (Sign & Date):						

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 44 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 2 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time:					**Print outs attachment: Yes □ / No □**	
Tablets No.	**Individual weight (mg) Limit: 190 – 210**		**Thickness (mm) Limit: 3.80 – 4.40**		**Hardness (Kp) Limit: 8.0 – 15.0**	
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
	Affix the in-process print out		***Affix the in-process print out***			
1						
2						
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5						
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7						
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9						
10						
Min.						
Max.						
Done by (Sign & Date):						
Verified by QA (Sign & Date):						

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 45 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 2 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time:					**Print outs attachment: Yes □ / No □**	
Tablets No.	**Individual weight (mg) Limit: 190 – 210**		**Thickness (mm) Limit: 3.80 – 4.40**		**Hardness (Kp) Limit: 8.0 – 15.0**	
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
	Affix the in-process print out		***Affix the in-process print out***			
1						
2						
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6						
7						
8						
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10						
Min.						
Max.						
Done by (Sign & Date):						
Verified by QA (Sign & Date):						

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 46 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 2 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time:					**Print outs attachment: Yes □ / No □**	
Tablets No.	**Individual weight (mg) Limit: 190 – 210**		**Thickness (mm) Limit: 3.80 – 4.40**		**Hardness (Kp) Limit: 8.0 – 15.0**	
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
	Affix the in-process print out		***Affix the in-process print out***			
1						
2						
3						
4						
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6						
7						
8						
9						
10						
Min.						
Max.						
Done by (Sign & Date):						
Verified by QA (Sign & Date):						

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 47 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 2 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time:					**Print outs attachment: Yes □ / No □**	
Tablets No.	**Individual weight (mg) Limit: 190 – 210**		**Thickness (mm) Limit: 3.80 – 4.40**		**Hardness (Kp) Limit: 8.0 – 15.0**	
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
	Affix the in-process print out		***Affix the in-process print out***			
1						
2						
3						
4						
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6						
7						
8						
9						
10						
Min.						
Max.						
Done by (Sign & Date):						
Verified by QA (Sign & Date):						

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 48 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 2 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time:						
					Print outs attachment: Yes □ / No □	
Tablets No.	**Individual weight (mg) Limit: 190 – 210**		**Thickness (mm) Limit: 3.80 – 4.40**		**Hardness (Kp) Limit: 8.0 – 15.0**	
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
	Affix the in-process print out		***Affix the in-process print out***			
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
Min.						
Max.						
Done by (Sign & Date):						
Verified by QA (Sign & Date):						

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 49 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 2 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time:						**Print outs attachment: Yes □ / No □**
Tablets No.	**Individual weight (mg) Limit: 190 – 210**		**Thickness (mm) Limit: 3.80 – 4.40**		**Hardness (Kp) Limit: 8.0 – 15.0**	
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
	Affix the in-process print out		***Affix the in-process print out***			
1						
2						
3						
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7						
8						
9						
10						
Min.						
Max.						
Done by (Sign & Date):						
Verified by QA (Sign & Date):						

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 50 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 2 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time:					**Print outs attachment: Yes □ / No □**	
Tablets No.	**Individual weight (mg) Limit: 190 – 210**		**Thickness (mm) Limit: 3.80 – 4.40**		**Hardness (Kp) Limit: 8.0 – 15.0**	
	RHS	**LHS**	**RHS**	**LHS**	**RHS**	**LHS**
	Affix the in-process print out		***Affix the in-process print out***			
1						
2						
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6						
7						
8						
9						
10						
Min.						
Max.						
Done by (Sign & Date):						
Verified by QA (Sign & Date):						

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 51 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 2 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time: **Print outs attachment: Yes □ / No □**

Tablets No.	Individual weight (mg) Limit: 190 – 210		Thickness (mm) Limit: 3.80 – 4.40		Hardness (Kp) Limit: 8.0 – 15.0	
	RHS	LHS	RHS	LHS	RHS	LHS
	Affix the in-process print out		*Affix the in-process print out*			
1						
2						
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8						
9						
10						
Min.						
Max.						

Done by (Sign & Date):

Verified by QA (Sign & Date):

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 52 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 4 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time		Friability (%) = (W1-W2) X 100 /W1 (Limit: NMT 1.0 % w/w)			Disintegration time (Limit: NMT 15 Minutes)	Done by (Sign & Date)	Verified by QA (Sign & Date)
		Initial (W1) (gm)	Final (W2) (gm)	% Friability=$\frac{W1-W2}{W1}$X100			
RHS							
LHS							
RHS							
LHS							
RHS							
LHS							
RHS							
LHS							
RHS							
LHS							
RHS							
LHS							

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 53 of 108**

INPROCESS CHECKS RECORD

For below parameters the in-process checks shall be performed as: Initial, end of the batch, every 4 hr. ± 15min and if any change in compression set parameter by PR

Date & Sampling Time		Friability (%) = (W1-W2) X 100 /W1 (Limit: NMT 1.0 % w/w)			Disintegration time (Limit: NMT 15 Minutes)	Done by (Sign & Date)	Verified by QA (Sign & Date)
		Initial (W1) (gm)	Final (W2) (gm)	% Friability=$\frac{W1-W2}{W1}$X100			
RHS							
LHS							
RHS							
LHS							
RHS							
LHS							
RHS							
LHS							
RHS							
LHS							
RHS							
LHS							

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 54 of 108**

Affix the in-process print out

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 55 of 108**

Affix the in-process print out

6.1.12 Repass the collected tablets from metal detector

• Repass the rejected tablets through the metal detector at slow speed. • If any tablets rejected from metal detector on second time, dissolve the tablet in water and inspect for any metal particle. If metal particle found batch shall be kept under hold, raise PNC and action shall be taken based on outcome of the investigation.	**Equipment No.**		
	No. of tablets collected from Metal detector		
	Start (Date & Time)		
	End (Date & Time)		
	No. of tablets rejected from Metal detector on second time		
	No. of tablets found with metal particle after dissolved in water		
	Done by (Sign & Date)		
	Checked by PR (Sign & Date)		
	Verified by QA (Sign & Date)		

6.1.13 Record the weight of the compressed tablets in double lined polyethylene bag in HDPE container. Close the HDPE Container(s) properly.

Balance ID: _____

Container No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Container No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Container No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)
								Total Net Wt. (Kg)			
Weighed by (Sign & Date):				**Checked by (Sign & Date):**				**Verified by QA (Sign & Date):**			

6.1.14 Collect the uncompressed blend left at feeders and hopper at the end of compression, in-process rejects and others (Specify if any). Weigh and label as rejects.

Container No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Weighed by (Sign & Date)	Checked by (Sign & Date)	Verified by QA (Sign & Date)
Total Net Wt. (Kg)						

6.1.15 Yield & reconciliation (Compression)

A	Theoretical batch size		:	Kg	Theoretical batch size (Units):	**Tablets**
B	Actual batch size (Blend)		:	Kg	Actual batch size (Units):	**Tablets**
C	Average wt. of compressed tablets (mg)		:	**Avg.Wt.** = $\frac{\text{Sum of Wt. of 10 Tablets at all intervals } X1000}{\text{Number of intervals } X10}$ =		
D	Actual yield		:	Kg	Actual Yield (Units):	
E	Startup rejects		:	Kg		
F	Sample for analysis	Hold time study	:	Kg	Units:	
		Validation	:	Kg	Units:	
		Other	:	Kg	Units:	
G	Left over blend		:	Kg	Units:	
H	Sample for in-process checks		:	Kg	Units:	
I	Other rejects		:	Kg	Units:	
J	Yield (%) = (D÷A) × 100 (Limit: NLT 96 %)		:			
K	Reconciliation {(D+E+F+G+H+I) ÷ B} ×100 (Limit: 99.0% - 100.5%)		:			
L	Unaccountable loss (If any)		:			

Checked by PR: **(Sign & Date)**	**Verified by QA:** **(Sign & Date)**

6.2 Coating process

6.2.1 List of the equipment

Name of the Equipment / Instrument	Model	Capacity / Size	Manufacturer's Details	Operating Procedure*	Cleaning Procedure*	Equipment Number	Type of cleaning (A / C)
Coating machine	BLC-120	71-312 Kg	Bectochem Loedige	PR093	PR093	PRE065	
	SC 700	120 - 450 Kg	ACG	PR103	PR103	PRE083 / PRE128 / PRE0241	
Solution preparation vessel	SPV-150 / GMP / SPV-300 / MV-500 / SPV-500 / TAP-SPV-250 / VG-SPV-500 FLP / GAC1700	150 L / 300 L / 500 L / 250 L	Bectochem / Pharmatech / Tapasya / Varco / Gansons	PR111 / PR086	PR111 / PR086		
Vernier calipers							
Weighing balance							

*Current version shall be followed.

Checked by PR (Sign & Date):_____ **Verified by QA (Sign & Date):**_____

IR Gun ID No.: _____ **Calibration Status: Ok / Not Ok**

Checked by PR (Sign & Date):_____ **Verified by QA (Sign & Date):**_____

6.2.2 List of persons involved in the coating activity

S. No.	Name of Person	Employee ID	Department	Sign	S. No.	Name of Person	Employee ID	Department	Sign

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 62 of 108**

6.2.3 Record the temperature, relative humidity and pressure differential of coating area

(Frequency: Temperature, relative humidity and pressure differential to be checked at the beginning, at the end of the process and for every two hours ±10 min during coating**)**

Room No.	Date	Time (Hrs)	Temperature 15°C - 25°C	Relative Humidity 40 % - 60 % RH	Pressure Differential (NLT 1.0mm of WC)	Checked by (Sign & Date)	Room No.	Date	Time (Hrs)	Temperature 15°C - 25°C	Relative Humidity 40 % - 60 % RH	Pressure Differential (NLT 1.0mm of WC)	Checked by (Sign & Date)

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 63 of 108**

6.2.4 Transfer of compression tablets

6.2.4.1 **Label details:** Refer batch manufacturing record of previous stage to record below details.

Product Name: Atorvastatin Calcium Tablets USP 20 mg	**Batch No.:** ___________	**Issued Quantity for Coating (Kg):** ________
Hold Time Valid up to (NMT 15 days): ___________	**Next Stage:** Coating	

6.2.4.2 Verify label details on container labels against the details as per in step no. 6.2.4.1.

Container No.	Label details	Container No.	Label details	Container No.	Label details	Container No.	Label details
	□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies
	□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies		□ Complies / □ Not complies
Checked by PR: **Sign & Date**				**Verified by QA:** **Sign & Date**			

Put "✓" mark as applicable. Note: If any non-compliance is observed, inform the superior immediately.

6.2.5 Coating suspension preparation

6.2.5.1 Collect the 78.173 Kg purified water in tared SS vessel and record in following table. **Balance ID:** _____

Purified Water AR No.	**Container No.**								
	Tare Weight (Kg)								
	Gross Weight (Kg)								
	Net Weight (Kg)								
	Total Net Weight (Kg):								

Coating suspension preparation			
6.2.5.2	• Take 78.173 Kg Kg of purified water in a SS vessel and add 10.660 Kg of OPADRY® WHITE (complete film coating system YS-1-7040) to purified water while stirring with suitable overhead stirrer. • After addition is completed reduce the speed of the stirrer and let the dispersion get stirred gently for at least 45 minutes till uniform dispersion is obtained.	**Equipment No.**	
		Start (Date & Time)	
		End (Date & Time)	
		Done by (Sign & Date)	
		Checked by (Sign & Date)	
		Verified by QA (Sign & Date)	

6.2.6 Coating instructions

- Operate the coating machine as per SOP and set the coating machine with the given parameters.
- Load the core tablets into the coating pan and inch intermittently for one minute to remove any dust.
- Check the spray rate for each individual gun at different peristaltic pump RPMs and record.
- Product temperature shall be monitored with calibrated IR Gun.
- Pre-warm the tablets at an inlet temperature 56°C – 68°C, Product temperature 45°C – 50°C and Pan RPM is 02. 50 tablets from six different locations for 3 times and record for 5 to 15 minutes.
- Start spraying the coating dispersion at bed temperature 40°C to 50°C.
- Check the in-process parameters.
- Continue the coating until the 3.0 % w/w (2.5 – 3.5 % w/w) buildup is achieved.
- Discard the extra quantity of coating dispersion after achieving required weight build up.
- Dry the coated tablets for 10 – 15 minutes at an inlet temperature 56°C - 68°C with 02 RPM of coating pan and record the average weight of dried tablets.
- Allow tablets to cool at room temperature.
- Unload the tablets into tared, pre-labeled SS bin(s)/ HDPE container(s) lined with double polyethylene bags and close them tightly without any air inside the pack. Close the SS Bin(s) / HDPE container(s) properly.
- Transfer the containers into hold area.

6.2.7 Verification of recipe

Pre-warming	Inlet air temperature (°C)		56 – 68	
	Product temperature (°C)		45 – 50	
	Exhaust temperature (°C)		To be monitored	
	Pan RPM		02	
	Time (min)		5 – 15	
Coating process			**For Bectochem ( )**	**For ACG SC 700 ( )**
	Inlet temperature (°C)	Initial to 30 minutes	62 ± 6 (56 – 68)	
		30 minutes to till end	63 ± 5 (58 – 68)	
	Product temperature (°C)		45 ± 5 (40 – 50)	
	Exhaust temperature (°C)		To be monitored	
	Pan RPM	Initial to 30 minutes	2 – 4	1 – 3
		30 minutes to till end	4 – 8	2 – 5
	Spray rate gm/min/gun	Initial to 30 minutes	10 – 20	20 – 60
		30 minutes to till end	20 – 30	30 – 90
	Atomization pressure (Kg / cm^2)		3.0 ± 0.5 (2.5 – 3.5)	2.5 ± 1.0 (1.5 – 3.5)
	Distance between the two guns (cm)		15	15 – 30
	Distance between spray gun and tablet bed (cm)		20 – 30 **Set Value:**	15 – 30 **Set Value:**
	Spray gun nozzle (mm)		1.2	1.2
	No. of guns		08	06
Drying	Inlet air temperature (°C)		62 ± 6 (56 – 68)	
	Product temperature (°C)		To be monitored	
	Exhaust temperature (°C)		To be monitored	
	Pan RPM		02	
	Time (min)		10 – 15	
Checked by PR: (Sign & Date)			**Verified by QA: (Sign & Date)**	

Note: Tick (√) appropriate equipment.

6.2.8 Set up the coating gun, measure the spray rate at least 3 different pump RPM against spray rate (gm/min/gun) and record the details below.

Balance ID No.: _____

6.2.8.1 For Bectochem

Gun Validation	Spray rate* (gm/min/gun)	Pump RPM	Gun-1	Gun-2	Gun-3	Gun-4	Gun-5	Gun-6	Gun-7	Gun-8
Tare weight (gms)	10									
Gross weight (gms)										
Net weight (gms)										
Average										
Tare weight (gms)	20									
Gross weight (gms)										
Net weight (gms)										
Average										
Tare weight (gms)	30									
Gross weight (gms)										
Net weight (gms)										
Average										

Note: Spray rate test to be performed for approx. minimum and maximum limit of spray rate during coating start up. During coating, peristaltic pump RPM shall be maintained within the range of spray test performed.

Done by (Sign & Date): _____ **Checked by (Sign & Date):** _____ **Verified by QA (Sign & Date):** _____

6.2.8.2 For ACG (SC 700)

Gun Validation	Spray rate* (gm/min/gun)	Pump RPM	Gun-1	Gun-2	Gun-3	Gun-4	Gun-5	Gun-6
Tare weight (gms)	20							
Gross weight (gms)								
Net weight (gms)								
Average								
Tare weight (gms)	55							
Gross weight (gms)								
Net weight (gms)								
Average								
Tare weight (gms)	90							
Gross weight (gms)								
Net weight (gms)								
Average								

Note: Spray rate test to be performed for approx. minimum and maximum limit of spray rate during coating start up. During coating, peristaltic pump RPM shall be maintained within the range of spray test performed.

Done by (Sign & Date): _____ **Checked by (Sign & Date):** _____ **Verified by QA (Sign & Date):** _____

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 69 of 108**

Process	Equipment No.	Date	Start Time	Finish Time	Done by (Sign & Date)	Affix pre-warm wt. print out
6.2.9 Pre-warming Load the core tablets in coating machine pan and start the pre-warming as per below parameters for 5 to 15 minutes.						

Parameters	Limits
Inlet air temperature (°C)	56 – 68
Product temperature (°C)	45 – 50
Exhaust temperature (°C)	To be monitored
Pan RPM	02

Checked by (Sign & Date): _____ **Verified by QA (Sign & Date):** _____

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 70 of 108**

Pre-warming										
Date / Time	**Inlet temp.**		**Exhaust temp.**	**Pan RPM**	**Product temperature**	**I (50 Tablets in gms)**	**II (50 Tablets in gms)**	**III (50 Tablets in gms)**	**X=I+II+III / 150 x1000 (Avg.wt in mg)**	**Done by (Sign & Date)**
	Set	**Actual**								
Limit	**56°C - 68°C**		**To be monitored**	**02**	**45°C - 50°C**					

After prewarming 150 tablets weight = _____gm **Average weight X = _____mg**

Checked by (Sign & Date): _____ **Verified by QA (Sign & Date): _____**

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 71 of 108**

Process	Equipment No.	Date	Start Time	Finish Time	Done by (Sign & Date)
6.2.10 If the coating parameters are within the limits, start the coating machine. Perform the in-process checks for every 30 ± 05 minutes interval and record.					
6.2.11 Continue coating activity until 3.0 % w/w (2.5 – 3.5 %) weight build up is achieved and record the coating parameters.					

Checked by (Sign & Date): _____ **Verified by QA (Sign & Date):** _____

6.2.12 In-process checks shall be done as per SOP "in-process checks during manufacturing and packing (QA027)". Record the coating process parameters for every 30 ± 05 minutes.

6.2.13 Coating process parameters from initial to 30 minutes

Date	Time	Inlet temp. (56°C – 68°C)		Exhaust temp.	Product temp. (40°C – 50°C)	Pan RPM BLC: 2 – 4 ACG 1 – 3	Pump speed	Atomization air pressure (Kg / cm^2) BLC: 2.5 – 3.5 ACG 1.5 – 3.5	I (50 Tablets in gms)	II (50 Tablets in gms)	III (50 Tablets in gms)	Y=I+II+III / 150 x1000 (Avg.wt in mg)	Weight buildup in mg = Y-X	% buildup = $\frac{(Y-X) \times 100}{X}$ (LIMIT: 2.5 % - 3.5 %)	Done by (Sign & Date)
		Set	Actual												

X= Pre-warmed average wt. of core tablet

Checked by (Sign & Date): _____ **Verified by QA (Sign & Date):** _____

6.2.14 Coating process parameters after 30 minutes to till end of process

Date	Time	Inlet temp. (58°C – 68°C)		Exhaust temp.	Product temp. (40°C – 50°C)	Pan RPM BLC: 4 – 8 ACG: 2 – 5	Pump speed	Atomization air pressure (Kg / cm^2) BLC: 2.5 – 3.5 ACG: 1.5 – 3.5	I (50 Tablets in gms)	II (50 Tablets in gms)	III (50 Tablets in gms)	Y=I+II+III / 150 x1000 (Avg.wt in mg)	Weight buildup in mg = Y-X	% buildup = $\frac{(Y-X) \times 100}{X}$ (LIMIT: 2.5 % - 3.5 %)	Done by (Sign & Date)
		Set	Actual												

BATCH NO.: undefined

BATCH MANUFACTURING RECORD

Product Name: Atorvastatin Calcium Tablets USP 20 mg

BMR No.: CBMR/ATOTIK2/01-08 | **Effective Date:** 05 JUN 2024 |

Date	Time	Inlet temp. (58°C – 68°C)		Exhaust temp.	Product temp. (40°C – 50°C)	Pan RPM BLC: 4 – 8 ACG: 2 – 5	Pump speed	Atomization air pressure (Kg / cm^2) BLC: 2.5 – 3.5 ACG: 1.5 – 3.5	I (50 Tablets in gms)	II (50 Tablets in gms)	III (50 Tablets in gms)	Y=I+II+III / 150 x1000 (Avg.wt in mg)	Weight buildup in mg = Y-X	% buildup = (Y-X) x100 / X (LIMIT: 2.5 % - 3.5 %)	Done by (Sign & Date)
		Set	Actual												

Checked by (Sign & Date): _____

Verified by QA (Sign & Date): _____

BATCH MANUFACTURING RECORD

Product Name: Atorvastatin Calcium Tablets USP 20 mg

BMR No.: CBMR/ATOTIK2/01-08 | **Effective Date:** 05 JUN 2024 |

Process	Equipment No.	Date	Start Time	Finish Time	Done by (Sign & Date)	Affix after drying wt. print out
6.2.15 After completion of coating, dry the coated tablets for 10 - 15 minutes by using below process parameters						
6.2.16 Record the curing process parameters for every 10 ± 5 minutes.						

Parameters	Limits
Inlet air temperature (°C)	62±6 (56 – 68)
Product temperature (°C)	To be monitored
Exhaust temperature (°C)	To be monitored
Pan RPM	02

Checked by (Sign & Date): _____

Verified by QA (Sign & Date): _____

BATCH NO.: undefined

BATCH MANUFACTURING RECORD

Product Name: Atorvastatin Calcium Tablets USP 20 mg

BMR No.: CBMR/ATOTIK2/01-08 | **Effective Date:** 05 JUN 2024 |

Date	Time	Inlet temp.		Exhaust temp.	Product temp.	Pan RPM	I (50 Tablets in gms)	II (50 Tablets in gms)	III (50 Tablets in gms)	Y=I+II+III / 150 x1000 (Avg.wt in mg)	Weight buildup in mg = Y-X	% buildup = (Y-X) x100 / X (LIMIT: 2.5 % - 3.5 %)	Done by (Sign & Date)
		Set	Actual										
Limit		56°C - 68°C				02							

Checked by (Sign & Date): _____

Verified by QA (Sign & Date): _____

6.2.17 Weigh the left-over quantity of coating solution and record total below

Quantity of coating solution prepared (Kg) (A)	Left over quantity of coating solution discarded (Kg) (B)	Total quantity sprayed (Kg) (C) = (A) - (B)

Done by (Sign & Date): _____ **Checked by (Sign & Date):** _____ **Verified by QA (Sign & Date):** _____

6.2.18 In-process parameters

S. No.	Parameter	Limits	Frequency	No. of Tablets Req./ lot
1	Appearance	White to off white film coated oval shaped tablet plain on one side and debossed with "114" on other side	After completion of Batch/Lot	100
2	Weight of 100 tablets (gm)	19.776 – 21.424		100
3	Thickness (mm)	3.90 – 4.50		10
4	Uniformity of weight (mg)	195.7 – 216.3		20

Uniformity of weight: 206.00 mg ± 5.0 % (195.70 – 216.30 mg)					**Affix wt. print out**
Date:		**Time:**			
Tablet weight in mg					
Appearance	**Weight of 100 tablets** **20.6 gm ± 4.0%** **Limit: 19.776 gm – 21.424 gm**	**Thickness** **Limit: 3.90 mm – 4.50 mm**			

Done by PR (Sign & Date):	**Verified by QA (Sign & Date):**

6.2.19 Record the weights of the coated tablets

Unload the coated tablets from the coating pan into in double lined polyethylene bag in HDPE container, closed tightly and label it.

Balance ID: _____

Container No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Container No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Container No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)
								Total Net Wt. (Kg)			

Weighed by (Sign & Date):	Checked by (Sign & Date):	Verified by QA (Sign & Date):

6.2.20 Weigh and label as rejects: Collect the reject tablets (In-process and Others), weigh and label as rejects

Container No.	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighed by (Sign &Date)	Checked by (Sign & Date)	Verified by QA (Sign & Date)

Step No.	Process
6.2.21	**Sampling details:** **Note:** For validation batches sample shall be collected as per approved sampling protocol. For routine commercial batches sampling shall be collected as per the minimum sampling quantity SOP No. QA028.

Sample type	Collected sample quantity (No.'s)	Sampled by (Sign & Date)
Total Quantity		

6.2.22 Yield and reconciliation (Coating)

A	Theoretical batch size		:	Tablets		
B	Actual batch size in units (from compression)		:	Tablets		
C	Average wt. of coated tablets (mg)		:	Avg. Wt. = $\frac{\text{Sum of Wt. of 100 Tablets of all the Lots } X1000}{\text{No. of Lots } X\ 100}$ =		
D	Actual yield		:	Kg	Units:	Tablets
E	Sample for analysis	Hold time study	:	Kg	Units:	Tablets
		Validation	:	Kg	Units:	Tablets
		Pooled sample	:	Kg	Units:	Tablets
		Other	:	Kg	Units:	Tablets
F	Sample for in-process checks		:	Kg	Units:	Tablets
G	Other rejections (if any)		:	Kg	Units:	Tablets
H	% Yield (D÷A) X 100 (Limit: NLT 95 %)		:			
I	Reconciliation (Limit: 99.0% – 100.5%) [(D+E+F+G) ÷ {(B X C) ÷1000000}] ×100		:			
J	Unaccountable loss (If any): _____					

Checked by PR (Sign & Date):	**Verified by QA (Sign & Date):**

6.3 Tablet inspection

6.3.1 List of the equipment

Name of the Equipment/Instrument	Model	Capacity / Size	Manufacturer's Details	Operating Procedure*	Cleaning Procedure*	Equipment Number	Type of cleaning (A / C)
Tablet / Capsule inspection machine	PT1-15	N/A	PARLE	PR069	PR070		
	Kevin / TIB15	N/A	Kevin	PR133	PR133		
	VG-TI	N/A	Varco	PR155	PR155		
Weighing balance							

*Current version shall be followed.

Checked by PR (Sign & Date):_____ **Verified by QA (Sign & Date):**_____

6.3.2 List of persons involved in the inspection activity

S. No.	Name of Person	Employee ID	Department	Sign	S. No.	Name of Person	Employee ID	Department	Sign

6.3.3 Record the temperature, relative humidity and pressure differential of inspection area

(Frequency: Temperature, relative humidity and pressure differential to be checked at the beginning, at the end of the process and for every two hours ± 10 min during inspection**)**

Room No.	Date	Time (Hrs)	Temperature 15°C - 25°C	Relative Humidity 40 % - 60 % RH	Pressure Differential (NLT 1.0mm of WC)	Checked by (Sign & Date)	Room No.	Date	Time (Hrs)	Temperature 15°C - 25°C	Relative Humidity 40 % - 60 % RH	Pressure Differential (NLT 1.0mm of WC)	Checked by (Sign & Date)

6.3.4 Inspection instructions

1 Transfer the tablets from the WIP area to inspection area.
2 Visually inspect the tablets for physical defects and remove the defective tablets.
3 Visual inspection shall be performed as per the SOP No.: PR063.
4 AQL shall be performed for the inspected tablets as per the SOP No.: QA032.
5 Label the inspected containers.
6 Weigh the rejected tablets and affix label.

Date	Equipment number	Inspection start time	Inspection end time	Persons involved	Checked by PR (Sign & Date)

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 86 of 108**

Inspection Form and Acceptance Sampling Plan

Sample Size:

Stage: Coated Tablets

S. No.	Nature of Defects	No of non-conforming units observed						
		Critical (0.0 %)	Major (0.40%)	Major-A (0.25%)	Major-B (0.40%)	Minor (1.50%)	Minor-A (1.50%)	Minor-B (2.50%)
			--				--	--
			--				--	--
			--				--	--
			--				--	--
			--				--	--
			--				--	--
			--				--	--
			--				--	--
			--				--	--
			--				--	--
Total No. of non-conforming units observed			--				--	--
Results (Pass / Fail)			--				--	--

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
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AQL limits for Tablets and Capsules (% of Sample Size):

Type of Product	Critical	Major	Major A	Major B	Minor	Minor A	Minor B
Uncoated Tablets (core)	0.0%	0.40%	--	--	1.50%	--	--
Coated Tablets	0.0%	--	0.25%	0.40%	1.50%	--	--
Imprinted Tablets	0.0%	0.40%	--	--	1.50%	--	--
Filled Capsules (Hard)	0.0%	0.40%	--			1.50%	2.50%

Table: Sampling plan with Acceptance Criteria

Batch Size in Units	Number of Samples		Acceptance Criteria						
	First Inspection	Re-Inspection	Critical (0.0%)	Major (0.40%)	Major-A (0.25%)	Major-B (0.40%)	Minor (1.50%)	Minor-A (1.50%)	Minor-B (2.50%)
1,201 – 3,200	125	250	0	1	0	1	2	2	3
3,201 – 10,000	200	400	0	1	1	1	3	3	5
10,001 – 35,000	315	630	0	1	1	1	5	5	8
35,001 – 150,000	500	1000	0	2	1	2	8	8	13
150,001 – 500,000	800	1600	0	3	2	3	12	12	20
Over 500,000	1,250	2500	0	5	3	5	19	19	31

Complete Lot/Batch Inspection Required: YES / NO

	AQL Done By
Name	
Sign & Date	

Step No.	Process
6.3.5	**Sampling details:** **Note:** For validation batches sample shall be collected as per approved sampling protocol. For routine commercial batches sampling shall be collected as per the minimum sampling quantity SOP No. QA028.

Sample type	Collected sample quantity (No.'s)	Sampled by (Sign & Date)
Total Quantity		

6.3.6 Record the weight of the inspected tablets. **Balance ID:** _____

Container No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Container No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Container No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)
								Total Net Wt. (Kg)			

Weighed by (Sign & Date):	Checked by (Sign & Date):	Verified by QA (Sign & Date):

6.3.7 Weigh and label as rejects: Collect the reject tablets (In process, AQL and Others [specify if any]), weigh and label as rejects.

Container No.	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighed by (Sign &Date)	Checked by (Sign & Date)	Verified by QA (Sign & Date)

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 91 of 108**

6.3.8 Yield and reconciliation (Inspection)

A	Theoretical batch size (Units)		:	Tablets		
B	Weight of tablets received for Inspection		:	Kg		
C	Weight of good tablets after Inspection		:	Kg		
D	Average wt. of coated tablets (mg)		:			
E	Actual yield (in Units) = Weight of good tablets / Avg. weight of coated Tablets X 1000000		:			
F	Inspection rejections		:	Kg	Units:	Tablets
G	Sample for AQL		:	Kg	Units:	Tablets
H	Sample for analysis	Hold time study	:	Kg	Units:	Tablets
		Validation	:	Kg	Units:	Tablets
		Other	:	Kg	Units:	Tablets
I	Other rejections (if any)		:	Kg	Units:	Tablets
J	Yield {(E ÷ A) × 100} (Limit: NLT 94 %)		:	%		
K	Reconciliation {(C+F+G+H+I) ÷ B} × 100 (Limit: 99.0% – 100.5%)		:	%		
L	Unaccountable loss (If any):		:			

Checked by PR (Sign & Date):	**Verified by QA (Sign & Date):**

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 92 of 108**

7.0 Yield and reconciliation

Theoretical batch size	Kg	No's
Actual quantity of blend received	Kg	
Compression		
Quantity of compressed tablets	Kg	No.'s
Yield (%)	**Limit: NLT 96 %**	%
Reconciliation (%)	**Limit: 99.0% – 100.5%**	%
Film coating		
Quantity of coated tablets	Kg	No's
Yield (%)	**Limit: NLT 95 %**	%
Reconciliation (%)	**Limit: 99.0% – 100.5%**	%
Inspection		
Quantity of coated tablets after inspection	Kg	No's
Yield (%)	**Limit: NLT 94 %**	%
Reconciliation (%)	**Limit: 99.0% – 100.5%**	%
Checked by PR (Sign & Date):	**Verified by QA (Sign & Date):**	

8.0 Blank pages (*Affix the in-process print outs and labels in blank pages)*

BATCH NO.: undefined

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 94 of 108**

Blank pages (*Affix the in-process print outs and labels in blank pages)*

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 95 of 108**

Blank pages (*Affix the in-process print outs and labels in blank pages)*

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 96 of 108**

Blank pages (*Affix the in-process print outs and labels in blank pages)*

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 97 of 108**

Blank pages (*Affix the in-process print outs and labels in blank pages)*

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 98 of 108**

Blank pages (*Affix the in-process print outs and labels in blank pages)*

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 99 of 108**

Blank pages (*Affix the in-process print outs and labels in blank pages)*

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 100 of 108**

Blank pages (*Affix the in-process print outs and labels in blank pages)*

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 101 of 108**

Blank pages (*Affix the in-process print outs and labels in blank pages)*

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
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Blank pages (*Affix the in-process print outs and labels in blank pages)*

9.0 Summary of process non-conformances & temporary change controls

S. No.	Page No.	Step No.	Date	PNC No. / Temporary Change Control No.	Brief Description of the PNC / Temporary Change Control	Sign & Date (Production)

10.0 Tablets division

Actual Yield (Kg's): _____	**Balance ID:** _____

Formula

Tablets Division= $\frac{\text{Packing to be done qty in No's(A) x Avg.Wt in mg(B)}}{1000\text{x}1000}$ = _____Kg

01. Tablets Division_____ Count = $\frac{\text{(A)} \quad \text{x (B)}}{1000\text{x}1000}$ = _____Kg

02. Tablets Division_____ Count = $\frac{\text{(A)} \quad \text{x (B)}}{1000\text{x}1000}$ = _____Kg

03. Tablets Division_____ Count = $\frac{\text{(A)} \quad \text{x (B)}}{1000\text{x}1000}$ = _____Kg

04. Tablets Division_____ Count = $\frac{\text{(A)} \quad \text{x (B)}}{1000\text{x}1000}$ = _____Kg

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 105 of 108**

S. No.	Count	To be issued Qty (Kg's)			Division done by PR (Sign & Date)	Checked by PR (Sign & Date)
		Tare Weight (A)	Net Weight (B)	Gross Weight (A+B)		
Total Qty (Kg's)					**Verified by QA (Sign & Date):**	
Remaining Qty (Kg's)						

S. No.	Count	To be issued Qty (Kg's)			Division done by PR (Sign & Date)	Checked by PR (Sign & Date)
		Tare Weight (A)	Net Weight (B)	Gross Weight (A+B)		
Total Qty (Kg's)					**Verified by QA (Sign & Date):**	
Remaining Qty (Kg's)						

BATCH MANUFACTURING RECORD		
Product Name: Atorvastatin Calcium Tablets USP 20 mg		
BMR No.: CBMR/ATOTIK2/01-08	**Effective Date:** 05 JUN 2024	**Page 107 of 108**

S. No.	Count	To be issued Qty (Kg's)			Division done by PR (Sign & Date)	Checked by PR (Sign & Date)
		Tare Weight (A)	Net Weight (B)	Gross Weight (A+B)		
Total Qty (Kg's)					**Verified by QA (Sign & Date):**	
Remaining Qty (Kg's)						

11.0 Document compilation and verification

This is to certify that operations described in this batch manufacturing record are properly executed and batch manufacturing record is complete and legible.

Checked by (Sign & Date): _____

Head of PR / Designee

Verified by (Sign & Date): _____

Head Quality / Designee