

PRODUCTION DEPARTMENT

|                             | BATO                                    | CH PACKI               | NG RECORD           |   |                          |  |  |
|-----------------------------|---|------------------------|---------------------|---|--------------------------|--|--|
| <b>Product Code:</b>        |   |                        | BPR No.:            |   | <b>1</b>                 |  |  |
| <b>Product Name:</b>        | Generic Name: Atenolol Tablets IP 50 mg |                        |                     |   |                          |  |  |
| Effective Date:             |   |                        |                     |   | <b>Page No.:</b> 1 of 23 |  |  |
| Batch No.:                  |   | Bato                   | ch Size:            |   | Supersedes No.: Nil      |  |  |
|                             |   |                        |                     |   |                          |  |  |
| Location:                   |   |                        |                     |   |                          |  |  |
| Block: Production Tablets ( | (PT)                                    |                        |                     |   |                          |  |  |
| Label Claim:                | Atenolol Excipient                      | P 50 s q. unset Yellow | mg<br>s.            |   |                          |  |  |
| Mfg. Lic. No.:              |   |                        |                     |   |                          |  |  |
| Product Lic. No.:           | NA                                      |                        |                     |   |                          |  |  |
| Self-Life:                  | me                                      | onths                  |                     |   |                          |  |  |
| Pack Style:                 | 20 x 14 T                               | ablets                 |                     |   |                          |  |  |
| Country Name:               | Domestic                                |                        |                     |   |                          |  |  |
| Change Control No.:         | NA                                      |                        |                     |   |                          |  |  |
| Mfg. Date:                  |   |                        |                     |   |                          |  |  |
| Exp. Date:                  |   |                        |                     |   |                          |  |  |
| BMR ISSUED NO.:             |   |                        |                     |   |                          |  |  |
| MRP:                        |   |                        |                     |   |                          |  |  |
|                             |   | Issue                  | ed By Stamp & Sign. | , |                          |  |  |

| Responsibility | Name | Designation | Sign | Date |
|----------------|------|-------------|------|------|
| Prepared By    |      |             |      |      |
| Checked By     |      |             |      |      |
| Approved By    |      |             |      |      |



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

| <b>Product Code:</b>   | BPR No.:                 |                          |
|------------------------|--------------------------|--------------------------|
| <b>Product Name:</b>   | Generic Name: Atenolol 7 | Γablets IP 50 mg         |
| <b>Effective Date:</b> |                          | <b>Page No.:</b> 2 of 23 |
| Batch No.:             | Batch Size:              | Supersedes No.: Nil      |

#### 1.0 GENERAL INSTRUCTIONS:

- > Good manufacturing practices should be followed during the entire process of packing.
- All the Equipments used for packing should be properly cleaned as per the relevant SOP.
- > All the Equipments and containers should have proper status label with Stage, Product name, B. No., Mfg. Date etc.
- All the equipments should be operated as per the relevant SOP's only.
- > Issued packing materials should be cross checked by production personnel against dispensing sheet before taking up for packing.
- Overwriting in BPR shall be strictly avoided & correcting shall be made as per SOP.
- All the activities should be carried out according to the BPR only. All the operations shall be carried out in clean and orderly manner.
- Any deviation in process shall be bought to knowledge of QA and prior approval of QA department should be taken.
- > Critical parameters like temperature, Humidity and pressure differences should be checked and monitored.
- > In process controls should be carried out throughout the packing operations as per relevant BPR and relevant SOP's.
- > Ensure that all the packing materials, in process materials and finished goods should be placed in respective areas with proper label to avoid mix up.
- Attach additional issue sheets from QA, wherever required.
- ➤ Attach system generated data sheets wherever applicable.

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

| <b>Product Code:</b>   | BPR No.:                                |                          |  |
|------------------------|---|--------------------------|--|
| <b>Product Name:</b>   | Generic Name: Atenolol Tablets IP 50 mg |                          |  |
| <b>Effective Date:</b> |   | <b>Page No.:</b> 3 of 23 |  |
| Batch No.:             | Batch Size:                             | Supersedes No.: Nil      |  |

### 2.0 DISPENSING OF PACKING MATERIALS:

| Data. |  |  |
|-------|--|--|
| Date: |  |  |

#### 2.1Instructions:

- 1. Follow the packing materials dispensing SOP.
- 2. Appropriate weighing balances should be used while issue.
- 3. Ensure that weighing balances are calibrated & Verified on daily basis.
- 4. Printed Al. Foil and Special /PVC should be issued in poly bags.
- 5. Each roll should be labeled separately.
- 6. Cartons should be issued in bundles.
- 7. Cartons should be kept in plastic/shippers crates covered with lid or supplier and properly labeled.
- 8. Carton should be closed with transparent Cello tape.
- 9. One complaint slip is pasted on inside flap of corrugated box.
- 10. Shippers should be issued in bundles with proper label.
- 11. Keep all issued materials on separate pallets in PM dispensing room.

#### 2.2 Line Clearance Checks:

| S.No. | Line Clearance Checks   | Observation | Checked by QA |
|-------|---|-------------|---------------|
| 1.    | Containers used for previous batch/product removed from area                              |             |               |
| 2.    | All status labels of previous batch/products are removed                                  |             |               |
| 3.    | BPR or any other documents related to the previous batch / product are removed from area. |             |               |
| 4.    | Absence of any previous product /batch materials.   |             |               |
| 5.    | Cleanliness of the area   |             |               |
| 6.    | Cleanliness of the area below balances/ pallets.  |             |               |

### 2.3 Line clearance certificate for area and equipment:

| Area                    | PM dispensing room |  | Equipment             | Weighing Balance |
|-------------------------|--------------------|--|-----------------------|------------------|
| Area Cleaned By:        |                    |  | Equipment No.:        |                  |
| Checked By:             |                    |  | Equipment Cleaned By: |                  |
| Previous Product:       |                    |  | Batch No.:            |                  |
| Checked By (Packing Su  | pervisor):         |  |                       |                  |
| Sign & Date             |                    |  |                       |                  |
| Line clearance Given By | (IPQA):            |  |                       |                  |
| Sign & Date             |                    |  |                       |                  |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### **BATCH PACKING RECORD**

| <b>Product Code:</b>   | BPR No.:                                |                          |  |  |
|------------------------|---|--------------------------|--|--|
| <b>Product Name:</b>   | Generic Name: Atenolol Tablets IP 50 mg |                          |  |  |
| <b>Effective Date:</b> |   | <b>Page No.:</b> 4 of 23 |  |  |
| Batch No.:             | Batch Size:                             | Supersedes No.: Nil      |  |  |

### **2.4 BILL OF PACKING MATERIALS:**

(BPR Copy) Dispensed on: \_\_\_\_\_

| S.<br>No. | Items  | Qty. for 1 Lac. | *Req. Qty.<br>in | Issued<br>Qty. in | A.R. No. | Issued<br>by | Chec<br>By |    |
|-----------|--|-----------------|------------------|-------------------|----------|--------------|------------|----|
|           |  | in kg/nos.      | kg/nos.          | kg/nos.           |          | Store        | Prod.      | QA |
| 1         | <b>Printed Foil</b> Foil Width = 198 mm  | 2.5 Kg          |                  |                   |          |              |            |    |
| 2         | <b>Base Foil:</b> Clear Transparent PVC film, Foil Width:204mm   | 12.0 Kg         |                  |                   |          |              |            |    |
| 3         | <b>CARTON</b> –Dim: 100x 38x96 mm (20X14 Tablets)  | 357 Nos.        |                  |                   |          |              |            |    |
| 4         | <b>5 PLY CORRUGATED BOX-</b> Dim (OD): 425(L)x405(W)x 391(H) mm, ( <b>160 Cartons per box 4x5x6</b> ) Mkt.by address is printed in corr. box length panel in red colour. | 3 Nos.          |                  |                   |          |              |            |    |
| 5         | <b>BOPP TAPE -</b> BOPP Pre Printed 48 mm x 65 mtrs.   | 1 Nos.          |                  |                   |          |              |            |    |
| 6         | Cello tape ½ inch  | 1 Nos.          |                  |                   |          |              |            |    |

Note: \*Calculate the materials as per required batch size

Dispensed By: Checked By: Verified By: (Store) (Prod. Supervisor) (QA)

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### **BATCH PACKING RECORD**

| Product Code:          | BPR No.:               |   |  |  |  |  |  |
|------------------------|------------------------|---|--|--|--|--|--|
| Product Name:          | Generic Name: Atenolol | Generic Name: Atenolol Tablets IP 50 mg |  |  |  |  |  |
| <b>Effective Date:</b> |                        | <b>Page No.:</b> 5 of 23                |  |  |  |  |  |
| Batch No.:             | Batch Size:            | Supersedes No.: Nil                     |  |  |  |  |  |

Store copy page No.: 5 of 22

### **BILL OF PACKING MATERIALS**

(STORE COPY) Dispensed on: \_\_\_\_\_

| S.<br>No. | Items   | 1 Lac.     | *Req. Qty.<br>in | Qty. in | A.R. No. | Issued<br>by | Chec<br>By | у  |
|-----------|---|------------|------------------|---------|----------|--------------|------------|----|
|           |   | in kg/nos. | kg/nos.          | kg/nos. |          | Store        | Prod.      | QA |
| 1         | <b>Printed Foil</b> Foil Width = 198 mm   | 2.5 Kg     |                  |         |          |              |            |    |
| 2         | <b>Base Foil:</b> Clear Transparent PVC film, Foil Width: 204 mm  | 12.0 Kg    |                  |         |          |              |            |    |
| 3         | <b>CARTON</b> –Dim: 100x 38x96 mm (20X14 Tablets)   | 357 Nos.   |                  |         |          |              |            |    |
| 4         | <b>5 PLY CORRUGATED BOX-</b> Dim (OD): 425(L)x405(W)x 391(H) mm, (160 Cartons per box 4x5x6) Mkt.by address is printed in corr. box length panel in red colour. | 3 Nos.     |                  |         |          |              |            |    |
| 5         | <b>BOPP TAPE -</b> BOPP Pre Printed 48 mm x 65 mtrs.  | 1 Nos.     |                  |         |          |              |            |    |
| 6         | Cello tape ½ inch   | 1 Nos.     |                  |         |          |              |            |    |

Note: \*Calculate the materials as per required batch size

Dispensed By: Checked By: Verified By: (Store) (Prod. Supervisor) (QA)

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### **BATCH PACKING RECORD**

| <b>Product Code:</b>   | BPR No.:                 |   |  |  |  |  |
|------------------------|--------------------------|---|--|--|--|--|
| <b>Product Name:</b>   | Generic Name: Atenolol T | Generic Name: Atenolol Tablets IP 50 mg |  |  |  |  |
| <b>Effective Date:</b> |                          | <b>Page No.:</b> 6 of 23                |  |  |  |  |
| Batch No.:             | Batch Size:              | Supersedes No.: Nil                     |  |  |  |  |

### 3.0 PACKING SPECIFICATION:

|       |                                    | Over Printing Matter Standards Over Printing Mat                              | Checked By |       |    |
|-------|------------------------------------|---|------------|-------|----|
| S.No. | Description                        | (For Example only)  Over Printing Mat   | ter Actual | Prod. | QA |
| Α.    | Primary Packi                      | ng:   |            |       |    |
| 1.    | Blister                            |   |            |       |    |
|       | Blister coding details             | B. No., MFG., EXP.<br>M.R.P. Rs. PER 14 TABS.INCL.OF ALL TAXES                |            |       |    |
| В.    | Secondary Pac                      | king:   |            |       |    |
|       | Unit Carton                        | Printed   |            |       |    |
|       | Carton details                     | 20 x14 Tablets  |            |       |    |
| 1.    | Carton coding details              | Batch No.: Mfg. Date: Exp. Date: MRP Rs.: (Incl. of all Taxes) Per 14 Tablets |            |       |    |
| C.    | Tertiary Packi                     | ng  |            |       |    |
|       | 5 ply shipper                      | 5 ply printed shipper   |            |       |    |
|       | Shipper<br>details                 | 160 cartons in one 5 ply shipper  |            |       |    |
| 1.    | Shipper coding details             | B.No.<br>MFG.<br>EXP.<br>Qty. 160 X 20 X 14 TABS.                             |            |       |    |
|       | Sealing of<br>Shipper/BOPP<br>Tape | Printed BOPP Tape in "H" type on top and bottom.                              |            |       |    |

### 3.1 STANDARD PACKING INSTRUCTIONS:

- Check and verify the status board/label.
- All the materials of previous batches should be removed and line clearance certificate to be obtain from IPQA before starting any activity.
- Transfer the QC Released Tablets of the Batch to the primary cubicle.

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

| <b>Product Code:</b>   | :           |   |                          |  |  |  |
|------------------------|-------------|---|--------------------------|--|--|--|
| <b>Product Name:</b>   | Generic     | Generic Name: Atenolol Tablets IP 50 mg |                          |  |  |  |
| <b>Effective Date:</b> |             |   | <b>Page No.:</b> 7 of 23 |  |  |  |
| Batch No.:             | Batch Size: |   | Supersedes No.: Nil      |  |  |  |

- Produce the blister of 2x14 tablets using 198 mm printed aluminum foil & 204 mm base foil on a blister packing machine. The blister foil should be duly overprinted with the respective batch legend.
- Blister sealing leak test should be performed periodically to monitor the sealing.
- Each blister should be visually inspected to reject the defective ones.
- 20x14 such inspected blister should be packed inside each printed carton. The carton should be duly overprinted with the respective batch legend.
- 160 such inspected unit cartons should be packed inside the each shipper.
- The shipper should be properly labeled using coder. The coding details should be overprint with the respective batch legend on the shipper label.
- Each shipper should be sealed using Pre-printed BOPP tape in "H" type on top and bottom.
- After completion of the batch packing, intimate IPQA department through the transfer ticket.
- Complete the BPR for reconciliation of the batch after that transfer the packed shippers to the Finish Goods Store.

| 3.2 PACKING - | <b>Date:</b> |
|---------------|--------------|
|---------------|--------------|

#### **Instructions:**

- a. Gowning should be follows as per SOP.
- b. Masks and gloves should be used in the primary packing.
- c. Check for the cleanliness of the area and equipment.
- d. Check the Temperature, Humidity, and differential Pressure as per BPR or as per SOP
- e. Check that batch/product is released by QC for packing before starting of packaging operations and transfer to primary packing.
- f. Check the status label on the area on the display board outside the packing cubical.
- g. Operate blister packing machine as per SOP.
- h. Line clearance should be given take during any shift change.
- i. Line clearance procedure should also be followed in case of change in stereo or any major breakdown which can affect the packing quality.

### 3.3 Line clearance check (Initial/shift change over):

Line Clearance of Packing Line \_\_\_\_\_\_Please Tick √ If Yes & X If No or Not Applicable

| S.No. | Clearance Checks                               | Date |  |  |  |  |  |
|-------|--|------|--|--|--|--|--|
|       |  | Time |  |  |  |  |  |
| 1.    | Product name:                                  |      |  |  |  |  |  |
| 2.    | Area Cleanliness below/ Balance/ Pallets/ etc. |      |  |  |  |  |  |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

|  | F                             | BATCH PACKI        | NG REC  | CORD  |                       |             |      |           |         |   |
|--|-------------------------------|--------------------|---------|-------|-----------------------|-------------|------|-----------|---------|---|
| Produ  | ct Code:                      |                    |         | BPR N | o.:                   |             |      | •         |         |   |
| Product Name: Generic Name: Atenolol Tablets I |                               |                    |         |       |                       | IP 50 mg    |      |           |         |   |
| Effective Date: Page                           |                               |                    |         |       | e <b>No.:</b> 8 of 23 |             |      |           |         |   |
| Batch  | No.:                          |                    | Batch S | Size: |                       |             | Supe | rsedes No | o.: Nil |   |
|  | Г                             |                    |         |       |                       |             |      |           |         |   |
| 3.   | Machine Cleanliness           |                    |         |       |                       |             |      |           |         |   |
| 4.   | Packaging material or remove. | of previous produc | et      |       |                       |             |      |           |         |   |
| 5.   | Over coding details           | on blister         |         |       |                       |             |      |           |         |   |
| G N  |                               | Date               | :       |       |                       |             |      |           |         |   |
| S.No.  | Clearance Checks              | Time               | e       |       |                       |             |      |           |         |   |
| 6.   | Over coding details           | on unit carton     |         |       |                       |             |      |           |         |   |
| 7.   | Pasting cello tape            |                    |         |       |                       |             |      |           |         |   |
| 8.   | Over coding details           | on outer carton    |         |       |                       |             |      |           |         |   |
| 9.   | Product Packaging I           | nsert              |         |       |                       |             |      |           |         |   |
| 10.  | Specimen of 5 Ply S           | hipper coding      |         |       |                       |             |      |           |         |   |
| 11.  | Correctness of status         | s label            |         |       |                       |             |      |           |         |   |
| 12.  | Daily Verification of         | f balances         |         |       |                       |             |      |           |         |   |
| Check  | ed by Production (Si          | gn/Date)           |         |       |                       |             |      |           |         |   |
| Verific  | ed by IPQA (Sign/Da           | te)                |         |       |                       |             |      |           |         |   |
| 3.4 Vei  | rification of Tablet re       | eceived from core  | area:   | 1     | L                     | 1           | l    | l         |         |   |
| Tot  | al Container No.              | Total W            | eight   | Cl    | necked b              | y Productio | n    | Verified  | by IPQ  | A |
|  |                               |                    | •       |       |                       |             |      |           |         |   |
| 3.5 Ste  | reo detail:                   |                    |         | •     |                       |             | •    |           |         |   |

Issue the required number of stereos to operator and retrieve the same from them after completion of activity and record shall be maintained as per table given below;

|        | No. of stereos<br>received from QA |        | No. of stereos given to operator |        | f stereos<br>by Operator | Total No. of stereos submitted to QA |         | Submitted<br>by | Retrieved |
|--------|------------------------------------|--------|----------------------------------|--------|--------------------------|--------------------------------------|---------|-----------------|-----------|
| Carton | Blister                            | Carton | Blister                          | Carton | Blister                  | Carton                               | Blister | (Packing)       | By (IPQA) |
|        |                                    |        |                                  |        |                          |                                      |         |                 |           |

#### 3.6 Line clearance overprinting of carton:

**Date** 

- Line clearance of the area and machine.
- ii. Affix the specific batch stereo and prepare a specimen proof for the approval of packing supervisor and then by IPQA supervisor & affix in the BPR.
- iii. After approval start coding of carton and check the each carton for correctness and legibility of the batch detail.
- iv. In-process, rejection and destruction of rejected cartons shall be recorded.

|                  | Line clearance c | ertificate for area and equipmer | nt                    |
|------------------|------------------|----------------------------------|-----------------------|
| Area:            |                  | <b>Equipment:</b>                | Carton coding machine |
| Area Cleaned By: |                  | Equipment No.:                   |                       |
|                  | Prepared By      | Checked By                       | Approved By           |
| Signature        |                  |                                  |                       |



PRODUCTION DEPARTMENT

#### BATCH PACKING RECORD

| Battentaen                                | THE RECORD                              |                          |
|---|---|--------------------------|
| <b>Product Code:</b>                      | BPR No.:                                |                          |
| Product Name:                             | Generic Name: Atenolol Tablets IP 50 mg |                          |
| <b>Effective Date:</b>                    |   | <b>Page No.:</b> 9 of 23 |
| Batch No.:                                | Batch Size:                             | Supersedes No.: Nil      |
|   |   |                          |
| Checked By:                               | Equipment Cleaned I                     | By:                      |
| Previous Product:                         | Batch No.:                              |                          |
| Checked By (Packing Supervisor): Sign & D | ate                                     |                          |
| Line clearance Given By(IPQA): Sign & Dat | e                                       |                          |

### Over coding detail for Blister, carton and shipper

|          | Over print  | ing details    |         | Carton | Shipper |
|----------|---|----------------|---------|--------|---------|
| S.No.    | Details on PM<br>(for example)                    | Actual details | Blister |        |         |
| 1.       |   |                |         |        |         |
| 2.       | Batch No.:  |                |         |        |         |
| 3.       | Mfg. Date:  |                |         |        |         |
| 4.       | Exp. Date:  |                |         |        |         |
| 5.       | M.R.P.:<br>(Incl. of all taxes)<br>Per 14 Tablets |                |         |        |         |
| 6.       | Qty. 160 X 20 X 14 TABS.                          |                |         |        |         |
| Doolring | Signature   |                |         |        |         |
| Packing  | Date  |                |         |        |         |
| IDO A    | Signature   |                |         |        |         |
| IPQA     | Date  |                |         |        |         |

Note: Which is not applicable mention NA and put tick mark which is applicable.

### **3.7 Reconciliation of Packing Material:**

| S.No. | Particulars                    | Cartons | Shipper |
|-------|--------------------------------|---------|---------|
| 1.    | Quantity Issued                |         |         |
| 2.    | Quantity coded                 |         |         |
| 3.    | Good inspected quantity        |         |         |
| 4.    | Quantity rejected              |         |         |
| 5.    | Qty. destroyed                 |         |         |
| 6.    | Qty. destroyed by              |         |         |
| 7.    | Checked by Prod. (Sign/Date)   |         |         |
| 8.    | Verified by IPQA (Sign / Date) |         |         |

### 3.8 Shipper coding:

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

| <b>Product Code:</b>   | BPR No.:                 |                           |
|------------------------|--------------------------|---------------------------|
| <b>Product Name:</b>   | Generic Name: Atenolol T | Tablets IP 50 mg          |
| <b>Effective Date:</b> |                          | <b>Page No.:</b> 10 of 23 |
| Batch No.:             | Batch Size:              | Supersedes No.: Nil       |

- i. Arrange the klass marker of respective batch no. for coding on unit carton and arrange the alphabets for shipper label coding as per information given in the BMR and first take a specimen on carton and shipper label coding specimen on plain A4 size paper & get the approval from packing supervisor and then from IPQA.
- ii. After approval all the unit carton/shipper of the batch shall be coded and if any unit carton/shipper rejected during coding same shall be destructed and record shall be maintained.

### 4.0 BLISTER PACKING:

#### 4.1 Machine Setting:

1. Take line clearance from IPQA.

| Line clearance certificate for area and equipments: |                      |                 |  |
|---|----------------------|-----------------|--|
| Area  | Equipment            | Blister Machine |  |
| Area Cleaned By                                     | Equipment No.        |                 |  |
| Checked By  | Equipment Cleaned By |                 |  |
| Previous Product                                    | Batch No.            |                 |  |
| Checked By (Packing Supervisor): Sign & Date        |                      |                 |  |
| Line clearance Given By (IPQA): Sign & Date         |                      |                 |  |

- 2. Check the change parts as per product specification.
- 3. Mount the rollers and check the cavity alignment of sealing roller.
- 4. Mount BCP, and affix stereos.
- 5. Adjust forming & sealing temperature and pressure.
- 6. Load the printed and plain foil, and adjust machine to smooth foil run and take out proof of Batch coding. Get the approval from packing supervisor and IPQA.
- 7. Set the sealing temperature 180°C to 200°C. Forming Temp150°C to 160°C.
- 8. Ensure proper Knurling and cutting length.
- 9. Check status label on Tablets containers.
- 10. Load the hopper with Tablets to be stripped.
- 11. Operate the blister packing machine as per SOP.
- 12. Check the leak test of blister as per Leak Test SOP. Record it in in-process control record.
- 13. Attach approved specimen sample to BPR duly signed by Packing Supervisor and OA Personnel.

#### 4.2 General instruction:

- 1. Carry out blistering operation after batch printing approval by production supervisor & IPQA.
- 2. Record the parameters at a stated frequency.
- 3. Carry out the Leak test as per SOP.
- 4. Note the changes in foil rolls and splices.
- 5. Check the coding on each splice and foil at the start and end. Check at least 1 meter section of each side.
- 6. Foil rolls / Splices should be numbered.
- 7. Attach the sample of every new foil roll and every splice in each roll with BPR.

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### **BATCH PACKING RECORD**

| <b>Product Code:</b>   | BPR No.:                 |                           |
|------------------------|--------------------------|---------------------------|
| <b>Product Name:</b>   | Generic Name: Atenolol 7 | Tablets IP 50 mg          |
| <b>Effective Date:</b> |                          | <b>Page No.:</b> 11 of 23 |
| Batch No.:             | Batch Size:              | Supersedes No.: Nil       |

8. Note the Machine start, stop and end time.

### 4.3 Blister Packing Start up Control Checks:

- 1. Run the machine and collect few initial blisters.
- 2. Check for Knurling, Cutting, sealing, batch overprinting, etc. and observation shall be recorded.
- 3. If the initial parameters are satisfactory, continue packing.
- 4. In process test observation shall be recorded both by packing and IPQA supervisor as per table No.4.4
- 5. Reasons for machine stop should be recorded. In the following tables.

### 4.4 Secondary and tertiary packing:

- 1. Pack the number of blister in carton then followed by outer carton and finally in shipper as per requirement given in section 2.0 (packing specification).
- 2. Each carton and shipper shall weigh to identify the shortage if any.
- 3. Close the shipper by BOPP tape properly.
- 4. Person involve in the packing shall be recorded as per following table:

| Date  |    |    |    |    |
|---|----|----|----|----|
| Time  | То | То | То | То |
| Inspection of blister done by               |    |    |    |    |
| Counting of blister done by                 |    |    |    |    |
| Carton                                      |    |    |    |    |
| Insertion of blister & Carton done by       |    |    |    |    |
| Inspection of over coding on carton done by |    |    |    |    |
| Shipper coding done by                      |    |    |    |    |
| Insertion of Carton in shipper done by      |    |    |    |    |
| Shipper sealed and weighed by               |    |    |    |    |
| Checked by:                                 |    |    |    |    |
| Production/packing                          |    |    |    |    |
| IPQA  |    |    |    |    |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### BATCH PACKING RECORD

| <b>Product Code:</b>   | BPR No.:                  |                           |
|------------------------|---------------------------|---------------------------|
| <b>Product Name:</b>   | Generic Name: Atenolol Ta |                           |
| <b>Effective Date:</b> |                           | <b>Page No.:</b> 12 of 23 |
| Batch No.:             | Batch Size:               | Supersedes No.: Nil       |

### 5.0 IN PROCESS CHECK:

5.1 In-process check by production at initial and every 30 min.

| S.    | In process  | Date   |  |  |  |  |  |  |
|-------|---|--------|--|--|--|--|--|--|
| No.   | checks  | Time   |  |  |  |  |  |  |
| 1.    | Temp.   |        |  |  |  |  |  |  |
| 2.    | RH  |        |  |  |  |  |  |  |
| 3.    | Forming roller temperature                              | r      |  |  |  |  |  |  |
| 4.    | Sealing roller<br>Temperature                           |        |  |  |  |  |  |  |
| 5.    | Check workin<br>NFD by remo<br>one tablet from<br>track | ving   |  |  |  |  |  |  |
| 6.    | Tab. with fore black particle                           | ign /  |  |  |  |  |  |  |
| 7.    | Foil shifting   |        |  |  |  |  |  |  |
| 8.    | Batch detail o  | n foil |  |  |  |  |  |  |
| 9.    | No. of tab/ Bl  | ister  |  |  |  |  |  |  |
| 10.   | Proper cutting blister                                  | of     |  |  |  |  |  |  |
| 11.   | Leak test<br>(Hourly)                                   |        |  |  |  |  |  |  |
| 12.   | Proper gluing carton                                    |        |  |  |  |  |  |  |
| 13.   | No. of blister printed carton                           |        |  |  |  |  |  |  |
| 14.   | Batch detail of printed carton                          |        |  |  |  |  |  |  |
| 15.   | Seal the cartor cello tape                              |        |  |  |  |  |  |  |
| 16.   | No. of carton shipper                                   |        |  |  |  |  |  |  |
| 17.   | Batch details of shipper label                          | on     |  |  |  |  |  |  |
| 18.   | Pasting of BO   |        |  |  |  |  |  |  |
| Check | xed by (Produc  | tion)  |  |  |  |  |  |  |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### **BATCH PACKING RECORD**

| <b>Product Code:</b>   |  | BPR No.:                                |        |                     |  |  |
|------------------------|--|---|--------|---------------------|--|--|
| <b>Product Name:</b>   |  | Generic Name: Atenolol Tablets IP 50 mg |        |                     |  |  |
| <b>Effective Date:</b> |  |   | Page N | <b>o.:</b> 13 of 23 |  |  |
| Batch No.: Batch S     |  | Size:                                   | Supers | edes No.: Nil       |  |  |

### In-process check by production at initial and every 30 min.

|                          |   | 1      | • |  |  | 1 |  | uai ana |  |  | 1 | 1 |  |
|--------------------------|---|--------|---|--|--|---|--|---------|--|--|---|---|--|
| S.                       | In process  | Date   |   |  |  |   |  |         |  |  |   |   |  |
| No.                      | checks  | Time   |   |  |  |   |  |         |  |  |   |   |  |
| 1.                       | Temp.   |        |   |  |  |   |  |         |  |  |   |   |  |
| 2.                       | RH  |        |   |  |  |   |  |         |  |  |   |   |  |
| 3.                       | Forming roller temperature                                | r      |   |  |  |   |  |         |  |  |   |   |  |
| 4.                       | Sealing roller<br>Temperature                             |        |   |  |  |   |  |         |  |  |   |   |  |
| 5.                       | Check workin<br>NFD by remove<br>one tablet from<br>track | ving   |   |  |  |   |  |         |  |  |   |   |  |
| 6.                       | Tab. with fore black particle                             | ign /  |   |  |  |   |  |         |  |  |   |   |  |
| 7.                       | Foil shifting   |        |   |  |  |   |  |         |  |  |   |   |  |
| 8.                       | Batch detail or   | n foil |   |  |  |   |  |         |  |  |   |   |  |
| 9.                       | No. of tab/ Bli   | ister  |   |  |  |   |  |         |  |  |   |   |  |
| 10.                      | Proper cutting blister                                    |        |   |  |  |   |  |         |  |  |   |   |  |
| 11.                      | Leak test<br>(Hourly)                                     |        |   |  |  |   |  |         |  |  |   |   |  |
| 12.                      | Proper gluing carton                                      |        |   |  |  |   |  |         |  |  |   |   |  |
| 13.                      | No. of blister printed carton                             |        |   |  |  |   |  |         |  |  |   |   |  |
| 14.                      | Batch detail or printed carton                            |        |   |  |  |   |  |         |  |  |   |   |  |
| 15.                      | Seal the cartor cello tape                                |        |   |  |  |   |  |         |  |  |   |   |  |
| 16.                      | No. of carton ishipper                                    |        |   |  |  |   |  |         |  |  |   |   |  |
| 17.                      | Batch details of shipper label                            |        |   |  |  |   |  |         |  |  |   |   |  |
| 18. Pasting of BOPP tape |   |        |   |  |  |   |  |         |  |  |   |   |  |
| Check                    | Checked by (Production)                                   |        |   |  |  |   |  |         |  |  |   |   |  |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### **BATCH PACKING RECORD**

| <b>Product Code:</b>   | BPR No.:               | BPR No.:                                |  |  |  |  |
|------------------------|------------------------|---|--|--|--|--|
| <b>Product Name:</b>   | Generic Name: Atenolol | Generic Name: Atenolol Tablets IP 50 mg |  |  |  |  |
| <b>Effective Date:</b> |                        | <b>Page No.:</b> 14 of 23               |  |  |  |  |
| Batch No.:             | Batch Size:            | Supersedes No.: Nil                     |  |  |  |  |

### In-process check by production at initial and every 30 min.

|           |  |              | - F |  | ~J P- |  |  | uai anu | J - |  |  |  |
|-----------|--|--------------|-----|--|-------|--|--|---------|-----|--|--|--|
| S.<br>No. | In process<br>checks                                       | Date<br>Time |     |  |       |  |  |         |     |  |  |  |
| 1.        | Temp.  | 111116       |     |  |       |  |  |         |     |  |  |  |
| 2.        | RH   |              |     |  |       |  |  |         |     |  |  |  |
|           | Forming roller   | •            |     |  |       |  |  |         |     |  |  |  |
| 3.        | temperature  | -            |     |  |       |  |  |         |     |  |  |  |
| 4.        | Sealing roller<br>Temperature                              |              |     |  |       |  |  |         |     |  |  |  |
| 5.        | Check working<br>NFD by remove<br>one tablet from<br>track | ving         |     |  |       |  |  |         |     |  |  |  |
| 6.        | Tab. with fore black particle                              | ign /        |     |  |       |  |  |         |     |  |  |  |
| 7.        | Foil shifting  |              |     |  |       |  |  |         |     |  |  |  |
| 8.        | Batch detail or  | n foil       |     |  |       |  |  |         |     |  |  |  |
| 9.        | No. of tab/ Bli  | ster         |     |  |       |  |  |         |     |  |  |  |
| 10.       | Proper cutting blister                                     | of           |     |  |       |  |  |         |     |  |  |  |
| 11.       | Leak test<br>(Hourly)                                      |              |     |  |       |  |  |         |     |  |  |  |
| 12.       | Proper gluing carton                                       |              |     |  |       |  |  |         |     |  |  |  |
| 13.       | No. of blister i   |              |     |  |       |  |  |         |     |  |  |  |
| 14.       | Batch detail or printed carton                             |              |     |  |       |  |  |         |     |  |  |  |
| 15.       | Seal the cartor cello tape                                 |              |     |  |       |  |  |         |     |  |  |  |
| 16.       | No. of carton i shipper                                    |              |     |  |       |  |  |         |     |  |  |  |
| 17.       | Batch details of shipper label                             | on           |     |  |       |  |  |         |     |  |  |  |
| 18.       | Pasting of BO  |              |     |  |       |  |  |         |     |  |  |  |
| Check     | Checked by (Production)                                    |              |     |  |       |  |  |         |     |  |  |  |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### **BATCH PACKING RECORD**

| <b>Product Code:</b>   | BPR No.:                 | BPR No.:                  |  |  |  |  |
|------------------------|--------------------------|---------------------------|--|--|--|--|
| <b>Product Name:</b>   | Generic Name: Atenolol T | Tablets IP 50 mg          |  |  |  |  |
| <b>Effective Date:</b> |                          | <b>Page No.:</b> 15 of 23 |  |  |  |  |
| Batch No.:             | Batch Size:              | Supersedes No.: Nil       |  |  |  |  |

### In-process check by production at initial and every 30 min.

|           |   | _              | n-proces | <br>ој рго | <u> </u> | <br> | covery c | , o 1111111 |      |  |
|-----------|---|----------------|----------|------------|----------|------|----------|-------------|------|--|
| S.<br>No. | In process checks                                       | Date<br>Time   |          |            |          |      |          |             |      |  |
| 1.        | Temp.   | _              |          |            |          |      |          |             |      |  |
| 2.        | RH  |                |          |            |          |      |          |             |      |  |
| 3.        | Forming roller temperature                              | r              |          |            |          |      |          |             |      |  |
| 4.        | Sealing roller<br>Temperature                           |                |          |            |          |      |          |             |      |  |
| 5.        | Check workin<br>NFD by remo<br>one tablet from<br>track | ving<br>n each |          |            |          |      |          |             |      |  |
| 6.        | Tab. with fore black particle                           | ign /          |          |            |          |      |          |             |      |  |
| 7.        | Foil shifting   |                |          |            |          |      |          |             |      |  |
| 8.        | Batch detail or   |                |          |            |          |      |          |             |      |  |
| 9.        | No. of tab/ Bli   |                |          |            |          |      |          |             |      |  |
| 10.       | Proper cutting blister                                  | of             |          |            |          |      |          |             |      |  |
| 11.       | Leak test<br>(Hourly)                                   |                |          |            |          |      |          |             |      |  |
| 12.       | Proper gluing carton                                    |                |          |            |          |      |          |             |      |  |
| 13.       | No. of blister printed carton                           |                |          |            |          |      |          |             |      |  |
| 14.       | Batch detail or printed carton                          |                |          |            |          |      |          |             |      |  |
| 15.       | Seal the cartor cello tape                              |                |          |            |          |      |          |             |      |  |
| 16.       | No. of carton shipper                                   |                |          |            |          |      |          |             |      |  |
| 17.       | Batch details of shipper label                          | on             |          |            |          |      |          |             | <br> |  |
| 18.       | Pasting of BO   | PP tape        |          |            |          |      |          |             |      |  |
| Check     | xed by (Produc  | tion)          |          |            |          |      |          |             |      |  |

Attach additional sheet if required....

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### **BATCH PACKING RECORD**

| <b>Product Code:</b>   |       | BPR No.:                                |               |                     |  |  |
|------------------------|-------|---|---------------|---------------------|--|--|
| <b>Product Name:</b>   |       | Generic Name: Atenolol Tablets IP 50 mg |               |                     |  |  |
| <b>Effective Date:</b> |       |   | Page N        | <b>o.:</b> 16 of 23 |  |  |
| Batch No.:             | Size: | Superso                                 | edes No.: Nil |                     |  |  |

### 5.2 In-process check by IPQA for initial and every 60 min

| S.<br>No. | In process<br>checks                                      | Date           |  |  |  |  |  |  |
|-----------|---|----------------|--|--|--|--|--|--|
|           |   | Time           |  |  |  |  |  |  |
| 1.        | Temp.   |                |  |  |  |  |  |  |
| 2.        | RH  |                |  |  |  |  |  |  |
| 3.        | Forming roller temperature                                | •              |  |  |  |  |  |  |
| 4.        | Sealing roller<br>Temperature                             |                |  |  |  |  |  |  |
| 5.        | Check workin<br>NFD by remove<br>one tablet from<br>track | ving<br>n each |  |  |  |  |  |  |
| 6.        | Tab. with fore black particle                             | ign /          |  |  |  |  |  |  |
| 7.        | Foil shifting   |                |  |  |  |  |  |  |
| 8.        | Batch detail or   | n foil         |  |  |  |  |  |  |
| 9.        | No. of tab/ Bli   |                |  |  |  |  |  |  |
| 10.       | Proper cutting blister                                    | of             |  |  |  |  |  |  |
| 11.       | Leak test<br>(Bi-hourly)                                  |                |  |  |  |  |  |  |
| 12.       | Proper gluing carton                                      |                |  |  |  |  |  |  |
| 13.       | No. of blister printed carton                             |                |  |  |  |  |  |  |
| 14.       | Batch detail or printed carton                            |                |  |  |  |  |  |  |
| 15.       | Seal the cartor cello tape                                |                |  |  |  |  |  |  |
| 16.       | No. of carton shipper                                     |                |  |  |  |  |  |  |
| 17.       | Batch details of shipper label                            | on             |  |  |  |  |  |  |
| 18.       | Pasting of BO   | PP tape        |  |  |  |  |  |  |
| Check     | ked by (IPQA)   |                |  |  |  |  |  |  |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### BATCH PACKING RECORD

| <b>Product Code:</b>   |         | BPR No.:                 |           |                      |
|------------------------|---------|--------------------------|-----------|----------------------|
| <b>Product Name:</b>   |         | Generic Name: Atenolol T | ablets IF | 9 50 mg              |
| <b>Effective Date:</b> |         |                          | Page N    | <b>(o.:</b> 17 of 23 |
| Batch No.:             | Batch S | Size:                    | Supers    | edes No.: Nil        |

### In-process check by IPQA for initial and every 60 min

|            | in process eneck by it QAT for initial and every ov initi |                |  |  |  |  |  |  |  |  |  |
|------------|---|----------------|--|--|--|--|--|--|--|--|--|
| Sr.<br>No. | In process<br>checks                                      | Date<br>Time   |  |  |  |  |  |  |  |  |  |
| 1.         | Temp.   | Time           |  |  |  |  |  |  |  |  |  |
| 2.         | RH  |                |  |  |  |  |  |  |  |  |  |
| 3.         | Forming roller temperature                                | r              |  |  |  |  |  |  |  |  |  |
| 4.         | Sealing roller<br>Temperature                             |                |  |  |  |  |  |  |  |  |  |
| 5.         | Check workin<br>NFD by remove<br>one tablet from<br>track | ving<br>n each |  |  |  |  |  |  |  |  |  |
| 6.         | Tab. with fore black particle                             | ign /          |  |  |  |  |  |  |  |  |  |
| 7.         | Foil shifting   |                |  |  |  |  |  |  |  |  |  |
| 8.         | Batch detail or   | n foil         |  |  |  |  |  |  |  |  |  |
| 9.         | No. of tab/ Bli   |                |  |  |  |  |  |  |  |  |  |
| 10.        | Proper cutting blister                                    | of             |  |  |  |  |  |  |  |  |  |
| 11.        | Leak test<br>(Bi-hourly)                                  |                |  |  |  |  |  |  |  |  |  |
| 12.        | Proper gluing carton                                      |                |  |  |  |  |  |  |  |  |  |
| 13.        | No. of blister in printed carton                          |                |  |  |  |  |  |  |  |  |  |
| 14.        | Batch detail or printed carton                            |                |  |  |  |  |  |  |  |  |  |
| 15.        | Seal the cartor cello tape                                |                |  |  |  |  |  |  |  |  |  |
| 16.        | No. of carton shipper                                     |                |  |  |  |  |  |  |  |  |  |
| 17.        | Batch details of shipper label                            | on             |  |  |  |  |  |  |  |  |  |
| 18.        | Pasting of BO   | PP tape        |  |  |  |  |  |  |  |  |  |
| Check      | xed by (IPQA)   |                |  |  |  |  |  |  |  |  |  |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### **BATCH PACKING RECORD**

| <b>Product Code:</b>   | BPR No.:                 |                           |
|------------------------|--------------------------|---------------------------|
| <b>Product Name:</b>   | Generic Name: Atenolol T | Tablets IP 50 mg          |
| <b>Effective Date:</b> |                          | <b>Page No.:</b> 18 of 23 |
| Batch No.:             | Batch Size:              | Supersedes No.: Nil       |

### In-process check by IPQA for initial and every 60 min

|       | In-process check by IPQA for initial and every 60 min   |                |  |  |  |  |  |  |  |  |  |
|-------|---|----------------|--|--|--|--|--|--|--|--|--|
| Sr.   | In process  | Date           |  |  |  |  |  |  |  |  |  |
| No.   | checks  | Time           |  |  |  |  |  |  |  |  |  |
| 1.    | Temp.   |                |  |  |  |  |  |  |  |  |  |
| 2.    | RH  |                |  |  |  |  |  |  |  |  |  |
| 3.    | Forming rolle temperature                               |                |  |  |  |  |  |  |  |  |  |
| 4.    | Sealing roller<br>Temperature                           |                |  |  |  |  |  |  |  |  |  |
| 5.    | Check workin<br>NFD by remo<br>one tablet from<br>track | wing<br>m each |  |  |  |  |  |  |  |  |  |
| 6.    | Tab. with fore black particle                           |                |  |  |  |  |  |  |  |  |  |
| 7.    | Foil shifting   |                |  |  |  |  |  |  |  |  |  |
| 8.    | Batch detail o  | n foil         |  |  |  |  |  |  |  |  |  |
| 9.    | No. of tab/ Bl  | ister          |  |  |  |  |  |  |  |  |  |
| 10.   | Proper cutting blister                                  | g of           |  |  |  |  |  |  |  |  |  |
| 11.   | Leak test<br>(Bi-hourly)                                |                |  |  |  |  |  |  |  |  |  |
| 12.   | Proper gluing carton                                    | of             |  |  |  |  |  |  |  |  |  |
| 13.   | No. of blister printed carton                           |                |  |  |  |  |  |  |  |  |  |
| 14.   | Batch detail o  | n              |  |  |  |  |  |  |  |  |  |
| 15.   | Seal the carto  |                |  |  |  |  |  |  |  |  |  |
| 16.   | No. of carton shipper                                   |                |  |  |  |  |  |  |  |  |  |
| 17.   | Batch details shipper label                             | on             |  |  |  |  |  |  |  |  |  |
| 18.   | Pasting of BO   | PP tape        |  |  |  |  |  |  |  |  |  |
| Check | ked by (IPQA)   |                |  |  |  |  |  |  |  |  |  |

Attach additional sheet if required....

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



Date

# PHARMA DEVILS

PRODUCTION DEPARTMENT

|                       | BATCH 1                         | PACKING RE   | COR   | D             |           |                           |                  |
|-----------------------|---------------------------------|--------------|-------|---------------|-----------|---------------------------|------------------|
| <b>Product Code</b>   | •                               |              | BP    | R No.:        |           | <b>'</b>                  |                  |
| Product Name          | e:                              |              | Ge    | neric Name: A | tenolol T | Tablets IP :              | 50 mg            |
| <b>Effective Date</b> | :                               |              |       |               |           | Page No                   | .: 19 of 23      |
| Batch No.:            |                                 | Batch        | Size: |               |           | Superse                   | des No.: Nil     |
|                       | VEIGHING RECORD filled shipper: | Kg to _      |       |               |           |                           |                  |
| Shipper No.           | Gross wt. In Kg.                | Weighing don | e by  |               | Gross v   | wt. In Kg.                | Weighing done by |
| 1.                    |                                 |              |       | 20.           |           |                           |                  |
| 2.                    |                                 |              |       | 21.           |           |                           |                  |
| 3.                    |                                 |              |       | 22.           |           |                           |                  |
| 4.                    |                                 |              |       | 23.           |           |                           |                  |
| 5.                    |                                 |              |       | 24.           |           |                           |                  |
| 6.                    |                                 |              |       | 25.           |           |                           |                  |
| 7.                    |                                 |              |       | 26.           |           |                           |                  |
| 8.                    |                                 |              |       | 27.           |           |                           |                  |
| 9.                    |                                 |              |       | 28.           |           |                           |                  |
| 10.                   |                                 |              |       | 29.           |           |                           |                  |
| 11.                   |                                 |              |       | 30.           |           |                           |                  |
| 12.                   |                                 |              |       | 31.           |           |                           |                  |
| 13.                   |                                 |              |       | 32.           |           |                           |                  |
| 14.                   |                                 |              |       | 33.           |           |                           |                  |
| 15.                   |                                 |              |       | 34.           |           |                           |                  |
| 16.                   |                                 |              |       |               |           |                           |                  |
| 17.                   |                                 |              |       |               |           |                           |                  |
| 18.                   |                                 |              |       |               |           |                           |                  |
| 19.                   |                                 |              |       |               |           |                           |                  |
| Min. Shipper V        | Weight:                         |              |       | Max. Shipper  | Weight:   |                           |                  |
| Chec                  | eked By (Production S           | upervisor)   |       |               | Verif     | y By (IPQ                 | <b>A</b> )       |
|                       |                                 |              |       |               |           | -                         |                  |
|                       |                                 |              |       |               |           |                           |                  |
| Loose Shipper N       | No.:                            |              | ,     |               |           |                           |                  |
|                       | Prepare                         | d By         |       | Checked By    |           | $\mathbf{A}_{\mathbf{j}}$ | pproved By       |
| Signature             |                                 |              |       |               |           |                           |                  |



PRODUCTION DEPARTMENT

| RA | TCH | $\mathbf{P}\mathbf{A}$ | CKING | RECORD |
|----|-----|------------------------|-------|--------|
|    |     |                        |       |        |

| <b>Product Name:</b>   | Generic Name: At   | enolol Tablets IP 50 mg   |
|------------------------|--------------------|---------------------------|
| <b>Effective Date:</b> |                    | <b>Page No.:</b> 20 of 23 |
| Batch No.:             | <b>Batch Size:</b> | Supersedes No.: Nil       |

#### 7.0 RECONCILIATION OF PACKING MATERIAL:

| S.No. | Material                        | Printed Aluminum foil | Base foil | Printed<br>Cartons | BOPP Tape | Shippers |
|-------|---------------------------------|-----------------------|-----------|--------------------|-----------|----------|
| 1.    | Std. Qty.                       |                       |           |                    |           |          |
| 2.    | Quantity Issued                 |                       |           |                    |           |          |
| 3.    | Extra Qty. issued               |                       |           |                    |           |          |
| 4.    | Qty. used                       |                       |           |                    |           |          |
| 5.    | Qty. returned (attach MRN)      |                       |           |                    |           |          |
| 6.    | Qty. destroyed after coding     |                       |           |                    |           |          |
| 7.    | Qty destroyed after pkg.        |                       |           |                    |           |          |
| 8.    | Total qty. destroyed            |                       |           |                    |           |          |
| 9.    | Qty. destroyed by               |                       |           |                    |           |          |
| 10.   | Checked by Prod. (Sign/date)    |                       |           |                    |           |          |
| 11.   | Verified by IPQA<br>(Sign/date) |                       |           |                    |           |          |
| 12.   | Remarks                         |                       |           |                    |           |          |

### 8.0 FINISH PRODUCT SAMPLING AND QUALITY CONTROL APPROVAL:

Production person shall raise the sample request and provide to IPQA for sampling. IPQA shall perform sampling as per respective SOP and sent to QC.

| <b>Requisition raised By (Packing Supervisor):</b> | Sampled By (IPQA): |  |
|--|--------------------|--|
|  | 1 , 0 ,            |  |

### **Sampling Details:**

| Sr.No.                 | Sample detail       | Date | Quantity | Sampled By |
|------------------------|---------------------|------|----------|------------|
| 1.                     | Sample for analysis |      |          |            |
| 2.                     | Control Samples     |      |          |            |
| 3.                     | Stability Samples   |      |          |            |
| 4.                     | Other Sample        |      |          |            |
| Total Qty. of samples= |                     |      |          |            |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



Date

# PHARMA DEVILS

PRODUCTION DEPARTMENT

|                    | BAT  | CH PACKING R                       | ECORD      |                   |               |             |
|--------------------|--|------------------------------------|------------|-------------------|---------------|-------------|
| Produc             | ct Code:                                       |                                    | BPR No.:   |                   |               |             |
| Produc             | ct Name:                                       |                                    | Generic Na | ame: Atenolol 7   | Γablets IP 50 | O mg        |
| Effecti            | ve Date:                                       |                                    |            |                   | Page No.:     | 21 of 23    |
| Batch 1            | No.:   | Batc                               | h Size:    |                   | Supersed      | es No.: Nil |
| Trai<br><b>Dat</b> | IISHED GOODS TRANS                             |                                    |            | ch a copy of T.T. | . to BPR      |             |
|                    | No. of shippers packed                         |                                    |            |                   |               |             |
|                    | er shipper                                     |                                    |            |                   |               |             |
|                    | blister per Carton  Tablets transferred to BSR |                                    |            |                   |               |             |
|                    | shippers transferred to BS                     |                                    |            |                   |               |             |
|                    | er note No.                                    | N.                                 |            |                   |               |             |
|                    | f Packing Supervisor                           |                                    |            |                   |               |             |
|                    | f BSR Supervisor                               |                                    |            |                   |               |             |
|                    | TCH RECONCILIATIO                              | DN:                                |            |                   |               |             |
| S.No.              |  | Particulars                        |            | In F              | Κg            | In No.      |
| 1.                 | Qty of Tablets received                        | by packing departme                | ent        |                   |               |             |
| 2.                 | Partial  |                                    |            |                   |               |             |
| 3.                 | Packing loss (Non recov                        | erable)                            |            |                   |               |             |
| 4.                 | Quantity actually transfe                      | rred to FG Store                   |            |                   |               |             |
| 5.                 | Sample:  |                                    |            |                   |               |             |
| 5a.                | Analysis Sample Qty.                           |                                    |            |                   |               |             |
| 5b.                | Control Samples Qty.                           |                                    |            |                   |               |             |
| 5c.                | Stability Sample Qty.                          |                                    |            |                   |               |             |
| 5d.                | Other Sample Qty.                              |                                    |            |                   |               |             |
| 6.                 | Total packed Quantity (4                       | 1+5a+5b+5c+5d)                     |            |                   |               |             |
| 7.                 | Accountability=                                |                                    |            |                   |               |             |
|                    | Reconciliation of Batch                        | Yield:                             |            |                   |               |             |
|                    | В  | ity Packed (6) + Part<br>atch size |            |                   |               |             |
|                    | =  | % (NLT 97.0                        | %)         |                   |               |             |
| Remark             | <b>::</b>                                      |                                    |            |                   |               |             |
|                    | (Packing Superviser)                           |                                    |            | (II               | PQA)          |             |
|                    | Pre  | pared By                           | Check      | ed Bv             | An            | proved By   |
| Signat             |  | J                                  |            |                   | P             |             |



PRODUCTION DEPARTMENT

|                                 | BATCH PACKI        | NG KECOKD                 |                       |                      |
|---------------------------------|--------------------|---------------------------|-----------------------|----------------------|
| Product Code:                   |                    | BPR No.:                  |                       |                      |
| Product Name:                   |                    | Generic Na                | ame: Atenolol Tablets | IP 50 mg             |
| <b>Effective Date:</b>          |                    |                           | Page                  | <b>No.:</b> 22 of 23 |
| Batch No.:                      |                    | Batch Size:               | Super                 | rsedes No.: Nil      |
| 11.0 DEVIATION APPRO            | OVAL:              |                           |                       |                      |
| Deviation No.                   | Reason for dev     | viation                   |                       |                      |
| 12.0 REVIEW OF BPR:             |                    |                           | Date:                 |                      |
| Particulars                     |                    |                           | Status                | Checked By QA        |
| Signature of Authorized Per     | sons               |                           |                       |                      |
| <b>Contents and Enclosures:</b> |                    | 1                         |                       |                      |
| PM Requisition                  |                    |                           |                       |                      |
| PM Issue Order                  |                    |                           |                       |                      |
| Excess material issue note, i   | fany               |                           |                       |                      |
| PM return note (if applicabl    | e)                 |                           |                       |                      |
| Specimens of Packing mater      | rial               |                           |                       |                      |
| In Process packing control r    |                    |                           |                       |                      |
| TR of Finished Product Pac      | k                  |                           |                       |                      |
| COA of Finished Product         |                    |                           |                       |                      |
| FG Goods Transfer Note          |                    |                           |                       |                      |
| Final Dispatch Note             |                    |                           |                       |                      |
| Destruction and approvals       |                    |                           |                       |                      |
| Deviation and its Justification | on                 |                           |                       |                      |
| Reconciliation and Yields       |                    |                           |                       |                      |
| Legibility of contents          |                    |                           |                       |                      |
| 13.0 DISPATCH ADVI              |                    |                           |                       |                      |
| Product:                        |                    | OR THE USE OF QA O<br>-   | ONLY) Batch No:       |                      |
| Qty. Released:                  |                    |                           | A.R. No:              |                      |
| Released Date:                  |                    |                           |                       |                      |
| The BPR has been                | reviewed and the a | bove batch is released fo | or Dispatch.          |                      |
| Signature of QA M               | anager/Designee:   |                           | Date:                 |                      |
|                                 |                    |                           |                       |                      |
|                                 |                    |                           |                       |                      |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |



PRODUCTION DEPARTMENT

### BATCH PACKING RECORD

| <b>Product Code:</b>   | BPR No.:                                | I                         |  |
|------------------------|---|---------------------------|--|
| <b>Product Name:</b>   | Generic Name: Atenolol Tablets IP 50 mg |                           |  |
| <b>Effective Date:</b> |   | <b>Page No.:</b> 23 of 23 |  |
| Batch No.:             | Batch Size:                             | Supersedes No.: Nil       |  |

### 14.0 HISTORY SHEET:

| BPR No. | New BPR No. | Revision No. | Reason of revision | Change Control No. |
|---------|-------------|--------------|--------------------|--------------------|
|         |             | 00           |                    |                    |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |