



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

- 1.1 To lay down a procedure for Cleaning and Operation of Barcode Printer to create the Barcode Labels, Selection of GTIN for different Packing levels and procedure for Coding and Labeling of Secondary and Tertiary Packaging Material.

2.0 SCOPE:

- 2.1 This procedure is applicable for Cleaning and Operation of Barcode Printer to create the Barcode Labels, Selection of GTIN for different Packing levels and procedure for Coding and Labeling of Secondary and Tertiary Packaging Material. in production department.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate Production: For execution of coding activity
- 3.2 Officer and Executive: Cleaning and operation for Barcode Printer for Label Generation.
- 3.3 IPQA – For Specimen approval.
- 3.4 Head-Production/ Designee: SOP compliance.

4.0 DEFINITION (S):

- 4.1 **GTIN:** It stands for Global Trade Item Number and contains 14 digits unique number which used to identify the trade items. GTIN is uniquely assigned to every levels of packaging of product.

Example of GTIN for US market:

Example of GTIN for other market:

- 4.2 **NDC:** It stands for National Drug Code, is a unique 10-digit, 3-segment number. It is a universal product identifier for human drugs in the United States. The 3-segments of the NDC identify the labeler, the product, and the commercial package size. The first set of numbers in the NDC identifies the labeler (manufacturer, re-packer, or distributor). The second set of numbers is the product code, which identifies the specific strength, dosage form (i.e., capsule, tablet, liquid) and formulation of a drug for a specific manufacturer. Finally, the third set is the package code, which identifies package sizes and types. The labeler code is assigned by the FDA, while the product and package code are assigned by the labeler.

Example of NDC: 33342-050-10

33342: Identify the labeler (manufacturer, re-packer, or distributor).



PHARMA DEVILS

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Department: Production	SOP No.:
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Supersedes: Nil	Review Date:
Issue Date:	Page No.:

050 : Identify the product Code.

10 : Identify the Package Code.

4.3 **Secondary Packing Material:** Packing Material such as cartons, outer cartons, 3 or 5 ply inner shippers etc.

4.4 **Tertiary Packing Materials:** Packing Material such as 5 ply, 7 ply Outer Shipper.

5.0 PROCEDURE:

5.1 CLEANING

- 5.1.1 Ensure that all the materials of previous batch are removed from the printer.
- 5.1.2 Switch 'OFF' the utility supply before cleaning.
- 5.1.3 Clean the control panels with clean and dry lint free cloth.
- 5.1.4 Clean the top and outer surface of printer with the dry lint free cloth.

5.2 OPERATION PROCEDURE:

5.2.1 Procedure for selection of GTIN number for US market:

GTIN for US market shall be consisting of 14 Digits as NDC based as follow:

Indicator Digit (Packing Level): 1 Digit

Country Code: 2 Digits

NDC number assigned for the product: 10 Digits

Check Digit: 1 Digit

Indicator digit would change depending upon the differesnt packing levels i.e. Primary, Secondary Tertiary and Pallet.

5.2.2 A typical GTIN number would look like 00333342054074 which is of 14 digits where in :

- 0 represent the Indicator Digit for Primary Packing Level.
- 03 02 digits represent the Country Code
- 3334205407 10 digits Stands for NDC number of the product
- 4 represent the check Digit.

5.2.3 The indicator digit would change depending upon the different levels of packing.

There can be multiple packing levels and indicator digit would be in increment pattern as per the packing sequence of product for US markets.

5.2.4 Example discussed below for elaboration by considering the different packing patterns in bottle pack.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Case1: If labeled bottles are packed in inner shipper and then outer shipper

- 0** It would be the indicator digit for GTIN on sticker label of bottle pack.
GTIN would be 00333342054074
- 1** It would be the indicator digit for GTIN of inner shipper.
GTIN would be 10333342054074
- 5** It would be the indicator digit for GTIN of outer shipper.
GTIN would be 50333342054074
- 6** It would be the indicator digit for GTIN for pallet level.
GTIN would be 60333342054074

Case2: If labeled bottles are packed in carton then inner shipper and then outer shipper.

- 0** It would be the indicator digit for GTIN on sticker label of bottle pack.
GTIN would be 00333342054074
- 1** It would be the indicator digit for GTIN of carton containing the Bottles.
GTIN would be 10333342054074
- 2** It would be the indicator digit for GTIN of inner shipper containing cartons.
GTIN would be 20333342054074
- 5** It would be the indicator digit for GTIN of outer shipper containing inner shippers.
GTIN would be 50333342054074
- 6** It would be the indicator digit for GTIN for pallet level.
GTIN would be 60333342054074

5.2.5 Example discussed below for elaboration by considering the different packing patterns in Blister pack.

Case 1: If blisters are packed in carton and then in outer shipper.

- 0** It would be the indicator digit for GTIN on Blister pack (If Applicable).
GTIN would be 00333342054074
- 1** It would be the indicator digit for GTIN of carton.
GTIN would be 10333342054074
- 5** It would be the indicator digit for GTIN of outer shipper.
GTIN would be 50333342054074



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6 It would be the indicator digit for GTIN for pallet level.
GTIN would be 60333342054074

Case 2: If blisters are packed in inner carton and outer carton then in outer shipper.

0 It would be the indicator digit for GTIN on Blister pack (If Applicable).
GTIN would be 00333342054074

1 It would be the indicator digit for GTIN of inner carton.
GTIN would be 10333342054074

2 It would be the indicator digit for GTIN of outer carton.
GTIN would be 20333342054074

5 It would be the indicator digit for GTIN of outer shipper.
GTIN would be 50333342054074

6 It would be the indicator digit for GTIN for pallet level.
GTIN would be 60333342054074

5.3 Procedure for selection of GTIN number for other market:

GTIN for other market shall be consisting of 14 Digits as follow:

Indicator Digit (Packing Level) : 1 Digit

GS1 based company Code: 7 Digits

ERP based product code: 5 Digits

Check Digit: 1 Digit

Indicator digit would change depending upon the different packing levels i.e. Primary, Secondary Tertiary and Pallet.

5.3.1 A typical GTIN number would look like 08901463057985 which is of 14 digits where in :

- 0 represent the Indicator Digit for Primary Packing Level.
- 8901463 07 digits Stands for GS1 based Company Code.
- 05798 05 digits Stands for FG Code (Last 5 Digit from FG Code).
- 5 represent the check Digit.

5.3.2 The indicator digit would change depending upon the different levels of packing.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

There can be multiple packing levels and indicator digit would be in increment pattern as per the packing sequence of product for other markets.

Case 1: If labeled bottles are packed in inner shipper and then in outer shipper.

- 0** It would be the indicator digit for GTIN on sticker label of bottle pack.
GTIN would be **0**8901463057985
- 1** It would be the indicator digit for GTIN of inner shipper containing the Bottles.
GTIN would be **1**8901463057985
- 5** It would be the indicator digit for GTIN of outer shipper containing inner shipper.
GTIN would be **5**8901463057985
- 6** It would be the indicator digit for GTIN for pallet level.
GTIN would be **6**8901463057985

Case 2: If labeled bottles are packed in carton then inner shipper and then outer shipper.

- 0** It would be the indicator digit for GTIN on sticker label of bottle pack.
GTIN would be **0**8901463057985
- 1** It would be the indicator digit for GTIN of carton containing the Bottles.
GTIN would be **1**8901463057985
- 2** It would be the indicator digit for GTIN of inner shipper containing cartons.
GTIN would be **2**8901463057985
- 5** It would be the indicator digit for GTIN of outer shipper containing inner shippers.
GTIN would be **5**8901463057985
- 6** It would be the indicator digit for GTIN for pallet level.
GTIN would be **6**8901463057985

5.4 Procedure for Coding of Secondary and Tertiary Packaging Material :

- 5.4.1 Technical associate production shall collect the Rubber letter from designated place. Coder shall be set by technical associate production as per the given information and instruction in Batch Packaging Record.
- 5.4.2 Impression shall be taken on a blank A4 size paper after completion of setting.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.4.3 Impression shall be verified by production officer / Executive for correctness of details and final approval by IPQA officer / Executive as per details provided in batch packaging record and attach the same with Batch Packaging Record.
- 5.4.4 Technical associate production shall collect the Rubber letter from designated place.
- 5.4.5 Coder shall be set by technical associate production as per the given information and instruction in Batch Packaging Record.
- 5.4.6 Impression shall be taken on a blank A4 size paper after completion of setting and final approval by IPQA officer / Executive as per details provided in batch packaging record and attach the same with Batch Packaging Record.
- 5.4.7 If impression is not matching with requirement of Batch Packaging Record in view of information, spelling, pack profile etc. then again correct the coder and again take approval from production as well as IPQA officer / executive and attach the same with Batch Packaging Record.
- 5.4.8 After approval, start the coding activity of secondary as well as tertiary packaging material as required.
- 5.4.9 After completion of the coding activity again take the impression on a blank A4 size paper and same impression shall be verified by production officer / executive, take the approval from Quality Assurance, in view of correct information attach the approved sheet to the Batch Packaging Record.
- 5.4.10 If any letter missing in last impression then all coded packaging material shall be re-verified for the correct impression, If any fault found in the coding then it shall be rectified with consultation of Head of Production and Quality Assurance.
- 5.4.11 In case of Loose or less quantity of product in secondary and tertiary packaging material strikes out the quantity printed on shipper and specimen and write the actual quantity manually.
- 5.4.12 After completion of coding activity remove all rubber letter, from coder, Clean the coder and rubber Letter with the help of lint free duster soaked with IPA followed by dry lint free duster.
- 5.4.13 Store The rubber Letter at designated place.
- 5.4.14 In case of Hand coder collect the coder along with rubber stereos from designated place and again after completion of coding and cleaning of coder activity, store the hand coder at designated place.
- 5.5 Labeling (paper label) of secondary and tertiary packaging material**
- 5.5.1 Prepare the label with the help of computer as per the requirement of the market and Batch Packaging Record with all required data. Refer the document like work order, Batch Packaging Record etc. to prepare labels.



PHARMA DEVILS

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STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
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Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.5.2 Take first print, verify the printing details by production and take the approval from IPQA as per the Batch Packaging Record and attach the approved specimen to the Batch Packaging Record.
- 5.5.3 If the label is not matching with requirement of Market or Batch Packaging Record in view of information, spelling, pack profile etc. then again correct the label and again take approval from production as well as IPQA officer / executive and attach the same with Batch Packaging Record.
- 5.5.4 After approval take print of all required number of label.
- 5.5.5 In case of loose inner / shipper take two print for label with revised quantity, Verify by production, take approval from IPQA and attach one label to the Batch Packaging record as specimen and one to the respective secondary and tertiary packaging material, Apply "LOOSE" Tape on the loose shipper.
- 5.6 **Procedure for label creation without ERP on barcode printer.**
- 5.6.1 Switch on the mains of printer from front side Open the printer. Double click Nicelabel Pro icon on Computer screen and create new label.
- 5.6.2 Then press next button in computer till label dimension screen appear. Enter the size of the label in label width and label height window then press finish button to create new label.
- 5.6.3 To enter text matter on label select Text Button present on left side of the Screen then click on the label. Text Object Screen will appear on display put entry in window and click on finish button, Set font as per requirement by changing font size also rotate the object by rotate button present on right side of screen and put it on label as per requirement.
- 5.6.4 Repeat the above procedure for every font to be put on label.
- 5.6.5 For Barcode printing select Barcode option on right side of screen then click on label then Barcode wizard screen will appear click on define button and select GS1 and then GS1-128 option.(Or select Barcode option as per requirement)
- 5.6.6 Then press next button on screen then list of application identifier screen will appear for Selection.
- 5.6.7 Then select application identifier, which is required click on next button till application value screen appears and enter the value and click finish button.
- 5.6.8 If another application required in same line the press add button and enter the value then click finish button.
- 5.6.9 Set Barcode as per requirement by changing size also rotate the object by rotate button present on right side of screen and put it on label as per requirement.
- 5.6.10 Repeat the above procedure for every barcode generation to be put on label.
- 5.6.11 Generate the Barcode label as per requirement and check the barcode correctness by using barcode reader.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.6.12 GTIN number shall be entered in system. Then click on the print option and take required quantity print also reconcile the label.

5.7 Procedure for label printing through ERP system on barcode printer.

5.7.1 Generation of serial number for Secondary packing Level for USA.

5.7.1.1 On connecting to the ERP system, Go to Manufacturing menu option, click Production, click on A. Work Order. Double click on A. Work Order as displayed in Figure 1.

5.7.1.2 Now select the "Search Option" from upper right side of window and then select "View Data" from upper left side of window.

5.7.1.3 All the data will be come out of products for which work order no. generated in ERP system. Enter the desired lot number (for which barcode label to be generated) in space given against the "Filter" option at upper right side of the window and click on icon near "Filter".

5.7.1.4 Desired lot number with product name and other detail will be list out. Right click on the transaction and select "Secondary Number Generate" option as display in figure 1.

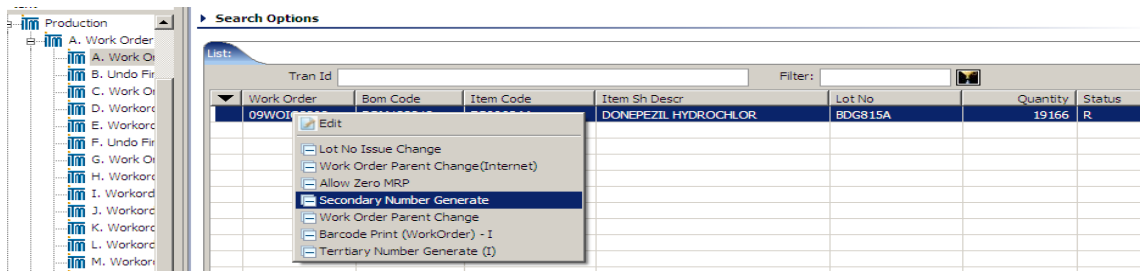


Figure 1

5.7.1.5 A window would appear with the data populated from the transaction selected above and as displayed in figure 2. Click on GTIN NO and Enter the GTIN as per packing level .Click on the 'Generate' button to generate the serial numbers for barcode labels. System shall display message as "Request done Successfully".

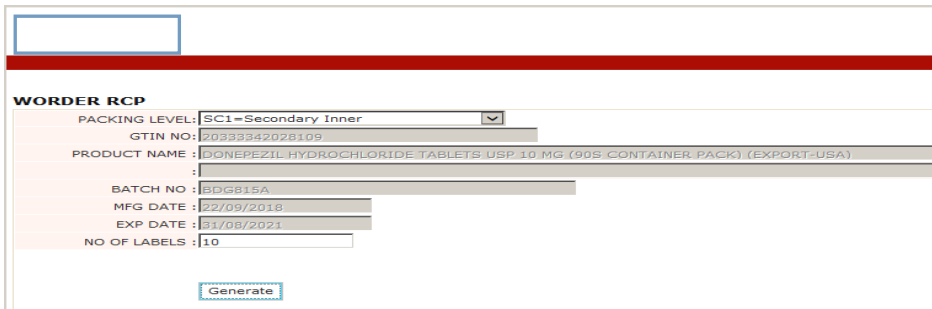


Figure 2



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.7.1.6 After Clicking on Generate, System shall display message as “Request done successfully”.

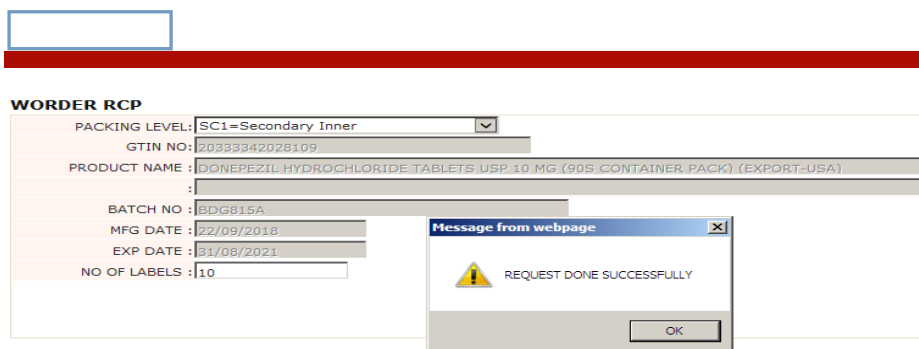


Figure 3

5.7.2 Procedure for printing of Secondary barcode labels through ERP System for USA market.

5.7.2.1 Connecting to the ERP system, Go to Manufacturing menu option, click on Production, then click on A. Work Order. Double click on A. Work Order as displayed in

Figure 4. Now select the “Search Option” from upper right side of window and then select “View Data” from upper left side of window.

5.7.2.2 All the data will be come out of products for which work order no. generated in ERP system.

5.7.2.3 Enter the desired lot number (for which barcode label to be generated) in space given against the “Filter” option at upper right side of the window and click on icon near “Filter”.

5.7.2.4 Desired lot number with product name and other detail will be list out.

5.7.2.5 Right click on the work order transaction and select “Barcode Print (Workorder)-I ” option as display in Figure 4.

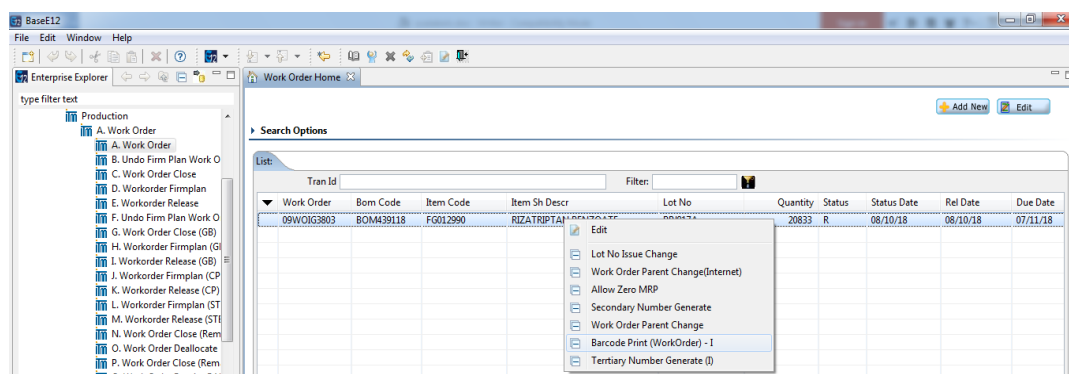


Figure 4



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.7.2.6 A window would appear with the data populated and shall be displayed as in Figure 5. For Secondary barcode label, User shall select the label type as 'Secondary'. Storage and Manufactured For option shall be remains blank in Label Print.

Label Print

TRAN ID: S9WOLG2106	GTIN: 10316714919017	PRINT FORMAT: MM/YYYY
ITEM: PRAMIPEXOLE DIHYDROCHLORIDE EXTENDED - RELEASE TABLETS 2.25 MG (30S)		
BATCH No. BPB32104B	MFG. DATE: 27/05/2021	EXPIRY DATE: 30/04/2024
Qty/Shipper: 36	Qty/Secondary: 6	Label Type: Secondary Inner ▼
Storage:	Manufactured For:	-Select Tertiary Secondary Inner
Manufactured By: MACLEODS PHARMACEUTICALS LTD.BADDI,HIMACHAL PRADESH,INDIA		
For Market: USA ▼	Label Between: 1	9999

GET DATA

Figure 5

5.7.2.7 Click on the 'Get Data' option to displays the details and Click on the 'Print' button to print the secondary barcode labels. Refer Figure 6.

Label Print

TRAN ID: S9WOLG2106	GTIN: 10316714919017	PRINT FORMAT: MM/YYYY
ITEM: PRAMIPEXOLE DIHYDROCHLORIDE EXTENDED - RELEASE TABLETS 2.25 MG (30S)		
BATCH No. BPB32104B	MFG. DATE: 27/05/2021	EXPIRY DATE: 30/04/2024
Qty/Shipper: 36	Qty/Secondary: 6	Label Type: Secondary Inner ▼
Storage:	Manufactured For:	
Manufactured By: MACLEODS PHARMACEUTICALS LTD.BADDI,HIMACHAL PRADESH,INDIA		
For Market: USA ▼	Label Between: 1	9999

GET DATA

Select Printer	SATO CL4NX 305dpi ▼
Reprint No	▼ ExpFormat MM/YYYY
Label to print	2DUSA ▼

SR.N	Item Name	Lot Number	Expiry	GTIN	SSCC	cc ▲
0	PRAMIPEXOLE DIHYDROCHLORIDE E	BPB32104B	30/04/2024	60316714919012	221001881939	▲
1	PRAMIPEXOLE DIHYDROCHLORIDE E	BPB32104B	30/04/2024	60316714919012	221001881939	▲
2	PRAMIPEXOLE DIHYDROCHLORIDE E	BPB32104B	30/04/2024	60316714919012	221001881940	▲
3	PRAMIPEXOLE DIHYDROCHLORIDE E	BPB32104B	30/04/2024	60316714919012	221001881941	▲
4	PRAMIPEXOLE DIHYDROCHLORIDE E	BPB32104B	30/04/2024	60316714919012	221001881942	▲
5	PRAMIPEXOLE DIHYDROCHLORIDE E	BPB32104B	30/04/2024	60316714919012	221001881943	▲
6	PRAMIPEXOLE DIHYDROCHLORIDE E	BPB32104B	30/04/2024	60316714919012	221001881944	▲

Print

Figure 6

5.7.2.8 If any improper overprinting observed on label; Reprint Provision is given to over print the subjected label by slecting the label between option from template..

5.7.2.9 Standard Format for Secondary packing label shall be as Figure 7.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

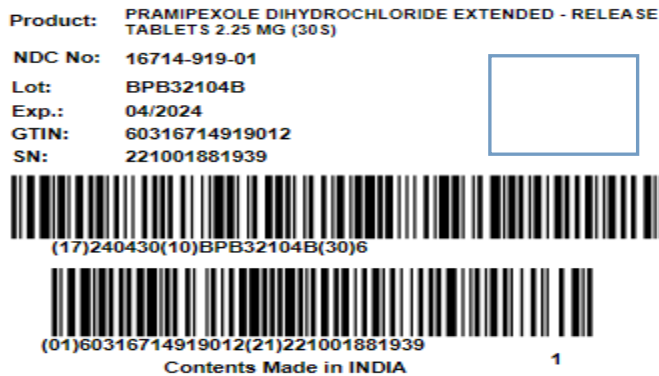


Figure 7

5.7.2.10 Standard label of Secondary packing level contains the following contents:

1. 2D Code (Data Matrix Code) having application identifier as (01)(21)(17)(10).
2. Liner Barcode Contains application identifier as (17)(10) (30) on first barcode.
3. Liner Barcode Contains application identifier as (01)(21) on Second barcode.

5.7.3 Procedure for printing of Secondary labels (Without Barcode) through ERP System.

5.7.3.1 Connecting to the ERP system, Go to Manufacturing menu option, click on Production, then click on A. Work Order. Double click on A. Work Order as displayed in

Figure 8. Now select the “Search Option” from upper right side of window and then select “View Data” from upper left side of window.

5.7.3.2 All the data will be come out of products for which work order no. generated in ERP system.

5.7.3.3 Enter the desired lot number (for which labels to be generated) in space given against the “Filter” option at upper right side of the window and click on icon near “Filter”.

5.7.3.4 Desired lot number with product name and other detail will be list out.

5.7.3.5 Right click on the work order transaction and select “Inner pack Label w/o 2D” option as display in Figure 8.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
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Supersedes: Nil	Review Date:
Issue Date:	Page No.:

The screenshot shows a software interface with a navigation tree on the left and a search results table on the right. The navigation tree includes options like 'Production', 'A. Work Order', 'B. Undo Firm Plan Worl', and 'C. Work Order Close'. The search results table is titled 'List:' and has a filter set to 'BVV2101A'. The table contains one row of data:

Work Order	Bom Code	Item Code	Item Sh Descr	Lot No	Quantity	Status	Status Date	Rel Date
S9WOLG2102	BOM159020	FG013224	VARDENAFIL HYDROCHLO	BVV2101A	34107	R	10/06/21	10/06/21

Figure 8

- 5.7.3.6 A window displayed with the data as in Figure 9. for secondary label, user shall verify batch details with respect of batch packing records .
- 5.7.3.7 Number of label to be enter in system as per quantity dispensed in BOM sheet.
- 5.7.3.8 Click on “GET DATA to print the labels from ERP system.

The screenshot shows a 'Label Print' form with the following fields:

- TRAN ID:** S9WOLG2102
- PRINT FORMAT:** MM-YYYY
- ITEM:** VARDENAFIL HYDROCHLORIDE TABLETS 5 MG (JAMP-VARDENAFIL 5 MG)(1X4S CARTON PACK)(CANADA)
- PACK STYLE:** 24X10X1X1X4
- BATCH No.:** BVV2101A
- EXPIRY DATE:** 04-2023
- MFG DATE :** 05-2021
- Number of Labels:** 1

A 'GET DATA' button is located at the bottom of the form.

Figure 9

- 5.7.4 **Procedure for generation of Tertiary packing serial number through ERP for USA and Other Market.**
 - 5.7.4.1 On connecting to the ERP system, Go to Manufacturing menu option, click Production, click on A. Work Order. Double click on A. Work Order as displayed in Figure 10. Now select the “Search Option” from upper right side of window and then select “View Data” from upper left side of window.
 - 5.7.4.2 All the data will be come out of products for which work order no. generated in ERP system.
 - 5.7.4.3 Enter the desired batch no. (for which barcode label to be generated) in space given against the “Filter” option at upper right side of the window and click on icon near “Filter”. Desired Lot number with product name and other detail will be list out.
 - 5.7.4.4 Right click on the transaction and select “Tertiary Number Generate” option as display in figure 10.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

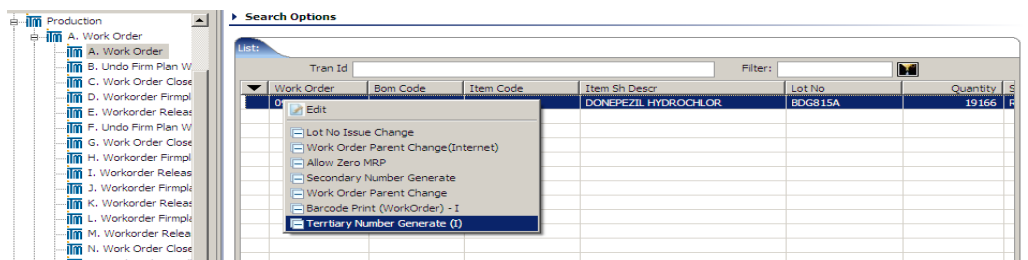


Figure 10

5.7.4.5 A window would appear with the data populated from the transaction selected above and as displayed in Figure 11.

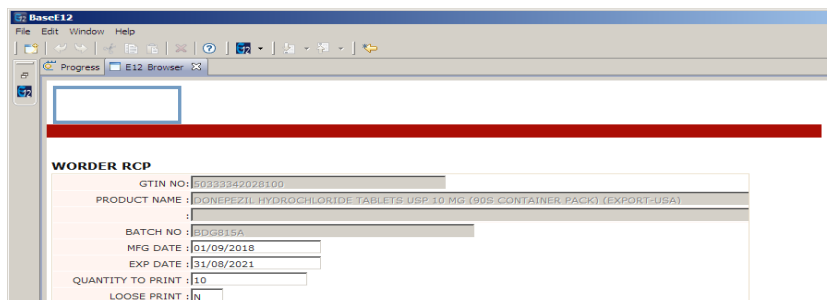


Figure 11

5.7.4.6 Click on the 'Generate' option from button to generate serial numbers for tertiary labels. System shall display message as "Request done successfully".

5.7.5 Procedure for printing of Tertiary barcode labels through ERP for USA and Non USA market.

5.7.5.1 On connecting to the ERP system, Go to manufacturing menu option, click Production, click on A. Work Order. Double click on A. Work Order as displayed in Figure 11. Now select the "Search Option" from upper right side of window and then select "View Data" from upper left side of window.

5.7.5.2 All the data will be come out of products for which work order no. generated in ERP system.

5.7.5.3 Enter the desired lot number (for which barcode label to be generated) in space given against the "Filter" option at upper right side of the window and click on icon near "Filter".

5.7.5.4 Desired lot number with product name and other detail will be list out.

5.7.5.5 Right click on the work order transaction and select "Barcode Print (Workorder)" option as display in Figure 12.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

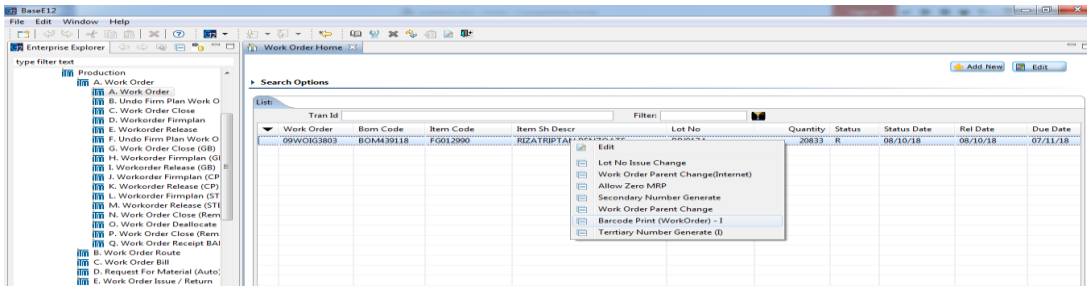


Figure 12

5.7.5.6 A window would appear with the data populated from the transaction selected above and as displayed in Figure 13.

Label Print			
TRAN ID:	S9WOLG2106	GTIN:	10316714919017
ITEM:	PRAMIPEXOLE DIHYDROCHLORIDE EXTENDED - RELEASE TABLETS 2.25 MG (30S)		
BATCH No.	BPB32104B	MFG. DATE:	27/05/2021
Qnty/Shipper:	36	Qnty/Secondary:	6
Storage:	[See USP Controlled Room Temperature].	Label Type:	Tertiary
Manufactured For:	MACLEODS PHARMA USA, Inc. Plainsboro, NJ 08536		-Select Tertiary Secondary Inner
For Market:	USA	Label Between:	1 9999
GET DATA			

Figure 13

5.7.5.7 Select the label type as Tertiary Label form Label type.

5.7.5.8 Fill the blank details in Label Print Display (Like: Storage, Manufactured For, Manufactured By and For Market select USA/ROW etc.).

5.7.5.9 For USA market select the Market as “USA” and for other Market, select market as ‘ROW’. Then Click on the ‘Get Data’ option to displays the serial numbers for barcode labels. Refer Figure 14 for USA Market and Figure 15 for Other Market.

Label Print			
TRAN ID:	S9WOLG2106	GTIN:	10316714919017
ITEM:	PRAMIPEXOLE DIHYDROCHLORIDE EXTENDED - RELEASE TABLETS 2.25 MG (30S)		
BATCH No.	BPB32104B	MFG. DATE:	27/05/2021
Qnty/Shipper:	36	Qnty/Secondary:	6
Storage:	Store at 20° to 25°C (68° to 77°F); excurs.	Label Type:	Tertiary
Manufactured For:	MACLEODS PHARMA USA, Inc. Plainsboro, NJ 08536		
Manufactured By:	MACLEODS PHARMACEUTICALS LTD.BADDI,HIMACHAL PRADESH,INDIA		
For Market:	USA	Label Between:	1 9999
GET DATA			

Figure 14



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Label Print					
TRAN ID:	S9WOLG2261	GTIN:	58901463159854	PRINT FORMAT:	MM/YYYY
ITEM:	DOLUTEGRAVIR SODIUM 50 MG LAMIVUDINE 300 MG AND TENOFOVIR DISOPROXIL FUMARATE 300 MG TABLETS (90S COUNT)				
BATCH No.	BDF12167A	MFG. DATE:	19/05/2021	EXPIRY DATE:	30/04/2024
Qty/ Shipper:	160	Qty/ Secondary:	1	Label Type:	Tertiary
Storage:	Do not store above 30°C, protect from light				
Manufactured By:	MACLEODS PHARMACEUTICALS LTD. BADDI, HIMACHAL PRADESH, INDIA				
For Market:	ROW	Label Between:	1	9999	
GET DATA					

Figure 15

5.7.5.10 Click on the 'Print' button to print the Tertiary barcode labels. Standard Format for Tertiary shipper label shall be as Figure 16 for USA market and Figure 17 for other market.


Product Name: PRAMIPEXOLE DIHYDROCHLORIDE EXTENDED - RELEASE TABLETS 2.25 MG (30S)

Manufactured for:


Manufactured by:

Storage Condition: Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

NDC No: 16714-919-01 **Shipper No:** 1 **Gross Weight** **Kg.**
Expiry: 04/2024 **Lot No:** BPB32104B **Quantity:** 36



(17)240430(10)BPB32104B(30)36



(01)10316714919017(21)182155289143
Contents Made in INDIA

Figure 16 (For USA Market)



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:




Product Name: DOLUTEGRAVIR SODIUM 50 MG LAMIVUDINE 300 MG AND TENOFOVIR DISOPROXIL FUMARATE 300 MG TABLETS (90 S COUNT)(MOZAMBIQUE)		
Manufactured for: NA		
Manufactured by:		
Storage Condition: Do not store above 30°C, protect from light. Stored in the original container.		
Mfg.Dt.: 05/2021	Shipper No: 1	Gross Weight Kg.
Exp.Dt.: 04/2024	Lot No: BDF12167A	Quantity: 160
		
(17)240430(10)BDF12167A(30)160		
		
(01)58901463159854(21)182155273142		
Contents Made in INDIA		

Figure 17(For Other Market)

5.7.5.11 Standard label of Tertiary packing level contains the following contents for USA market:

1. 2D Code (Data Matrix Code) having application identifier as (01)(21)(17)(10).
2. Liner Barcode Contains application identifier as (17)(10)(30) on first barcode.
3. Liner Barcode Contains application identifier as (01)(21) on Second barcode.

5.7.5.12 Standard label of Tertiary packing level contains the following contents for other than USA market

1. 2D Code (Data Matrix Code) having application identifier as (01)(21)(17)(10).
2. Liner Barcode Contains application identifier as (17)(10)(30) on first barcode.
3. Liner Barcode Contains application identifier as (01)(21) on Second barcode.

5.8 Procedure for Generation of Loose shipper label.

5.8.1 For the generation of loose shipper label SOP No. ITD/062 (Generation of Secondary and Tertiary packing label in ERP) shall be followed.

5.9 Procedure for the sequence of the 2D barcode of different Contents for different markets at different packing levels.

5.9.1 For the details of sequence of different Application identifiers (AI) of 2D barcode SOP No. ITD/062 shall be followed.

5.10 Procedure for Customer/Consignee/market specific requirement to overprint details on shipper label.

5.10.1 MPC shall guide for overprint any Customer/Consignee/market specific requirement on



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

shipper labels (Inner and Outer).

5.10.2 Same instruction shall be include the Batch packing record as per MPC.

5.10.3 IT department intimated for incorporate the the same instruction in ERP system.

5.10.4 If any instruction is not given in the MPC/BPR then Annexure - I; Annexure for Approval to incorporate the special instruction in the overprinting details on the shipper (Inner/ Outer) Labels.) shall be followed to include that instruction in the shipper (Inner and Outer) labels.

5.11 Precaution

5.11.1 If contents of label are appearing with red color it indicates the object is out of the margin then readjusts it.

5.11.2 Expiry date format must be as YYMMDD.

5.11.3 During overprinting if any improper overprinting observed then subjected label to be reprint.

5.11.4 Never run machine without ribbon or label in the printer.

Sequence of different Application identifiers (AI) of 2D barcode and linear barcode at different packing level and market shall be followed as per SOP (Generation of Secondary and Tertiary packing label in ERP).

5.11.5 Specimen proof to be attach in Batch packing record at initial and end of the batch.

5.11.6 If any breakdown of printer during printing / label tear off during handling/ overprinting error on label observed then specimen proofs shall be re-verified and approved by production and IPQA personnel.

6.0 ABBREVIATION (S):

6.1 SOP: Standard Operating Procedure

6.2 YYMMDD : YY for Year, MM for Month and DD for Date.

6.3 GTIN – Global Trade Item Number

6.4 NDC – National Drug Code

6.5 GS1 – Global Standard for business Communication

6.6 USA – United State America

6.7 AI - Application Identifiers

7.0 REFERENCE (S):

7.1 ITD/044 - Generation of GTIN number.

7.2 ITD/062 - Generation of Secondary and Tertiary packing label in ERP

7.3 ITD/086 - Track and Trace Labelling Requirements.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure - I	Annexure for Approval to incorporate the special instruction in the overprinting details on the shipper (Inner/ Outer) Labels.		Controlled Copy

9.0 DISTRIBUTION:

- 9.1 Master copy: Quality Assurance
- 9.2 Controlled Copy (s): Production (2 Copy)
- 9.3 Reference copy(s): Production (4 Copy)

10.0 REVISION HISTORY:

S. No.	Version No.	Change Control No.	Reason (s) for Revision	Details of Revision	Effective Date



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation of barcode printer to create the barcode labels, selection of GTIN for different packing levels and procedure for coding and labeling of secondary and tertiary packaging material	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE I

Approval to incorporate the special instruction in the Overprinting details on the Shipper (Inner/Outer)Labels

- 1.0 Procedure for incorporating the Special Customer /Consignee/Any Market Specific requirement for overprinting on secondary and tertiary shipper labels.

Product Description:

Product Name:	
Pack Size:	
Market/Customer:	
FG Code:	
MPC No.:	
BPR No.:	

Instruction of Customer /Consignee/Any Market specific requirement:

Initiated By Sign/Date (Production)	Verified By Sign/Date (IPQA)	Verified By Sign/Date (PPIC)	Verified By Sign/Date (Head Production)	Approved By Sign/Date (Head QA)	Updation Done By (Sign/Date) (IT Dept.)