



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure of creating Barcode and selection of GTIN number for different Packing levels	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure of creating Barcode and selection of GTIN number for different packing levels.

2.0 SCOPE:

This procedure is applicable for creating the Barcode and selection of GTIN number for different Packing levels in production department.

3.0 RESPONSIBILITY:

Officer/ Executive- Production: Creating Barcode and printing of Barcode Label.

Head-Production/ Designee: SOP compliance.

IPQA: For Specimen approval.

4.0 DEFINITION (S):

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:

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-packager, 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: ...-....-..

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

... : Identify the product Code.

.. : Identify the Package Code.

5.0 PROCEDURE:

5.1 Procedure for selection of GTIN number for US market:



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure of creating Barcode and selection of GTIN number for different Packing levels	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

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 different packing levels i.e. Primary, Secondary Tertiary and Pallet.

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

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

5.1.2 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.

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

Case 1: 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 0.....

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

GTIN would be 1.....

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

GTIN would be 5.....

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

GTIN would be 6.....

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.....

1 It would be the indicator digit for GTIN of carton containing the Bottles.

GTIN would be 1.....

2 It would be the indicator digit for GTIN of inner shipper containing cartons.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure of creating Barcode and selection of GTIN number for different Packing levels	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

GTIN would be 2.....

5 It would be the indicator digit for GTIN of outer shipper containing inner shippers.

GTIN would be 5.....

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

GTIN would be 6.....

5.1.4 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 0.....

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

GTIN would be 1.....

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

GTIN would be 5.....

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

GTIN would be 6.....

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 0.....

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

GTIN would be 1.....

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

GTIN would be 2.....

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

GTIN would be 5.....

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

GTIN would be 6.....

5.2 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



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure of creating Barcode and selection of GTIN number for different Packing levels	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

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.

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

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

5.2.2 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 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.....

1 It would be the indicator digit for GTIN of inner shipper containing the Bottles.
GTIN would be 1.....

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

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

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.....

1 It would be the indicator digit for GTIN of carton containing the Bottles.
GTIN would be 1.....

2 It would be the indicator digit for GTIN of inner shipper containing cartons.
GTIN would be 2.....

5 It would be the indicator digit for GTIN of outer shipper containing inner shippers.
GTIN would be 5.....



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure of creating Barcode and selection of GTIN number for different Packing levels	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

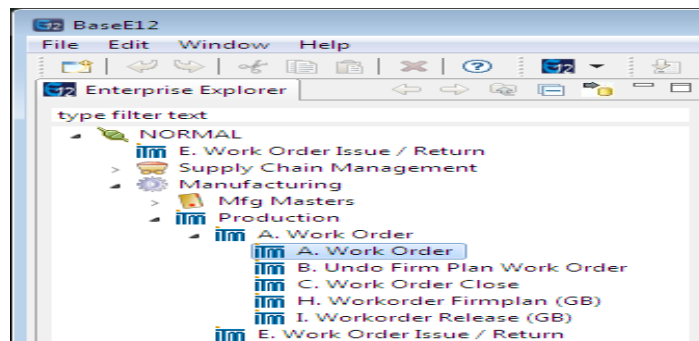
6 It would be the indicator digit for GTIN for pallet level.
GTIN would be 6.....

5.3 Procedure for generation of ERP generated Barcode labels:

5.3.1 Open the ERP system by double click on the icon “BaseE12” on the desktop.

5.3.2 Enter the “USER ID” and “PASSWORD”.

5.3.3 Select the “MANUFACTURING” then “PRODUCTION” then open the “WORK ORDER” option from the window.

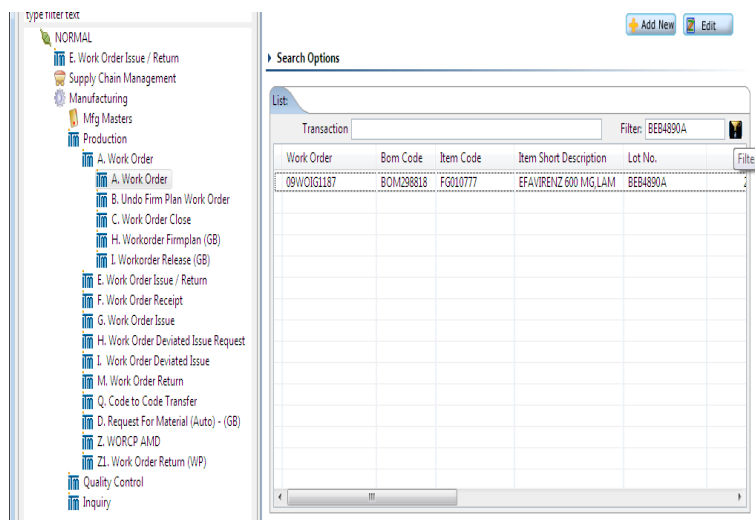


5.3.4 Now select the “SEARCH OPTION” from upper right side of window and then select “VIEW DATTA” from upper left side of window.

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

5.3.6 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”.

5.3.7 Desired batch no. with product name and other detail will be list out.





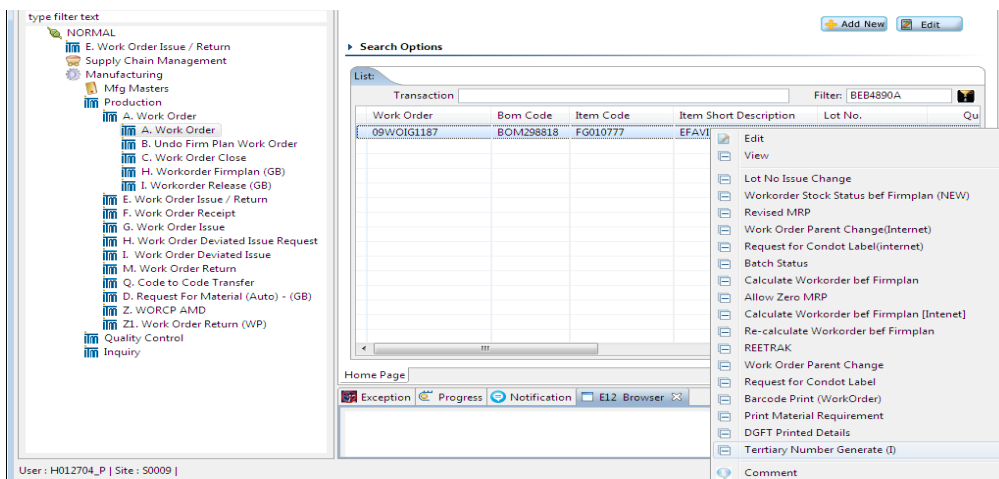
PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure of creating Barcode and selection of GTIN number for different Packing levels	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.3.8 Make right click on line into which all detail of product and select the “BARCODE PRINT”(work order) from the options given as displayed in given window:



5.3.9 New window will be displayed as below given:

WORDER RCP

GTIN NO:	58901463107770
PRODUCT NAME:	EFAVIRENZ 600 MG,LAMIVUDINE 300 MG AND TENOFOVIR DISOPROXIL FUMARATE 300 MG TABL ETS (30S) (PFSCM/UNICEF/GLOBAL FUND)
BATCH NO:	BEB4890A
MFG DATE:	01/05/2018
EXP DATE:	30/04/2020
QUANTITY TO PRINT:	100
LOOSE PRINT:	N
DATE FORMAT:	MM/YYYY
<input type="button" value="Print"/>	

5.3.10 Enter the MFG. DATE, EXP DATE, QUANTTTY TO PRINT and also select type the date format.

5.3.11 Select the “PRINT” option from bottom of window to print the barcode labels generated by system through ERP system.

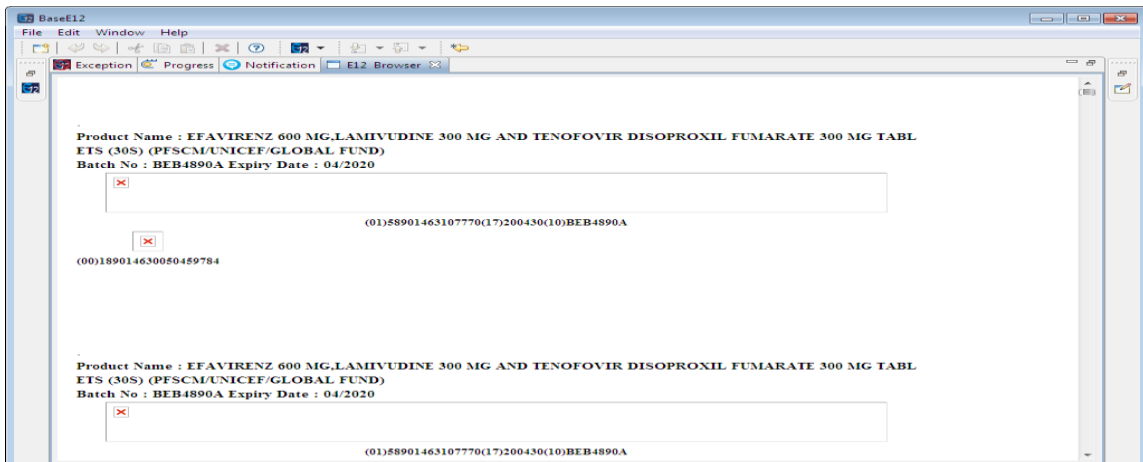


PHARMA DEVILS

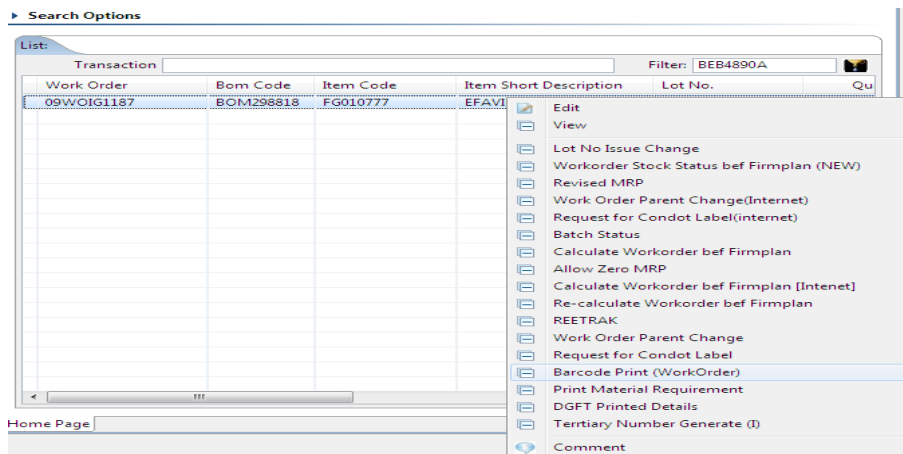
PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

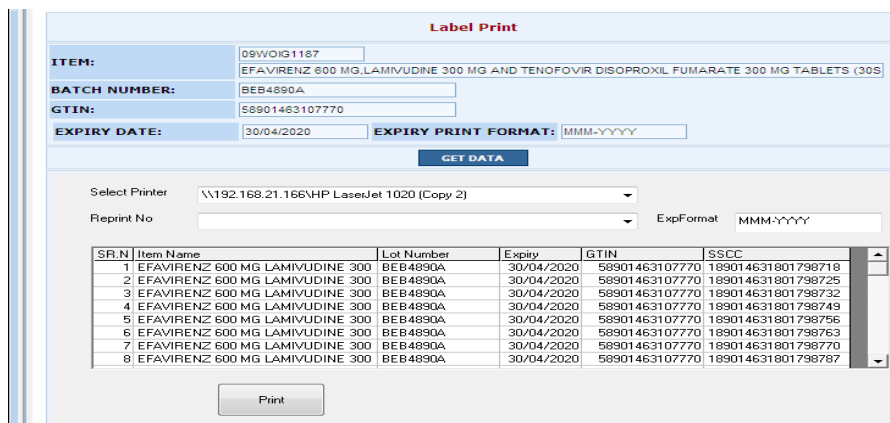
Department: Production	SOP No.:
Title: Procedure of creating Barcode and selection of GTIN number for different Packing levels	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



5.3.12 Now minimize the screen and select the make right click on selected lines and select the barcode Print (Work Order).



5.3.13 Following window would appear on screen and update the expiry date in respected column and click on “GET DATA” option.



5.3.14 Now click on print option to print the barcode labels from ERP system.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure of creating Barcode and selection of GTIN number for different Packing levels	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.4 Precaution:

5.4.1 Precaution to be taken during verification of GTIN for US market and other market.

6.0 ABBREVIATION (S):

SOP - Standard Operating Procedure

GTIN – Global Trade Item Number

NDC – National Drug Code

GS1 – Global Standard for business Communication.

US – United State

7.0 RERERENCE (S):

SOP: Generation of GTIN

8.0 ANNEXURE (S):

Nil

9.0 DISTRIBUTION:

Master Copy : Quality Assurance.

Controlled Copy (S): Production Department, Quality Assurance.

Reference Copy (S): Production Department.