

GS1 barcode requirements

On

Medicines/Drugs procured by Ministry of Health & Family Welfare (MoHFW), Govt. of India

These requirements cover medicines/drugs (except medical devices & other medical supplies for which separate GS1 barcode requirements apply) procured by Ministry of Health & Family Welfare (MoHFW), Govt. of India under various programs by different divisions for both branded & generic pharmaceuticals/drugs, meant for supply and distribution through MoHFW regulated distribution channel (PHCs, CHCs/FRUs Govt. hospitals etc).

Barcode requirements using GS1 identification standards are provided below at various levels of product packaging which include at primary, secondary and shipper/carton levels and need to be complied with while supplying medicines/drugs to MoHFW.

Section A) Primary Level Packaging

Primary Level Packaging: Is defined as the first level of packaging in direct contact with the product and marked with an AIDC (Automatic Identification and Data Capture) data carrier either on the packaging or on a label affixed to the packaging. It may consist of a single item or group of items for a single therapy such as a Kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.

Barcodes using GS1 standards are required to be marked onto the primary level of packaging encoding GS1 product identification code (called GTIN–Global Trade Item Number). Where product is packed in a mono carton (e.g. ointments, eye/ear drops etc), barcode encoding GTIN should be marked on the mono carton itself.

GTINs (Global Trade Item Numbers): It is the GS1 identification key used to uniquely identify each product type/variant. It is created using a GS1 or U.P.C. Company Prefix number. GTIN can be of 14 digits (i.e. GTIN -14) or 13 digits (i.e. GTIN -13) or 12 digits (i.e. GTIN -12) or 8 digits (i.e. GTIN -8) depending on barcode symbology used.

Note: Barcodes using GS1 standards are required to be marked on product packaging **in addition** to existing statutory labeling & marking requirements.

Barcode Symbology: GS1 DataMatrix (two dimensional) symbology is the preferred option.

GS1 DataMatrix symbology can encode product data in much smaller space than what is possible with one dimensional barcode symbology. This is an important consideration in healthcare sector due to very limited availability of printing space on product packaging, after complying with other statutory labeling & marking requirements. GS1 DataMatrix is thus the preferred option for marking in the healthcare sector.

Schematic example of GS1 DataMatrix symbology encoding GTIN-14 using Application Identifier (01) at Primary level packaging is as below:



(01)08901107000011

For specs related to GS1 DataMatrix barcode, refer to GS1 general specifications available on http://www.gs1india.org.in/gs1barcodes/pc_index.htm.

Other barcode symbologies (EAN/UPC, GS1–128 and GS1 Databar) on primary level packaging shall also be acceptable.

Details on other GS1 barcode symbologies (EAN/UPC, GS1 – 128, ITF-14, GS1 Databar), are available at http://www.gs1india.org.in/gs1barcodes/pc_index.htm

Section B) Secondary Level Packaging

Secondary Level Packaging: Is defined as a level of packaging that may contain one or more primary packages or a group of primary packages containing a single item.

NOTE: There may be additional intermediate packaging levels above the secondary level packaging, but below the Shipper / Carton level packaging. These intermediate packaging levels are not required to be barcoded at this time. Examples of these exclusions include:

- Inner packs (bundles)
- Intermediate packs (inner case)

At Secondary level packaging, the barcode should encode the following information:

- 1) Product identification code (Unique GTIN-14 of secondary pack)* using application identifier (01)
- 2) Expiry Date in YYMMDD format using application identifier (17)
- 3) Batch/Lot Number using application identifier (10) **or** Serial No using application identifier (21).

**Note:* GTIN-14 of secondary level packaging should be different from GTIN-14 of primary and shipper pack. For details on generation of same, refer to GS1 General Specifications.

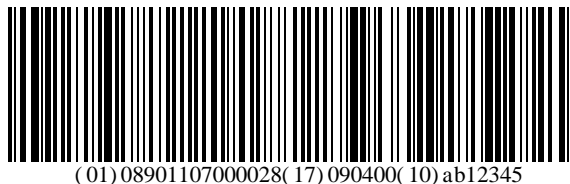
The above barcoding requirements shall be **in addition** to existing statutory labeling & marking requirements.

Barcode Symbology: Any of the following GS1 barcode symbologies can be used to encode above stated data in barcodes at Secondary level packaging:-

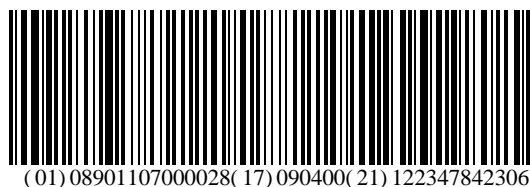
GS1-128, GS1 DataMatrix, GS1 DataBar.

Examples

- a) GS1-128 symbology, encoding GTIN + Expiry Date + Batch/Lot No is represented schematically as below:-



- b) GS1-128 symbology, encoding GTIN + Expiry Date + Serial No is represented schematically as below:-



Details on other GS1 barcode symbologies at secondary packaging level (GS1 Datamatrix and GS1 Databar) are available at

http://www.gs1india.org.in/gs1barcodes/pc_index.htm

Section C) Shipper/Carton Level Packaging

Shipper/Carton Level Packaging: Is defined as a level of packaging that may contain one or more primary/secondary levels of packaging.

Shippers/cartons can be considered orderable trade items (requires homogeneous pack) AND may also be considered logistics units (heterogeneous packs). The following rules apply to each variation:

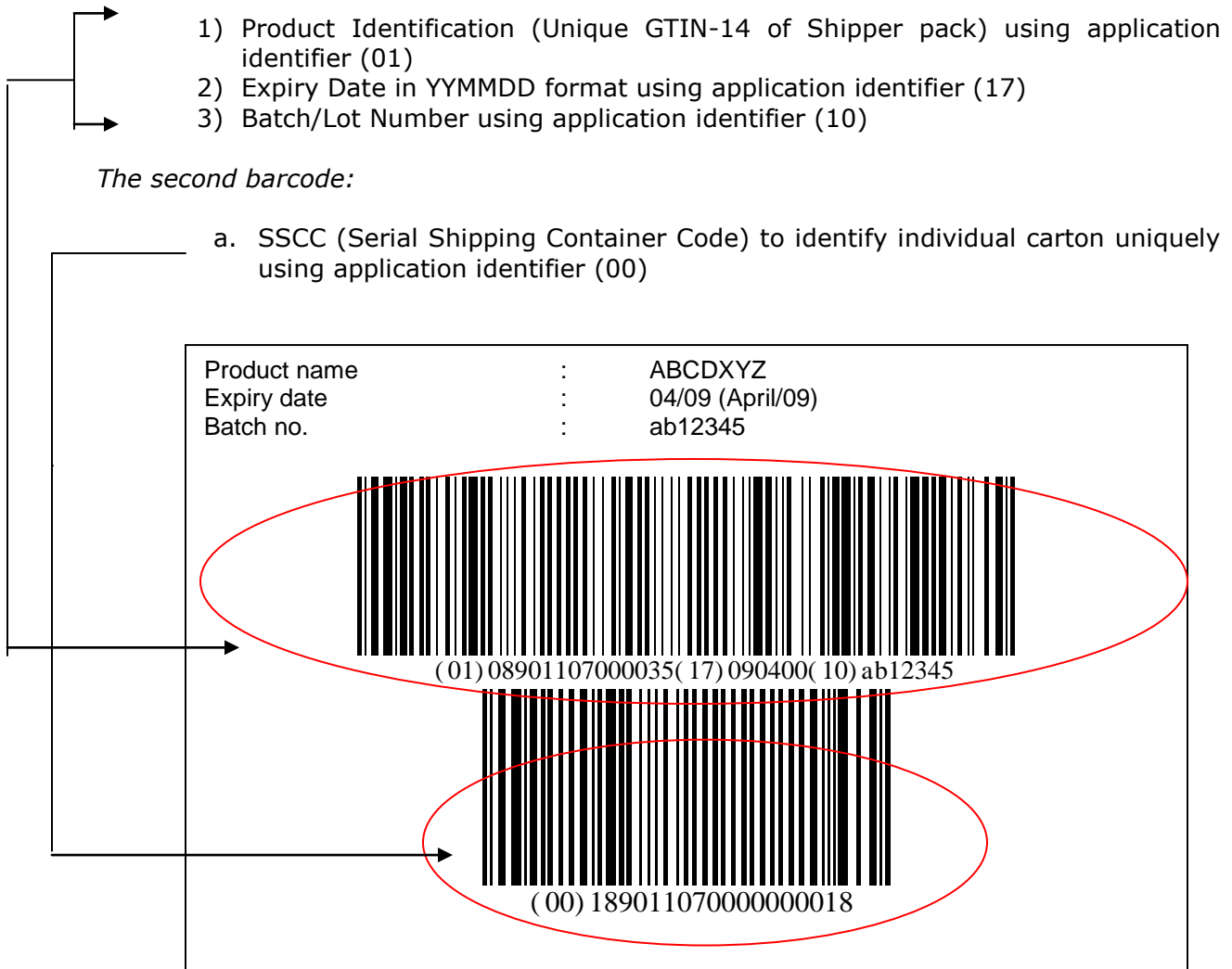
i) *The requirements for the orderable trade item (homogeneous pack):*

The first barcode:

- 1) Product Identification (Unique GTIN-14 of Shipper pack) using application identifier (01)
- 2) Expiry Date in YYMMDD format using application identifier (17)
- 3) Batch/Lot Number using application identifier (10)

The second barcode:

- a. SSCC (Serial Shipping Container Code) to identify individual carton uniquely using application identifier (00)



(Single Label for each carton)

*Note: GTIN-14 of shipper level packaging should be different from GTIN-14 of primary and secondary pack. For details on generation of same, refer to GS1 General Specifications.

Barcode Symbology: GS1-128 and GS1 DataMatrix symbologies can be used to generate the first barcode. The second barcode (SSCC) requires GS1-128.

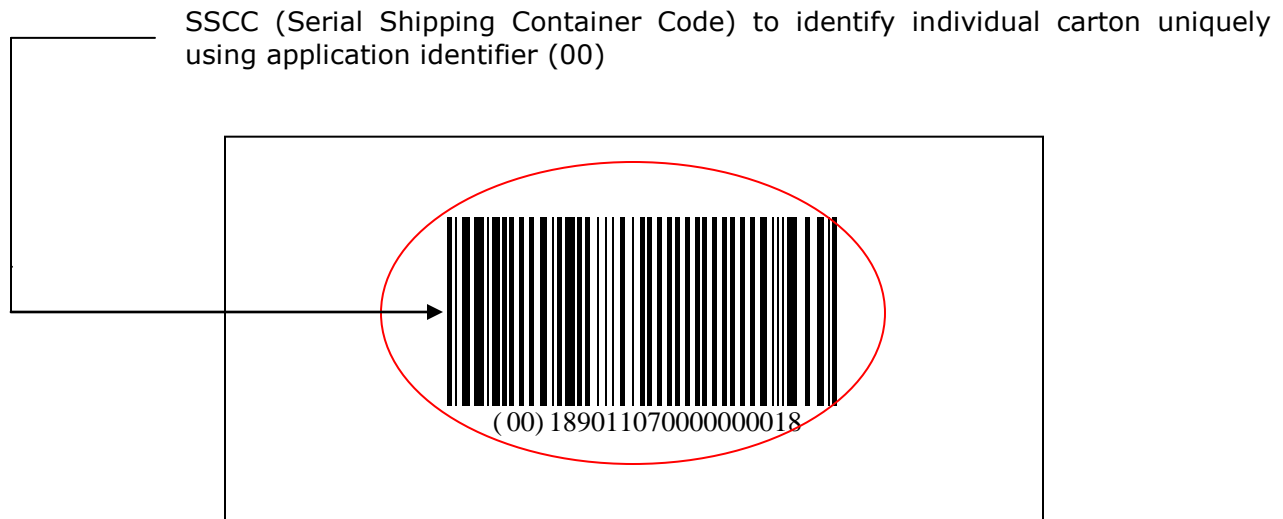
Human readable information on the label will be as per existing statutory labeling & marking requirements.

ii) The requirements for logistics unit (heterogeneous pack):

If multiple items are packed in a carton / shipper (heterogeneous pack), and / or the shipper / carton level packaging is not an orderable unit, only second barcode should be present (i.e. SSCC).

Human readable information on the label will be as per existing statutory labeling & marking requirements.

Schematic example of GS1-128 symbology for the logistics unit (heterogeneous pack) encoding above stated data at Shipper/ Carton Level Packaging is as below:



(Single Label for each carton)

General Notes:

1. While barcoding has been chosen as the automatic identification data capture (AIDC) technology currently, future requirements may demand use of any other data capture technology.
2. Data requirements as stipulated above, take into account minimum level of AIDC marking. MoHFW however reserves the right to modify the same and direct implementation of higher level of AIDC marking (additional data requirements) in future, in the event of higher perceived risks in line with GS1 General Specifications.
3. Complete details on GS1 standards along with technical guidelines can be downloaded from www.gs1india.org or www.gs1.org
4. For any assistance, you can contact Shri. Gopal Valecha at 011-26168720/721/725, email – gopal@gs1india.org