

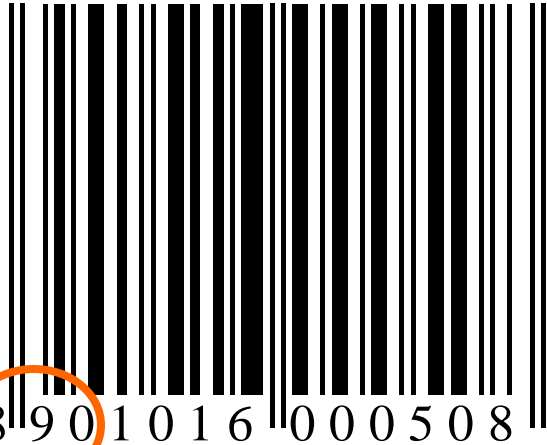
Complying with barcoding reqmts  
of DGFT and Min. of Health,  
Govt. of India

# GS1 India

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# Barcoding reqmnts of Min of Health, Govt. of India

No. Z- 16025/02/08-EPW  
Government of India  
Ministry of Health & Family Welfare  
(EPW Division)

Nirman Bhawan, New Delhi  
Dated: 06<sup>th</sup> May, 2011

## OFFICE MEMORANDUM

Subject: Implementation of Bar Codes on GOI Supplies

The undersigned is directed to refer to letter of AS(Admn.) bearing no Z-16025/02/08-EPW dated 20<sup>th</sup> October, 2009 regarding GS1 Barcode implementation on all procurements of drugs, devices and other medical supplies made by the Ministry with effect from 1<sup>st</sup> April, 2010 and to state that phase wise implementation of the same has now been finalised. The primary objectives of barcode implementation are:-

- (i) To enable efficient management and monitoring of stock levels of all medical supplies including drugs, medical devices etc procured under various programmes / schemes.
- (ii) To enable track & trace of all medical supplies to facilitate detection of spurious / counterfeit products and product authentication.

(2) Towards meeting the above objectives, letter of even number dated 20<sup>th</sup> October, 2009 was issued by the Additional Secretary (Admn.), MoHFW to all Programme Divisions. Detailed GS1 barcode requirements and user manuals were subsequently made available for access by industry etc through MoHFW's website at:  
[http://mohfw.nic.in/gs1\\_barcode\\_&\\_User\\_Manuals.htm](http://mohfw.nic.in/gs1_barcode_&_User_Manuals.htm).

(3) In response to the same, representations were received from industry requesting MoHFW to consider differentiating between medical devices and drugs from the implementation timelines specified.

(4) Few meetings were subsequently held with industry representatives and it was decided in a meeting held on 16<sup>th</sup> March, 2011 under the chairmanship of AS & DG, that MoHFW shall, adopt a phase-wise approach to facilitate compliance by industry. Details of phase-wise implementation is given in following paragraphs:-

### (a) Phase I – implementation by 1<sup>st</sup> October, 2011

All suppliers of drugs shall incorporate barcodes using GS1 standards at various packaging levels, encoding the following information:

- I. At primary level packaging – product identification code (GTIN – Global Trade Identification Number).
- II. At secondary level packaging – product identification code (GTIN), expiry date and batch no.
- III. At tertiary level packaging – product identification code (GTIN), expiry date, batch no. and SSCC (serial shipping container code).

**Note:** For primary packaging of small pharma products where due to space constraints, barcoding may not be possible, above information shall be printed in human readable form using GS1 standards.

Detailed barcode requirements and user manual to facilitate implementation by suppliers, is available at:  
[http://mohfw.nic.in/gs1\\_barcode\\_&\\_User\\_Manuals.htm](http://mohfw.nic.in/gs1_barcode_&_User_Manuals.htm).

### (b) Phase II – implementation by 1<sup>st</sup> April, 2012

All suppliers of drugs shall incorporate barcodes using GS1 standards at various packaging levels, encoding the following information:

- A) At primary level packaging – product identification code (GTIN – Global Trade Identification Number) and unique serial number of primary pack.
- B) At secondary level packaging – product identification code (GTIN), expiry date and batch no. and unique serial number of secondary pack.
- C) At tertiary level packaging – product identification code (GTIN), expiry date, batch no. and SSCC (serial shipping container code) of tertiary pack.

**Note:** For primary packaging of small pharma products where due to space constraints, barcoding may not be possible, above information shall be printed in human readable form using GS1 standards.

# Barcoding reqmnts of DGFT

To be published in the Gazette of India Extraordinary Part-I, Section-I

Government of India  
Ministry of Commerce and Industry  
Department of Commerce  
Directorate General of Foreign Trade  
Public Notice No. 59(RE-2010)/2009-2014  
New Delhi, Dated the 30<sup>th</sup> June, 2011

**Sub: Deferment in the date of effect for implementation of bar-coding on export consignment of pharmaceuticals and drugs for tracing and tracking purpose.**

In exercise of the powers conferred under Paragraph 2.4 of the Foreign Trade Policy, 2009-14, as amended from time to time, Director General of Foreign Trade hereby amends Public Notice No. 21 dated 10<sup>th</sup> January, 2011 and prescribes the following procedure for tracing and tracking of export consignments of pharmaceutical products.

2. (i) Exporters of pharmaceutical products will adopt a trace and track system and incorporate its features for exported medicines using barcode technology as per GS 1 global standards as detailed below:

**a. Primary Level packaging requirement:**

Incorporation of 2D (GS1 Data matrix) barcodes on medicines at strip/vial/bottle, etc. encoding unique product identification code (GTIN) and Unique Serial Number of the Primary pack.

**b. Secondary Level packaging requirement :**

Incorporation of barcodes (1D or 2 D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Unique Serial Number of the Secondary pack.

**c. Tertiary Level packaging requirement:**

Incorporation of barcodes (1 D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Unique Serial Number of the Tertiary pack (shipper/carton).

(ii) The trace and track technology as per serial number 2(i) above will come into effect as follows:

- |                               |  |
|-------------------------------|--|
| (a) Primary Level packaging   | - With effect from 1 <sup>st</sup> July, 2012    |
| (b) Secondary Level packaging | - With effect from 1 <sup>st</sup> January, 2012 |
| (c) Tertiary Level packaging  | - With effect from 1 <sup>st</sup> October, 2011 |

3. In case the importing country has mandated a specific requirement, the exporter can adhere to the same and it would not be necessary to comply with the stipulations at serial number a, b & c of para 2 above.

4. Under the track and trace system, manufacturers would be required to maintain serialized record of exported pharmaceutical products for a minimum period of six months after the expiry date of the product.

5. Authentication features will be added in due course and integrated with the trace and track system.

6. Government will set up a Central Portal for tracing and tracking exported pharmaceutical products.

7. Effect of this Public Notice:

Earlier the requirement of affixing barcodes was to come into effect from 01.07.2011. Now more time is being allowed.

(Anup K. Pujari)  
Director General of Foreign Trade  
E-mail: [dgft@nic.in](mailto:dgft@nic.in)

## Summary of DGFT requirements

Packaging level	Barcoding requirements	Timeline
<p><b><i>Tertiary level – definition</i></b></p> <p>Comprises highest level of packaging containing secondary and other intermediate packages meant for transport/logistics(cartons/pallets/shipments)</p>	<p>Incorporation of barcodes (1D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Unique Serial Number of the Tertiary pack (shipper/carton).</p>	<p>Phase 1 – by <b>1<sup>st</sup> Oct 2011</b></p>
<p><b><i>Secondary level – definition</i></b></p> <p>Packaging level containing primary level packages.</p>	<p>Incorporation of barcodes (1D or 2D) encoding unique product identification code (GTIN), Batch Number, Expiry date and Unique Serial Number of the secondary pack.</p>	<p>Phase 2 – by <b>1<sup>st</sup> Jan 2012</b></p>
<p><b><i>Primary level – definition</i></b></p> <p>Comprises first level of packaging in direct contact with the product e.g. medicine strip, vial, single therapy kit, or items packed in mono carton for sale to consumers.</p>	<p>Incorporation of 2D (GS1 DataMatrix) barcodes on medicines at strip/vial/bottle etc encoding unique product identification code Global Trade Identification Number (GTIN) and Unique Serial Number of the primary pack.</p>	<p>Phase 3 – by <b>1<sup>st</sup> July 2012</b></p>

## Summary of Min of Health, Govt. of India requirements

### Phase 1

Packaging level	Barcoding requirements	Timelines
Primary	GTIN only	Phase 1 – by <b>1<sup>st</sup> Oct 2011</b>
Secondary	GTIN + Expiry Date + Batch No.	
Tertiary	1 <sup>st</sup> Barcode : GTIN + Expiry Date + Batch No. 2 <sup>nd</sup> Barcode : SSCC	

### Phase 2

Primary	GTIN + <i>Serial No.</i>	Phase 2 – by <b>1<sup>st</sup> April 2012</b>
Secondary	GTIN + Expiry date + Batch No. + <i>Serial No.</i>	
Tertiary	1 <sup>st</sup> Barcode : GTIN + Expiry Date + Batch No. 2 <sup>nd</sup> Barcode : SSCC	

Definitions of Primary, Secondary and Tertiary level packaging are as explained in previous slide (as for DGFT).

## Procedure for generation of GTIN as per DGFT and Min of Health, Govt. of India requirements

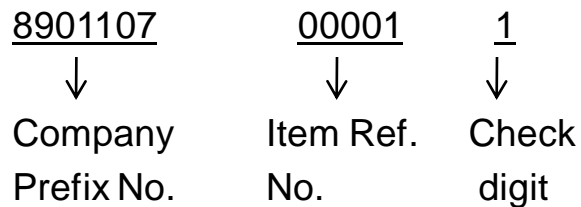
- Obtain GS1 Company Prefix (GCP) through registration with GS1 India . For registration procedure, log on to: <http://www.gs1india.org/Support/GetRegistered>
- Use GCP to generate GTINs as per steps below:
- Assign item reference number of applicant company's choice to each product type/variant
- Calculate check digit using online Check Digit Calculator available at the URL <http://www.gs1india.org.in/calculater.aspx>
- Generate GTIN using GCP, item reference number and check digit. Find more about how to generate GTIN at the URL [http://www.gs1india.org.in/gs1barcodes/number\\_development\\_guide.htm](http://www.gs1india.org.in/gs1barcodes/number_development_guide.htm)

# Implementing barcodes at primary level as per DGFT and Min of Health, Govt. of India reqmnts

Generate GTIN-14 for primary pack.

- a) GTIN (Global Trade Item Number) is the GS1 identification key used to uniquely identify each product type/variant.
- b) GTIN-14 is generated from GTIN-13, using prefix of “0” to convert to 14 digit code.
- c) Generating GTIN-13

GTIN-13 structure (e.g. 8901107000011)



8901107 - Company prefix no. allocated by GS1 India

00001 - Item Ref. No. allocated for each product type/variant/SKU by manufacturer/brand owner

1 - Check digit calculated based on preceding digits (calculator available at [www.gs1india.org](http://www.gs1india.org))

- d) Generating GTIN-14 from GTIN-13 by prefixing “0” .

GTIN-14 structure (from GTIN-13 illustrated above)

0 8901107000011

GTIN-14 structure evolved out of GTIN-13 structure as above

# Encoding product information in 2D (GS1 DataMatrix) barcode symbology as per DGFT reqmnts for primary level

Use GS1 general specs available at:

[http://gs1india.org/upload/menuupload/GS1\\_General\\_Specifications\\_v11.pdf](http://gs1india.org/upload/menuupload/GS1_General_Specifications_v11.pdf) for technical details on GS1 DataMatrix symbology.

## Schematic representation of GS1 DataMatrix at primary level



(01)08901107000011(21)abcd12345

(01)	Application Identifier to be prefixed to indicate GTIN information which follows it
08901107000011	GTIN-14 of the primary pack
(21)	Application Identifier to be prefixed to indicate serial number of primary pack.
Abcd12345	Serial no. of primary pack. Serial number should be alphanumeric up till 20 digits.

## Implementation as per DGFT mandate – Secondary Pack

### Unique identification of secondary pack

- GTIN using application identifier (01)
- Expiry Date in YYMMDD format using application identifier (17)
- Batch/Lot Number using application identifier (10)
- Serial No. of the secondary package using application identifier (21)

### Points to be noted:

- GTIN of secondary level packaging should be different from GTIN of primary and shipper package.
- The above barcoding requirements shall be in addition to existing statutory labeling & marking requirements.
- The parentheses (brackets) are not encoded in the bar code and they are represented in human readable form only for highlighting the application identifier number within the brackets.
- Fixed length data fields will always precede variable length fields.
- It is mandatory to print data encoded in barcodes as human readable information.
- In case the importing country has mandated a specific requirement, the exporter can adhere to the same and it would not be necessary to comply with the above requirement.

# Implementation as per DGFT mandate – secondary Pack

## Generation of (GTIN)

Refer to steps mentioned in the previous slides on implementation at primary pack

Encoding of GTIN, Expiry Date, Batch number and serial number

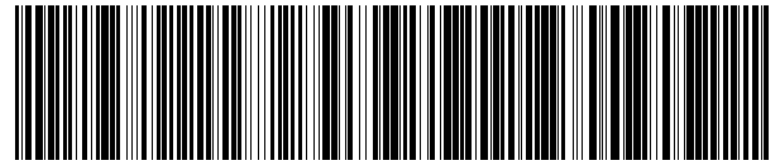
GS1 DataMatrix (2D):



(01)08901107000028 (17)090400  
(10)ab12345 (21)mnop09876

OR

GS1-128 barcode symbology (1D):



( 0 1 ) 0 8 9 0 1 1 0 7 0 0 0 0 2 8 ( 1 7 ) 0 9 0 4 0 0 ( 1 0 ) a b 1 2 3 4 5 ( 2 1 ) m n o p 0 9 8 7 6

Not more *than 48 characters* can be encoded in a single GS1 – 128 barcode. If the total number of characters exceeds 48, it should be split in two barcodes on a single label.

*Note: Suppliers may chose either 2D or 1D symbology as illustrated below*

(01)	The Application Identifier to indicate that the data following it is the GTIN
08901107000028	GTIN
(17)	The Application Identifier to indicate that the data following it is the expiration date of the product in YYMMDD format
090400	The expiration date of the product in YYMMDD format (April 2009 in this case)
(10)	The Application Identifier to indicate that the data following it is batch or lot number of product.
ab12345	The batch / lot number of the product
(21)	The Application Identifier to indicate that the data following it is the serial number of the product which should be alpha-numeric and of variable length field varying from 1 to 20 digits
mnop09876	The serial no. of secondary package

# Implementation as per DGFT mandate -at carton/shipper level

Allocation of Serial Shipping Container Code (SSCC)

SSCC is used for the unique identification of each Shipper/Carton/Tertiary level package as a logistic unit.

Data structure of Serial Shipping Container Code (SSCC):

Extension Digit	GS1 Company prefix > < Serial reference number																Check Digit
N <sub>1</sub>	N <sub>2</sub>	N <sub>3</sub>	N <sub>4</sub>	N <sub>5</sub>	N <sub>6</sub>	N <sub>7</sub>	N <sub>8</sub>	N <sub>9</sub>	N <sub>10</sub>	N <sub>11</sub>	N <sub>12</sub>	N <sub>13</sub>	N <sub>14</sub>	N <sub>15</sub>	N <sub>16</sub>	N <sub>17</sub>	N <sub>18</sub>

Steps to generate, SSCC (18 digits shipper identification code):-

- Assign the Extension digit ranging from 0-9 to increase the capacity of the Serial Reference within the SSCC
- Use GCP issued by GS1 India or any other GS1 member organizations in other countries
- Generated unique serial reference number to identify each Shipper/Carton/Tertiary level package..
- Calculate check digit using online Check Digit Calculator available at <http://www.gs1india.org.in/calculator.aspx>

Extension Digit	GS1 Company prefix > < Serial reference number																Check Digit	
1	8	9	0	1	1	0	7	0	0	0	0	0	0	0	0	0	1	8

The above example:

- Uses "1" as the first digit as extension digit to generate SSCC
- Uses company prefix number "8901107"
- Has been assigned serial reference number "00000001"
- Is the check digit calculated based on preceding 17 digits using check digit calculator

# Implementation at carton/shipper level - Homogeneous pack

Homogeneous Packs contain same type of secondary packs

Requirement for homogeneous packs

Two GS1-128 barcodes

*The first barcode contains:*

- Product Identification code (Unique GTIN-14 product code of the Shipper/Carton/Tertiary level packaging) using application identifier (01)
- Expiry Date in YYMMDD format using application identifier (17)
- Batch/Lot Number using application identifier (10)

*The second barcode:*

- SSCC to identify individual Shipper/Carton/Tertiary level packaging uniquely using application identifier (00)

*Note:* GTIN of shipper level packaging should be different from GTIN of primary and secondary package. Refer to steps mentioned in the 'Implementation at primary pack' section for generation of GTIN in 14 digit format

Product name	:	BRAND NAME
Expiry date	:	04/09 (April/09)
Batch no.	:	ab12345

(01) 08901107000035(17) 090400(10) ab12345

(00) 189011070000000018

(01)	The Application Identifier to indicate that the data following it is the GTIN-14 data format
08901107000035	The GTIN of Shipper/Carton/Tertiary level packaging.
(17)	The Application Identifier to indicate that the data following it is the expiration date of the product in YYMMDD format
090400	The expiration date of the product in YYMMDD format (April 2009 this case)
(10)	The Application Identifier to indicate that the data following it is batch or lot number of the product.
ab12345	The batch / lot number of the product.

*The second barcode represents:*

(00)	The Application Identifier to indicate that the data following it is the numeric serial number of the Shipper/Carton/Tertiary level packaging.
189011070000000018	The 18 digit numeric serial no. of the Shipper/Carton/Tertiary level packaging.

## Implementation as per DGFT: carton/shipper level-Heterogeneous pack

Homogeneous Packs contain different types of secondary packs

Requirement for homogeneous packs  
A GS1-128 barcode encoding

SSCC (Serial Shipping Container Code) to identify individual Shipper/Carton/Tertiary level packaging uniquely using application identifier (00)



In the above example

(00)	Is the Application Identifier to indicate that the data following it is the numeric serial number of the Shipper/Carton/Tertiary level packaging.
189011070000000018	Is the 18 digit numeric serial no. of the Shipper/Carton/Tertiary level packaging.

## Points to be noted

- Allocate different GTIN for different pack level , i.e.- primary, secondary and shipper package.
- The above barcoding requirements shall be in addition to existing statutory labeling & marking requirements.
- The parentheses (brackets) are not encoded in the bar code and they are represented in human readable form only for highlighting the application identifier number with in the brackets.
- Fixed length data fields will always precede variable length fields.
- It is mandatory to print data encoded in barcodes as human readable information.
- In case the importing country has mandated a specific requirement, the exporter can adhere to the same and it would not be necessary to comply with the above requirement.

# Summary of MoHFW Mandate

## Phase I

Packaging level	Requirements	Timeline
<p>Primary:</p> <p>The first level of packaging in direct contact with the product .</p> <p>Example : a single item such as a medicine strip, a vial etc or group of items for a single therapy such as a Kit.</p>	Incorporation of GS1 barcodes encoding unique product identification code ,i.e.- Global Trade Identification Number (GTIN).	(Phase 1) – 1 <sup>st</sup> October 2011 onwards
<p>Secondary:</p> <p>A group of primary packages containing a single item.</p>	Incorporation of barcodes (GS1 – 128 i.e. 1D or GS1 DataMatrix i.e. 2D) encoding unique product identification code (GTIN), Expiry Date, Batch Number	(Phase 1) – 1 <sup>st</sup> October 2011 onwards
<p>Tertiary:</p> <p>Shipper/Carton level packaging meant for transport &amp; logistics purpose</p>	Incorporation of GS1-128 barcode symbology (1D) encoding GTIN of the Shipper/Carton/Tertiary level packaging package, expiry date, batch number of the product and Serial Shipping containers code (SSCC) of the Shipper/Carton/Tertiary level packaging	(Phase 1) – 1 <sup>st</sup> October 2011 onwards
Primary & Secondary	Serialisation through the ( check previous presentation)	(Phase 2) – Not yet decided

*Note:* There may be additional intermediate packaging levels between secondary and Shipper/Carton /Tertiary 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)

# Implementation as per MoHFW mandate – Primary pack

- Get registered with GS1 India to obtain your GS1 Company Prefix ( GCP)
- Generate unique GTIN in 14 digit format using your GS1 Company Prefix ( GCP) as per the procedure explained in the DGFT section if you are using GS1 DataMatrix.

OR

GTIN-13 format can be encoded as EAN-13 barcode

- Encode data in suitable GS1 barcodes ( 1D : EAN-13, 2D: GS1 DataMatrix)

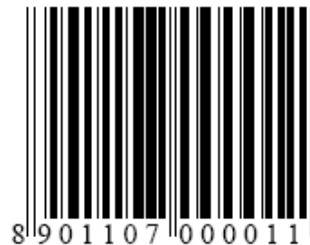
GS1 DataMatrix symbology encoding GTIN-14 using  
Application Identifier (01)



(01)08901107000011

OR

EAN-13 barcode encoding GTIN-13



Acceptable till 31<sup>st</sup> March,2012

# Implementation at secondary pack level

## Generation of (GTIN) at Secondary Level Packaging:

Refer to steps mentioned in the Implementation at primary pack 'section' for generation of GTIN and in 14 digit format

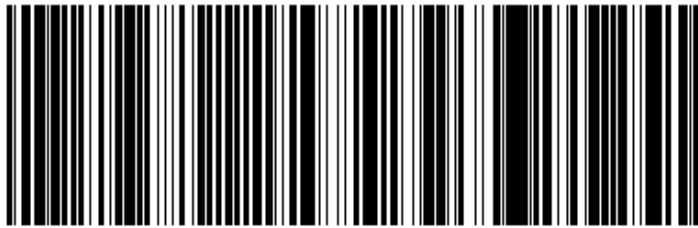
### Encoding of GTIN, Expiry Date, Batch number and serial number

A) In GS1 DataMatrix (2D):



(01)08901107000028 (17)090400(10)ab12345

B) In GS1-128 barcode symbology (1D):



(01)08901107000028(17)090400(10)ab12345

Not more than 48 characters can be encoded in a single GS1 – 128 barcode. If the total number of characters exceeds 48, it should be split in two barcodes on a single label.

(01)	The Application Identifier to indicate that the data following it is the GTIN
08901107000028	GTIN
(17)	The Application Identifier to indicate that the data following it is the expiration date of the product in YYMMDD format
090400	The expiration date of the product in YYMMDD format (April 2009 in this case)
(10)	The Application Identifier to indicate that the data following it is batch or lot number of product.
ab12345	The batch / lot number of the product

# Implementation at carton/shipper level

Allocation of Serial Shipping Container Code (SSCC)

SSCC is used for the unique identification of each Shipper/Carton/Tertiary level package as a logistic unit.

Data structure of Serial Shipping Container Code (SSCC):

Extension Digit	GS1 Company prefix > < Serial reference number																Check Digit
N <sub>1</sub>	N <sub>2</sub>	N <sub>3</sub>	N <sub>4</sub>	N <sub>5</sub>	N <sub>6</sub>	N <sub>7</sub>	N <sub>8</sub>	N <sub>9</sub>	N <sub>10</sub>	N <sub>11</sub>	N <sub>12</sub>	N <sub>13</sub>	N <sub>14</sub>	N <sub>15</sub>	N <sub>16</sub>	N <sub>17</sub>	N <sub>18</sub>

Steps to generate, SSCC (18 digits shipper identification code):-

- Assign the Extension digit ranging from 0-9 to increase the capacity of the Serial Reference within the SSCC
- Use GCP issued by GS1 India or any other GS1 member organizations in other countries
- Generated unique serial reference number to identify each Shipper/Carton/Tertiary level package..
- Calculate check digit using online Check Digit Calculator available at <http://www.gs1india.org.in/calculator.aspx>

Extension Digit	GS1 Company prefix > < Serial reference number																Check Digit	
1	8	9	0	1	1	0	7	0	0	0	0	0	0	0	0	0	1	8

The above example:

- Uses "1" as the first digit as extension digit to generate SSCC
- Uses company prefix number "8901107"
- Has been assigned serial reference number "00000001"
- Is the check digit calculated based on preceding 17 digits using check digit calculator

# Implementation at carton/shipper level- Homogeneous pack

Homogeneous Packs contain same type of secondary packs

Requirement for homogeneous packs

Two GS1-128 barcodes

*The first barcode contains:*

- Product Identification code (Unique GTIN-14 product code of the Shipper/Carton/Tertiary level packaging) using application identifier (01)
- Expiry Date in YYMMDD format using application identifier (17)
- Batch/Lot Number using application identifier (10)

*The second barcode:*

- SSCC to identify individual Shipper/Carton/Tertiary level packaging uniquely using application identifier (00)

*Note:* GTIN of shipper level packaging should be different from GTIN of primary and secondary package. Refer to steps mentioned in the 'Implementation at primary pack' section for generation of GTIN in 14 digit format

Product name	:	BRAND NAME
Expiry date	:	04/09 (April/09)
Batch no.	:	ab12345


(01) 08901107000035 (17) 090400 (10) ab12345


(00) 189011070000000018

(01)	The Application Identifier to indicate that the data following it is the GTIN-14 data format
08901107000035	The GTIN of Shipper/Carton/Tertiary level packaging.
(17)	The Application Identifier to indicate that the data following it is the expiration date of the product in YYMMDD format
090400	The expiration date of the product in YYMMDD format (April 2009 this case)
(10)	The Application Identifier to indicate that the data following it is batch or lot number of the product.
ab12345	The batch / lot number of the product.

*The second barcode represents:*

(00)	The Application Identifier to indicate that the data following it is the numeric serial number of the Shipper/Carton/Tertiary level packaging.
189011070000000018	The 18 digit numeric serial no. of the Shipper/Carton/Tertiary level packaging.

# Implementation at carton/shipper level- Heterogeneous pack

Homogeneous Packs contain different types of secondary packs

Requirement for homogeneous packs  
A GS1-128 barcode encoding

- SSCC (Serial Shipping Container Code) to identify individual Shipper/Carton/Tertiary level packaging uniquely using application identifier (00)



In the above example

(00)	Is the Application Identifier to indicate that the data following it is the numeric serial number of the Shipper/Carton/Tertiary level packaging.
189011070000000018	Is the 18 digit numeric serial no. of the Shipper/Carton/Tertiary level packaging.

GS1 India

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