



ASSOCIAÇÃO
BRASILEIRA
DE AUTOMAÇÃO

Support Guide for Codification of Medicines

To comply with RDC 157/2017 (Version 3)



Support:

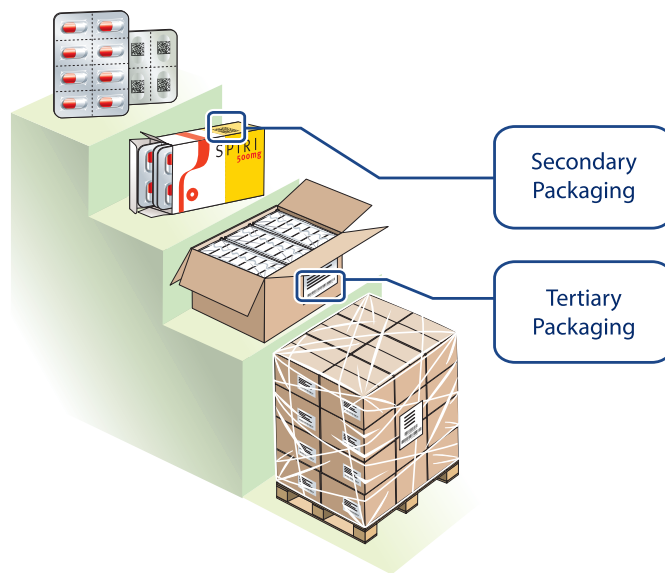


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INTRODUCTION

The Support Guide for Codification of Medicines aims to present best practices for the identification and codification of secondary (box/cartridge) and tertiary packaging (transport) complying with:

- LAW Nº 11.903, OF JANUARY 14th, 2009, as amended by Law # 13,410, dated December 28, 2016.
- RDC # 157, OF MAY 11, 2017



EXPECTED BENEFITS

- Technical support for proper application of the codes in secondary and tertiary packaging.
- Guidance to ensure quality in the printing of bar codes.
- Compliance with the requirements of RDC 157/2017.

APPLICATIONS

Secondary packaging

IDENTIFICATION: GTIN

The GTIN (Global Trade Item Number) is a number that uniquely identifies products and services. Although the GTIN is not mandatory, its use ensures interoperability in the supply chain and adherence to international markets.

When a GTIN has been assigned, the trademark/registry holder should link the identification number with

item features, such as a description, weight dimensions, active ingredient, etc., in their databases. The most common GTIN in Brazil for identification of medicines is the GTIN-13 (13-digits).

GTIN-13 - Structure

GS1 Company Prefix / Item Reference Number												Verification Digit
N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	N11	N12	N13

For more information concerning GTIN formation:

<http://www.gs1br.gs1/codigos-e-padres/chaves-de-identificacao/Paginas/GTIN.aspx>

CODIFICATION: GS1 DATAMATRIX

The GS1 DataMatrix is a two dimensional (2D) symbology that allows codification with the use of Application Identifiers (AI), a series of information such as: product identification (GTIN), expiration date, batch, serial number, etc.

The RDC 157/2017 states that the Datamatrix bar code symbol should encode at least the following data that makes up the IUM (Unique Medicine Identification) in the following order:

- I - GTIN - Global Trade Item Number
- II - ANVISA Medicine Registry Number
- III - Serial Number
- IV - Expiration Date
- V - Lot / Batch Number

The allowed number of data characters noted in RDC 157/2017 varies according to the table below. Note that the GS1 standard has, in some cases, an allowed larger data character.

Information to be inserted in the code:

AI (Application Indicator)	GS1 Standard	RDC 157/2017
(01) GTIN	Numeric 14	-
(713) ANVISA Registry Number	Alphanumeric up to 20	Alphanumeric up to 20
(21) Serial Number	Alphanumeric up to 20	Alphanumeric up to 20
(17) Expiration Date*	Numeric 6 YYMMDD	Numeric 6 YYMMDD Observation 1*
(10) Batch Number	Alphanumeric up to 20	Alphanumeric up to 20

To meet Brazilian Regulations, companies should follow the directions of the RDC 157/2017 column.

* Observation 1:

Depending on date use, the format will be different:

- Date on the IUM statement to ANVISA when necessary: MM / YY (RDC 157/2017)
- Encoded within the GS1 DataMatrix printed on the packaging for medicines: YYMMDD.
In the case of there being no relevant day, the value "00" must be entered
Where: (YY: year, MM: month, DD: day)
- Human readable date on the medicine pack: month/year (RDC 71/2009)

HOW TO ENCODE?

Function 1 character symbol (FNC1)

The GS1 DataMatrix uses a special starting combination to differentiate GS1 DataMatrix symbol from other DataMatrix ECC 200 symbols.

The Function 1 Symbol Character (FNC1) is used in the initial position of the encoded data. This symbol, in this position, indicates that it is GS1 DataMatrix specific symbology.

Within GS1 DataMatrix, the FNC1 is encoded in two different ways:

- QWhen used as a start character - ASCII 232:
- When used as a field separator - ASCII 29: <GS>

A GS1 DataMatrix is properly encoded when it has a leading FNC1. A properly configured bar code scanner / imagers will recognize "]d2 " at the beginning of the decoded data.] d2 is the Symbology Identifier for GS1 DataMatrix as standardized by ISO/IEC. More information: GS1 DataMatrix - An introduction and technical overview of the most advanced / GS1 Application Identifiers compliant symbology

The field separator character is used to indicate to the processing system the end of a variable length data element. Any variable length Application Identifiers (data elements) should be followed by a field separator character, unless it is the last field in the bar code symbol.

Concatenation

The use of GS1 DataMatrix allows multiple Application Identifiers (AI) and its data in a single symbol.

When the data is fixed-length, the field separator is not used and the next data element (AI) is entered in sequence.

When the AI data is variable-length, it must be followed by a field separator, as shown below.

Example of structure in the GS1 DataMatrix

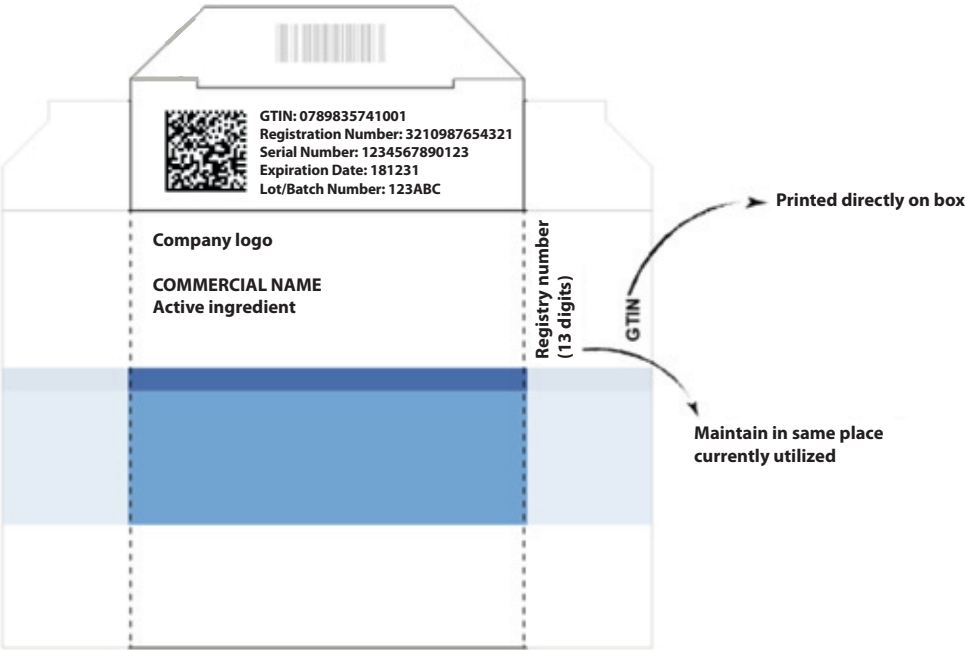
FNC1	AI 1	Data 1 (pre-defined length)	AI 2	Data 2 (variable length)	<GS>	AI 3	Data 3 (variable length)
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Location of Markings

On the package surface, use of only one bar code symbol is recommended to avoid potential mistakes in reading the proper symbol for the application. When determining the location for the bar code symbol on secondary packaging, consideration should be given to how the symbol will need to be accessed for scanning throughout the supply chain including how the secondary packages are contained within a tertiary package (carton or case).



Layout suggestion for compliance with RDC 157/2017 when imprinting the manufacture date, expiration date and batch data:



EXAMPLE

Suggestion on how to encode the RDC 157/2017 required data using a GS1 DataMatrix data carrier:



In the human readable part, it is possible to use the AI header (e.g. (10)123ABC) or to specify the information (e.g. Batch: 123ABC).

In accordance with the rule for concatenation of data, for the example above, the information would be organized in the following way in GS1 DataMatrix:

Within the Code

010789835741001571332109876543212112345678901231718123110123ABC
<initial>01078983574100157133210987654321<separator>211234567890123<separator>1718123110123ABC

Tertiary Packaging

Tertiary Packaging (cartons, cases, shippers and pallets) can be marked with either GTIN or Serial Shipping Container Code (SSCC) identifiers based upon whether they are considered "Trade Items" or "Logistic Units" (note 2).

Note2: Trade item - Any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain. Trade Items are identified with a GTIN.

Logistic unit - An item of any composition established for transport and/or storage that needs to be managed through the supply chain. It is identified with an SSCC.

IDENTIFICATION: GTIN-14

The manufacturer or supplier has the option to identify the tertiary packaging* with one unique identification number: the GTIN-13 or GTIN-14.

The GTIN-14 (14-digits) is recommended for the identification of homogeneous shipping boxes.

GTIN-14 can be used to identify each level of packaging (homogeneous grouping contained) within a packaging hierarchy by changing the Indicator Digit (N1). In each case the Check Digit will be recalculated.

GTIN-14 - Structure

Indicator	GTIN of items contained (without verification digits)	Check Digit
N1	N2 N3 N4 N5 N6 N7 N8 N9 N10 N11N12 N13	N14

For more information concerning GTIN formation:
<http://www.gs1br.gs1/codigos-e-padres/chaves-de-identificacao/Paginas/GTIN.aspx>

The Indicator Digit (N1) used in the GTIN-14 to grouping levels within the packaging hierarchy has the allowed value of 1 to 8.

Serial shipping container code: SSCC

According to RDC157/2017 - Article 7. Every transport package containing at least one medicinal product included in the SNCM experimental phase, from the registration holder's dispatch event instance, must have a unique identifier code that allows the relationship with the IUM of the medicinal products contained therein.

For this function, the use of the SSCC (Serial Shipping Container Code) is recommended.

The SSCC is a voluntary standard that establishes a system of identification that can be used by all parties in the supply chain, from the manufacturer to the carrier, distributor and retailer, to track the distribution of products. It is an 18-digit number that allows exclusive and serialized identification of logistical/ transport units.

Structure

AI	Extension Digit	Company GS1 Prefix / Serial Reference	Verification Digit
00	N1	N2 N3 N4 N5 N6 N7 N8 N9 N10 N11N12 N13 N14 N15 N16 N17	N18

When combined with shipment information provided in advance by electronic means (ASN, eCom, etc.), the SSCC will support applications such as shipping/receiving, inventory update, selection, reconciliation of purchased orders, product traceability, etc.

The SSCC is particularly suitable for identifying transport packaging including that which is mixed and / or contains serialized items, allowing the merchandise that is packed to be identified and thus enabling checking and control.

Secondary Packaging



Serialized products are separated and packed in boxes.

Tertiary Packaging (when it is a logistic unit)



Each box is identified with an SSCC for aggregation – establishing a hierarchical (parent/child) relationship.

Pallets



The boxes are placed on a pallet for shipping. The pallet is identified with a unique SSCC.

About the structure of the SSCC:



- AI (00) - The GS1 Application Identifier (00) indicates that the GS1 Application Identifier data field contains an SSCC (Serial Shipping Container Code).
- The extension digit is used to increase the SSCC's capacity (example: 0,1, 2, up to 9).
- The GS1 Company Prefix is assigned to the system user by GS1, making the SSCC unique worldwide, wherever it is assigned or used. Companies either already have or obtain from a GS1 Member Organization (MO) a GS1 Company Prefix to be able to generate SSCCs.
- The serial reference is assigned by the company to a logistic unit.
- The check digit is calculated from the previous seventeen digits, according to the GS1 standard algorithm.

CODIFICATION: GS1-128

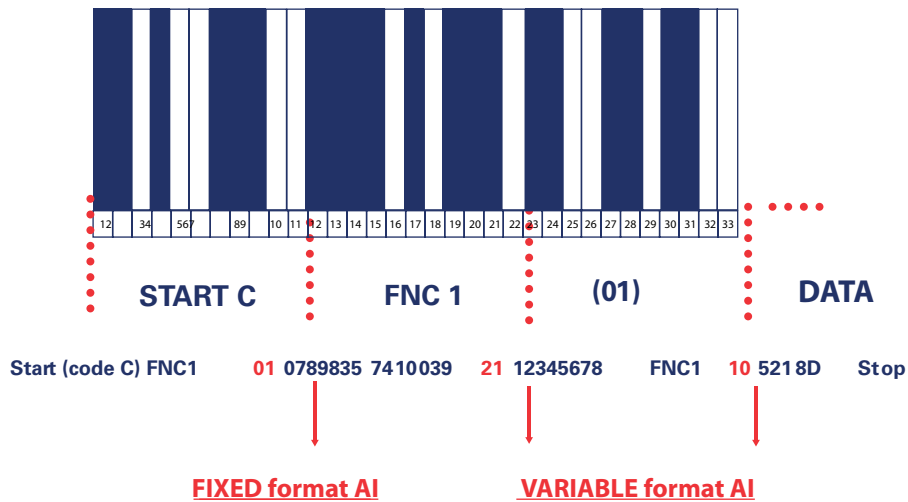
The GS1-128 bar code symbology (data carrier) is recommended to encode static and dynamic (variable) information and is ideally suited to the needs of identifying transport packaging for traceability. This is where information regarding the product, batch, expiration date and SSCC will be inserted, using the AI (Application Identifiers) structure.



- **Quiet zone:** A clear space which precedes the start character of a barcode and follows the stop character. Formerly referred to as “clear area” or “light margin”
- **Start C:** The use of Start C is most efficient for coding strings of numeric characters in GS1-128
- **FNC1:** FNC1 indicate to the coding system and application that the data is in a GS1 format
- **AI:** Application Identifier
- **DATA:** data corresponding to the AI used, with a defined format
- **D:** symbology check digit
- **Stop:** end character, which indicates the end of the bar code symbol to the scanner

Fixed and Variable Data:

The image below shows the structure of the code with fixed and variable data:



Quiet zone	Start C	FNC1	01 07898357410015	21 12345678	FNC1	10 1201	D	Stop
			<=Fixed Data @=>	<=Variable Data @=>		<=Variable Data @=>		

- **FNC1:** Group separator character. A variable length field must be immediately followed by this character, unless it is the last field in bar code symbol.
- **READING:** Bar code scanners will decode the information of the GS1-128 code in the following way:

JC1	01 07898357410015	21 12345678	<GS>	10 1201
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JC1 = Symbology Identifier, where:
J = Indicator character (ASCII 93). Indicates that the two following characters determine the type of
C = Code Character. Determines the type of symbology.
1 = Modifying Character. Indicates how the symbology will be used.

<GS> = Separator Character. Indicates the end of a field with variable format. If this field is the last in the string, its insertion is not necessary.

EXAMPLE

Suggestions for labeling of tertiary packages used as Logistic Units.

Homogeneous Box

- (00) SSCC – Serial Shipping Container Code : n2 + n18
- (01) GTIN – Global Trade Item Number: n2 + n14
- (17) USE BY / EXPIRATION – Date of Maximum Durability: n2 + n6
- (10) BATCH – Batch Number: n2 + .. 20

 ASSOCIAÇÃO BRASILEIRA DE AUTOMAÇÃO		Logistics Label
SSCC – Serial Shipping Container Code 07898357410000015		
GTIN – Global Trade Item Number 07898357410039		
EXPIRY / Expiration date 31/12/2021	BATCH/LOT / Batch or Lot Number ABC123	
 (01)07898357410039(17)211231(10)ABC123		
 (00)07898357410000015		

Heterogeneous Box

(00) SSCC – Serial Shipping Container Code



Note: For intermediate levels in the hierarchy of packaging, such as bundles, consult GS1 Brasil for recommendations.

BEST PRACTICES

PRINTING QUALITY:

Some factors must be considered to obtain quality printing, such as:

COLOR AND CONTRAST

Contrast is the technical name for the difference between dark and light areas of a bar code and, in particular, how the difference is “seen” by the scanner. The printing process must ensure the scanner can distinguish between light and dark areas of the symbol with ease.

The Contrast is highly affected by the color and reflection of the substrate and print process used. Below are some simple rules that assist in selecting the best combination of colors and help create a good contrast on the symbol:

- Black printed on white is the best color combination
- Dark areas should comprise of dark solid colors (black, blue or colors that contain a high percentage of black)
- Light areas should comprise of bright and reflective colors (white, yellow or red – note that some scanners use a red light, so the red “appears as white” to the scanner)
- No intermediate colors or shades (those that do not appear dark or light) should be used
- Certain substrate materials, particularly highly reflective metals and highly reflective ink (for example, gold or silver), should be avoided, since the reflection can “blind” the scanner

SIZE (X-DIMENSION)

Bar codes can be printed in various sizes. The size to be selected depends on the printing conditions, the scanning environment and the quantity of information to be entered. For each type of bar code, the size may vary between a minimum and a maximum.

Standard for reading items in the supply chain and retail: GS1 DataMatrix:

Symbol	X- Dimension (inches)			Minimum height of the symbol for x- dimension Mm (inches)			Blank margins		Minimum quality specification
	Minimum	Ideal Size	Maximum	For minimum x-dimension	For ideal x-dimension	For maximum -x-dimension	Left	Right	
GS1 DataMatrix ECC 200	0.396 (0.0156")	0.495 (0.0195")	0.990	Height is determined by the x-dimension of the encoded data			1X	1X	1.5/08/660

Using the recommended x-dimension and encoding the GTIN and the IUM, the minimum size of the GS1 DataMatrix will be around 10mm X 10mm. The ideal size is 13 mm x 13 mm.

Standard for reading in the supply chain: GS1-128:

- The minimum height of the bars is 31.75 mm (not including the numbers printed below the bars)
- The maximum width of the code is 165 mm including the quiet zone (or clear margins)
- The x-dimension of the code is scaled between 50% and 100%, where 50% represents a module of 0.495m and 100% represents a module of 1.016 mm

Symbol	X- Dimension (inches)			Minimum height of the symbol for x- dimension Mm (inches)			Blank margins		Minimum quality specification
	Minimum	Ideal Size	Maximum	For minimum x-dimension	For ideal x-dimension	For maximum -x-dimension	Left	Right	
GS1-128	0.495 (0.0195")	0.495 (0.0195")	1.016 (0.0400")	31.75 (1.250")	31.75 (1.250")	31.75 (1.250")	10X	10X	1.5/10/660

CODE CERTIFICATION

There are several ways to assess the quality of a bar code symbol. GS1 Brazil offers to its members a barcode quality verification service (Certification) and best practice guides.

The printing conditions should be checked regularly throughout the process to ensure that they have not deteriorated since the initial assessment.

GS1 Brasil is available to verify bar code quality for its members. Send bar code samples to GS1 Brasil.

GENERAL INFORMATION

- This is a quick reference guide. For more information, contact GS1 Brasil by phone (11) 3068-6229, or visit our website: www.gs1br.org.

All of the bar code symbols represented in this material are for illustrative purposes only. More information and details: GS1 System User Manual

REFERENCES

<http://www.gs1br.org/educacao-e-pratica/materiais-tecnicos>

- User Manual (“Manual do Usuário”)
- GS1 DataMatrix Guide (“Guia GS1 DataMatrix”)
- GS1 standards in the supply chain of the health sector (“Padrões GS1 na cadeia de suprimentos do setor da saúde”)
- Technical Booklet GS1-128 (“Encarte Técnico GS1-128”)
- Advanced Identification GS1 Guide (“Guia GS1 Identificação Avançada – Versão 1.0”)

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