



REPUBLIC OF TURKEY
MINISTRY OF HEALTH
Medicines & Medical Devices Agency

GUIDELINE ON IMPLEMENTATION OF THE IDENTIFICATION AND BARCODING OF MEDICINAL PRODUCTS FOR HUMAN USE

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1. OBJECTIVE, SCOPE, LEGAL BASIS AND DEFINITIONS

1.1. Objective and Scope

The objective of this guideline is to designate the principles related to the identification and barcoding of medicinal products for human use for the purpose of tracking drugs. To serve this purpose, the guideline encompasses the relevant information for generating barcodes and printing.

1.2. Legal Basis

This guideline has been drafted in accordance with Article 19 of the “Regulation Regarding the Packaging and Labeling of Medicinal Products for Human Use” published on the Official Gazette dated 12/08/2005, with No. 25904.

1.3. Definitions

To serve the purposes of this guideline, the following terms shall apply:

- ▲ **Ministry:** Republic of Turkey Ministry of Health,
- ▲ **Barcode Symbology:** Method that will be applied in the coding and decoding of information on the barcode (e.g.: EAN -13 Barcode Symbology, GS1-128 Barcode Symbology, ITF-14, etc.)
- ▲ **Barcode:** Technology consisting of a combination of lines of varying widths, spaces and numbers that allows numerical or alphabetical data to be transferred accurately and promptly to computers,
- ▲ **Barcoding:** Printing of data read by the barcode reader by using an appropriate barcode symbology and printing method on a specified surface,
- ▲ **Primary identifier:** The barcode,
- ▲ **General Directorate:** General Directorate of Pharmaceutical and Pharmacy,

- ▲ **Group Separator:** The character corresponding to FNC1 (function1) in the barcode symbology for GS1 - compatible systems
- ▲ **GS1:** International organization headquartered in Brussels that develops Effective Supply Chain Solutions and Standards, represented by TOBB-GS1 Türkiye in Turkey.
- ▲ **GS1 Application Identifier (AI):** Data headings used in determining the meaning of data that will be transferred to information systems by the barcode reader (e.g. 01= GTIN, 17=expiration date),
- ▲ **GTIN (Barcode Number, Global Trade Item Number):** Product number that allows commercial products to be uniquely identified on a global scale and whose content (structure) is specified by GS1,
- ▲ **Secondary identifier:** The version named in data matrix symbology format and printed on medicinal drug packages of the information of which the contents and structure are laid out in this guidance,
- ▲ **Data Matrix Symbology:** Two -dimensional barcode symbology that will take “ISO/IEC 16022 International Symbology Specification-Data Matrix ECC 200 Version” as its basis,
- ▲ **Pharmaceutical Code:** A coding system based on the pharmaceutical presentation and administration of the product.

2. IDENTIFICATION AND BARCODING OF MEDICINAL PRODUCTS FOR HUMAN USE

2.1. Identification of Products

The following identifiers will be used in the identification of Medicinal Products for Human Use:

- ▲ **GTIN- Global Trade Item Number:** This is a number composed of at most 14 digits used to uniquely identify products on a global scale. In circumstances when the commercial product is used at the retail sales point, the number placed on the product consists of the EAN-13 barcode symbology and has 13 digits. In such circumstances, the number “0” shall be placed before the 13 -digit number and a 14 -digit GTIN number will be composed.

GTIN consists of four parts. These are GS1 Country prefix, Company prefix, product reference number and check digit. The GTIN is determined by authorized/brand owners according to GS1 GTIN Allocation Rules.

Use of pharmaceutical code in GTIN is optional. If it is desired to use a pharmaceutical code, characters N9 and N10 may be used for pharmaceutical code.

The GS1 Application Identifier identifying the GTIN information is “01”.

Application Identifier (AI)	Barcode Number (GTIN TM)													
	Extension Digit	GS1 Company Prefix						Product Reference						Control Digit
01	0	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄

Example:

Application Identifier (AI)	Barcode Number (GTIN TM)		
01	0	869123456789	0

- ▲ **Serial Number:** This is a number used in identifying each unit of a product identified by GTIN. A serial number used for a product may not be used again for the same type of product. The length of the serial number may vary and may contain 20 alphanumeric characters at most. The marketing authorization holder designates a unique serial number.

The GS1 Application Identifier identifying the serial number is “21”.

Application Identifier (AI)	Serial Number
21	X ₁ ————— variable length —————> X ₂₀

Example:

Application Identifier (AI)	Serial Number
21	1323424679

- ▲ **Expiration Date:** It refers to the final date on which the product may be used safely. It is a numeric data composed of 6 characters. The format of the data shall be YYMMDD. YY will indicate the Year information in two digits, MM shall indicate the Month information in two digits whereas DD will indicate the day information in two digits.

For example; in 120731, 12 indicates the year 2012, 07 indicates the month July and 31 indicates the last day of that month.

If the manufactured product has an expiration of more than one month, digit of last day of the month or “00” shall be used for the day field in the expiration date. Example: If the expiration is two years of a product of which the manufacturing date is July 12 2010, its expiration date is July 31, 2012. This digit is indicated in the identifier in two ways: First is 120731 and second is 120700. Related software managed the digit “00” as the last day of that month.

The GS1 Application Identifier identifying the expiration date is “17”.

Application Identifier (AI)	Expiration Date		
	Year	Month	Day
17	N ₁ N ₂	N ₃ N ₄	N ₅ N ₆

Example: It indicates January 19 2007.

Application Date (AI)	Expiration Date		
	17	07	01

- ▲ **Batch/Lot Number:** This is a number used to differentiate one batch/lot from others during production. The number which, earlier on, used to be referred to as “Serial Number” for Medicinal Products for Human Use will be referred to as “Batch/Lot Number” in the new system. The Batch/Lot Number is of variable length and may contain 20 alphanumeric characters at most.

The GS1 Application Identifier identifying the Batch/Lot Number is “10”.

Application Identifier (AI)	Batch/Lot Number
10	X ₁ ————— variable length —————> X ₂₀

Example:

Application Identifier (AI)	Batch Number
21	X2512061322

- ▲ **Group separator (FNC1):** This character, which is used as a character corresponding to FNC1 (function1) in the barcode symbology for GS1 -compatible systems, shows barcode type when it is placed at the first or second position in the barcode symbology. In other positions, it is used as a character corresponding to field separator. When it is used as a field separator in the data matrix, it is transferred to applications by being converted to ASCII 29 character. If another field follows a field of variable length, group separator is placed between these two fields.

Only “0,1,2,3,4,5,6,7,8,9” numeric or “A,B,C,D,E,F,G,H,I,J,K,L,M,N,O,P,Q,R,S,T,U,X, W, V,Y,Z” alphanumeric characters could be used in serial number and batch/lot number areas in product encodings. Special symbols and small letters will not be used besides for these numbers and letters.

2.2. Barcoding of Products

- ▲ The GTIN (Barcode Number) in EAN -13 Barcode Symbology might be printed on the product package as the primary identifier.

- ▲ Data Matrix: All identifying information indicated in Article 4 will be included as secondary identifier in Data Matrix symbology on the package of the Medicinal Product for Human Use.
- ▲ The content of the new data matrix on the product shall be composed as follows.
 - ▼ The first character of the content of the data matrix shall always be the “Group Separator”. This character which indicates that the content is in harmony with GS1 will not be transferred to the computer applications by the readers.
 - ▼ The 14 -digit GTIN which is applied with the Application Identifier 01 shall be added. The GTIN occupies a total of 16 digits in the data matrix, including the application identifier.
 - ▼ Serial Number: The Serial Number, whose contents are determined by the manufacturer or importer, applied with the 21 Application Identifier, is of variable length and may contain 20 characters at most shall be added. The Serial Number occupies a maximum of 22 characters, including the two -digit Application Identifier.
 - ▼ The Group Separator indicating the end of the Serial Number at variable length shall be added.
 - ▼ 17 Application identifiers and 6-digit date information shall be added. The expiration date occupies a maximum of 8 characters in the data matrix, including the two -digit Application Identifier.
 - ▼ Batch Number: 10 Application identifiers and the Batch Number (with 20 characters at most) at variable length shall be added. The Batch Number occupies a maximum of 22 characters in the data matrix, including the two -digit Application Identifier.

Example: GTIN: “08691234567890”, Serial Number: “1323424679”, Expiration Date: “January 19, 2007”, Batch Number: “X2512061322”. The content of the data matrix

corresponding to this information shall be as follows. The Group Separator Character has been indicated as <FNC1>.

<FNC1> 0108691234567890211323424679<FNC1> 1707011910X2512061322

The data matrix corresponding to this content shall be as follows:

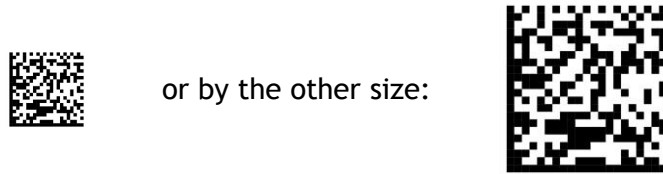


Figure 1

The data to be transferred to the computer upon the reading of the abovementioned data matrix shall be as follows:

0108691234567890211323424679<GS>1707011910X2512061322

It should be noted that the character <GS> containing the value ASCII 29 has been transferred as the Group separator to the computer application by the Barcode reader.

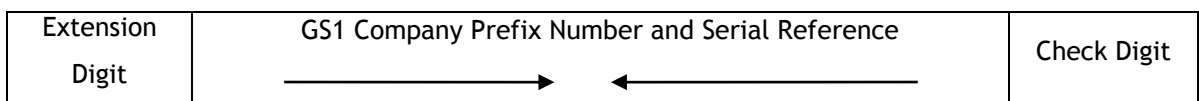
- ▲ **The expiration date** shall be written in the abovementioned format also for human readable information and will be printed separately according to provisions of the regulation in a different place other than this.
- ▲ **The DataMatrix**, as a DataMatrix barcode in ECC200 standards, may be printed in either the square or the rectangle form, as indicated in the mentioned standard. This printing form shall be determined by the manufacturer/importer.
- ▲ **Use of Global GTIN numbers:** If the products have GS1 -compliant Barcode Number (GTIN) in the countries they are manufactured, these numbers may be used after being declared to the Ministry.

3. IDENTIFICATION AND BARCODING OF TRANSPORT UNITS RELATING TO MEDICINAL PRODUCTS FOR HUMAN USE

3.1. Identification of Transport Units

The Transport units are tools which are in use to carry and store (commercial) products in the supply chain. (boxes, chassis, pallets, barrels, sacks, bags etc). There may be a commercial product or some various commercial products in one transport unit. In the GS1 system, transport units are defined and numerated by using SSCC number. SSCC is symbolized by GS1 - 128 (Application Identifier 00 barcode symbology). Defining and numerating the transport units ease logistics operations. It also causes to increase in fertility as making automation applications fast and true in logistics operations. For example, SSCC numbers which are using for transport units are on transport units as barcode. They are also in Electronic Data Interchange records which are among the electronic merchants. Therefore, there is a connection between same SSCC logistics operations and electronic transactions. SSCC, that is an Application Identifier (00), is used to define **unique** transport units. The **serial number**, which defines each transport units over the life of, is given to each transport units. SSCC has a **different** serial number for different transport units. More than one transport unit always contain the same kinds of products; SSCC number is also given in each transport units. SSCC number is used as an **access key** to access the information that is the definition and characteristics of the computer environment on the transport unit. Some elements of this information visibly written on transport unit and also are included as standard data fields in EVD records. (Example: Weight, destination address, expiration date, number of packages contained, etc.).

18 digit SSCC structure is as follows:



N ₁	N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ N ₈ N ₉ N ₁₀ N ₁₁ N ₁₂ N ₁₃ N ₁₄ N ₁₅ N ₁₆ N ₁₇	N ₁₈
----------------	---	-----------------

- ▲ **Extension Digit:** It is given by the company's internal needs. Generally use to identify type of transport unit. (containers, pallets, barrels , safety box, etc.)
- ▲ **GS1 Company Prefix:** It is a company prefix which is given by GS1 Numbering Organization to the transport unit producer firms.
- ▲ **Serial Reference:** It is a serial reference which identifies transport unit. This number is given by producer firm to transport unit.
- ▲ **Check Digit:** It is a check digit which is calculated by modulo-10 method.

SSCC barcode number is printed using GS1 -128 barcode symbology, Application Identifiers (00). Application Identifier (00) indicates data field that follows it, is 18 digit fixed length SSCC. **SSCC must take place on the GS1 Logistic Label of the transport units.**

An example of the SSCC barcode is given below:

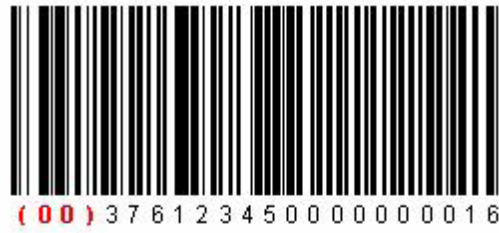


Figure 2

SSCC number and barcode is located on the GS1 Logistic Label of which a sample is given below; SSCC must take place on the GS1 Logistic Label.



Figure 3

4. PLACEMENT AND COMPOSITION OF BARCODES

4.1. Placement

The general rules used in the placement of other Barcodes shall apply also in the placement of the Barcodes of Medicinal Products for Human Use. Hence;

- ▲ Where possible, the barcode and data matrix should be on different planes; where not possible, there should be a distance of 1 cm. between the barcode and the data matrix. The human readable information relating to the data matrix may be included into this area.
- ▲ The position of the barcode and data matrix on the product package should facilitate the legibility of the barcode and data matrix. The GS1 System recommends similar positions on the product packages for barcodes and data matrices whose form and size are similar.
- ▲ The barcode should be on a flat (even) surface.
- ▲ The barcode should not be placed on parts where the package is folded / joined.
- ▲ The barcode and the data matrix should not be positioned in a point of the package where they may get creased; the section where the barcode and the data matrix are printed should not get creased and folded.
- ▲ The barcode and the data matrix should not be covered with any object or shape.

4.2. Composition of Barcodes

- ▲ The company owning the product shall be responsible for the smooth reading by the automatic data collectors (barcode readers) for the composition of the barcodes to be placed on Medical Products for Human Use.
- ▲ When designating the quality principles of the barcodes and data matrices to be composed, the following standards shall be taken as basis in relation with barcode verification:

- ▼ For Linear Barcodes (EAN -13, GS1 -128): TS EN ISO/IEC 15416 Information Technology - Automatic identification and data capture techniques - Barcode printing quality trial property; Linear symbols;
- ▼ For Dimensional Barcodes (Data Matrices): TS EN ISO 15415 Information technology - Automatic identification and data capture techniques - Barcode printing quality trial property specification - Two -dimensional symbols.

4.3. Human Readable Information

- ▲ The content of the barcodes to be placed on Medicinal Products for Human Use shall be printed in a human readable or legible manner below the barcode in linear barcodes and adjacent to the data matrix in data matrices.
- ▲ The application identifiers shall be specified in parentheses for the purpose of facilitating the reading. However, these parentheses shall not be included into content of the data matrix. In the human readable information of the DataMatrixed label seen in the example, the parentheses indicating the application identifiers are for demonstrative purposes and shall not be included into the data matrix content.
- ▲ The human readable information is described to meaningfully and collectively demonstrate the data matrix contents. In some small packages, because there is a problem with respect to available space, the expiration date and batch number may not be included in the human readable information, provided that they are indicated on other parts of the package. However, the GTIN and Serial Number should be on a place compatible with the data matrix and should be apprehensible.

4.4. Application

- ▲ There are no restrictions relating to the printing of the barcode and data matrix on the package. Registration/permit holders shall be free in performing the application with the most suitable method for them. However, in the data matrix applications to be performed with the label method on the outer package of the product, it should be

ensured that the labels are destroyed if they are removed or the removal of the adhesive part of the label is prevented. This scope shall also apply for cases where data matrix is applied upon modifying the labels prepared previously.

- ▲ For all barcode applications, the degree of the printing quality shall be by minimum at “D” grade. In serial production lines, it shall suffice to conduct product testing through sampling to ensure the same grade.

5. OTHER RULES

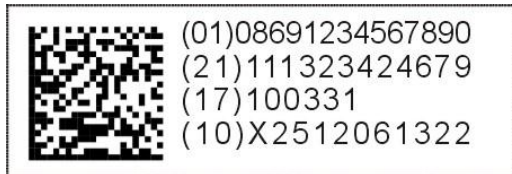
5.1. Identification of Locations

- ▲ An internationally recognized coding system is adopted for unifying fields of activity under a code system. The Global Location Number established by the GS1 organization shall be used to encode locations.
- ▲ Creating and using the Global Location Numbers shall be in accordance with the rules of GS1 Organization. For more information on GLN, refer to the “GLN Allocation Rules” document issued by the GS1 system.
- ▲ The Global Location Number shall be affixed on documents, where appropriate, using a bar code in the EAN13 bar code standard.

6. APPENDIX

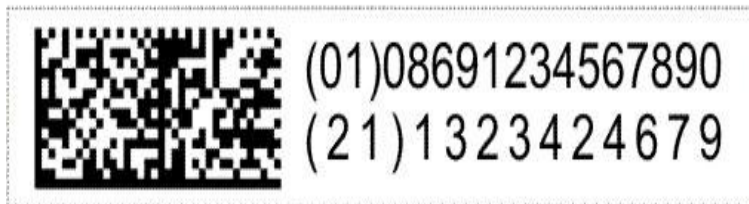
6.1. Sample Labels

6.1.1. A Product Label Sample with Standard-Compliant DataMatrix:



This figure shows a product label with standard - compliant data matrix. These parenthesis are using to make easy of human reading. Please be careful to use GTIN's AI as (01) and "0" at the beginning of GTIN.

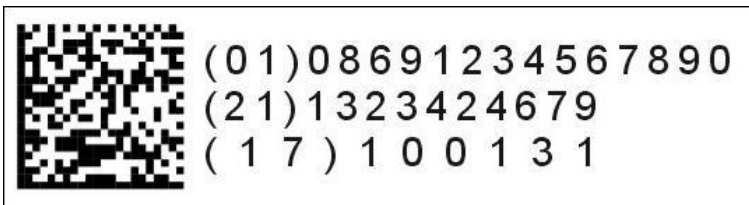
6.1.2. A Product Label Sample with Standard-Compliant Rectangular DataMatrix



In this figure, a user who wanted to write the code in one go using a smaller space used a rectangle DataMatrix and indicated the GTIN and Serial

Number next to it. It is recommended that the rectangle form of DataMatrix be used on the packages which have inclined surfaces. In this sample, it should be noted that the DataMatrix contains all of the 4 required information and the expiration date and batch number are indicated somewhere else on the package.

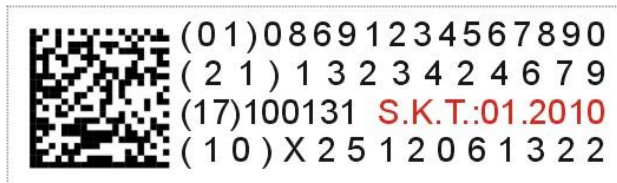
6.1.3. A Product Label Sample with a Three-Line DataMatrix



This figure shows a sample for the cases in which the batch number is not included in the human readable codes as it is

indicated somewhere else on the package. In this example, the batch number isn't indicated in the human readable codes, but the data matrix includes all of the 4 fields.

6.1.4. A DataMatrix Label Sample with Non-Standard Information



In this figure, it is shown that information other than the standard fields included in human readable information may be written. This information applies in the

cases where the expiration date and batch no are not indicated in a second place on the package. Such applications may be used provided that the information is written as close as possible to the standard. This information should be of an explanatory nature for the human readable information; they may not contain different information Bu.

(Use of red color is for demonstrating the difference, it is not mandatory to use different colors.)