مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

Drug Barcoding Specifications

Version 0.2

Gulf Health Council

Central Registration

Gulf Central committee for Drug Registration

مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

Table of Contents

1. INTRODUCTION

Unified standards for automatic identification in the health-care field provide an opportunity to make GCC's drug supply chain safer yet more efficient and accurate. The Gulf Health Council (GHC) Central Drug Registration believes that a standardized identification system from manufacture to patient delivery is imperative to comply with the increasing need for product integrity and traceability.

Therefore, and because the Global Standards (GS1) system, which the global health- care community has endorsed, is one of the most widely used trade item identification systems worldwide (GS1, 2011), the Gulf Health Council urges all drug manufacturers in GCC and international manufacturers exporting to GCC to adopt GS1 supply-chain standards. This document outlines this project's new requirements, benefits, and current and future objectives.

2. DEFINITIONS

2.1 GS1 Data Matrix 2-D Barcode

The GS1 DataMatrix barcode is a graphic representation of digital data in a two-dimensional format with high information-decoding capacity. The barcode can be read by optical equipment and provides the following:

- High storage capacity: encoding and marking of a greater amount of data within a smaller space
- Direct marking on items for which labels may not be practical
- Image readability

2.2 Global Trade Item Number (GTIN)

The GS1 Global Trade Item Number (GTIN) is an identification key that uniquely identifies products worldwide. It can be encoded in various types of data carriers, including DataMatrix.

A GTIN may be an eight, twelve, thirteen or fourteen-digit string. These strings will be unique when they incorporate a GS1 Company Prefix, U.P.C. Company Prefix or GS1-8 Prefix as required, and if they are always treated as a data string of digits plus a final check digit. The check digit is used as a verification to ensure that the number is correctly composed.(figure1)

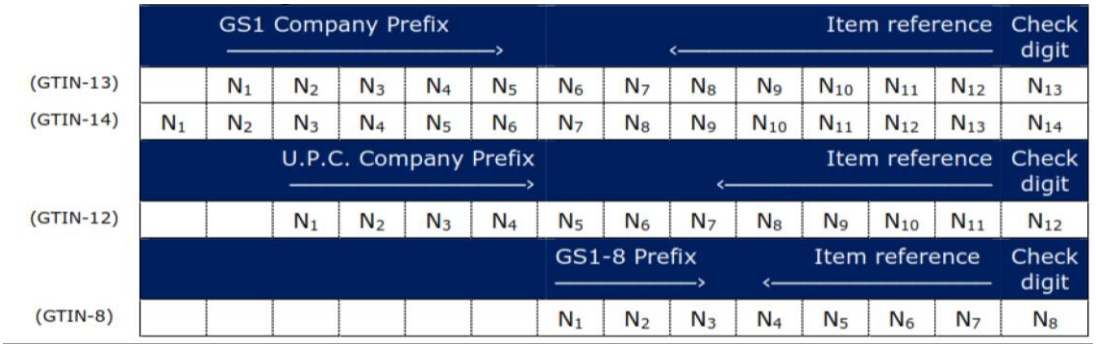


Figure 1: Overview of GTIN formats

When any of these GTINs is encoded in a data carrier that must encode a fixed-length data string of 14-digits, the GTINs less than 14-digits in length must be prefixed by leading zeros that simply act as filler digits.(figure2)

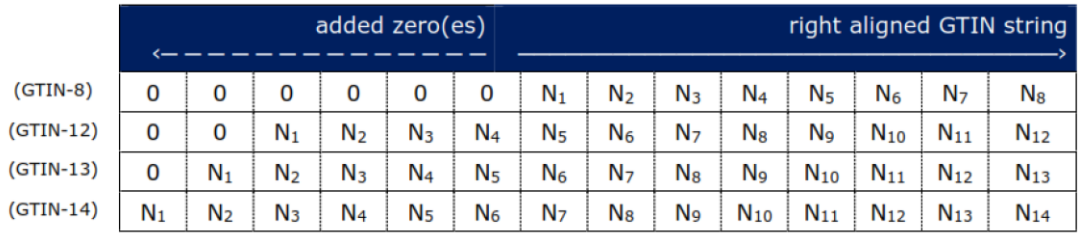


Figure 2: 14-digit representation of the four GTIN formats

The presence or lack of these leading zeros does not change the GTIN concerned.

Note: GTINs may be stored with or without leading zeros in the same database field, depending on the requirements of the particular application.

2.3 GTIN-14

GTINs are available in several lengths. GTIN-14 is a 14-digit number used to identify trade items at various packaging levels and it is the accepted GTIN by GHC. It is also used to identify different packaging level for the same item packed in higher packaging level, for example a product A with GTIN: 06280000000000 when packed in a box the GTIN will be 26280000000000 and if the pallet contains boxes of the same item the GTIN-14 will be 36280000000000

2.4 Global Location Number (GLN)

The global location number (GLN) is a globally unique GS1 identification number that can identify any location in the supply chain that needs to be uniquely identified.

2.5 Serialization Number (SN)

The serialization number (SN) is used to identify each product unit of product identified by GTIN. The SN used for a product cannot be used again for the same product. The SN can be up to 20 alphanumeric characters in length. The SN determined by the pharmaceutical company and it does not need a third party to get the SN. Generating SN must be in a randomized manner.

2.6 Function 1 Symbol Character (FNC1)

Function 1 Symbol Character (FNC1) is a separator used as a barrier in between different data entry components that do not have a fixed character count. Seeing that both serial numbers and batch numbers are variables, an FNC code will be entered after each one of them to notify the scan reader that this number has ended.

2.7 Application Identifier (AI)

Application identifiers are introductory codes of two, three or four digits used to distinguish every entry from the other in the data matrix contents by setting specific introductory numbers for each one of them. The way it works is by writing the identifying number at the start of a GTIN to define that this number is a GTIN and not a serial number. Regardless of the entry that follows an application identifier, it does not affect its character count.

2.8 Aggregation

Aggregation defines the hierarchy relationship between the parent and child where each of the packaging level will be barcoded allowing the receiver of the product to scan one code and understand exactly what is in the whole shipment—every case, bundle, or individual carton.

2.9 Serial Shipping Container Code (SSCC)

Serial Shipping Container Code is an 18-digit number used to identify logistics units, which can be any combination of trade items packaged together for storage and/ or transport purposes; for example a case, pallet.

3. OBJECTIVES

- Increase patient safety.
- Reduce medication errors.
- Enable the tracking of each unit of drug in the supply chain which will lead to:
    - Detect counterfeits.
    - Ensure traceability and fast product recalls and withdrawals.
    - Ensure accurate, real-time information flow among stakeholders.
    - Support the optimal use of drug.

4. REQUIREMENTS

4.1 GS1 Data Matrix

All drugs' markings must be upgraded from linear barcodes (Figure A) to GS1 Data Matrix barcodes (Figure B).

Figure A: Linear barcode

Figure B: GS1 Data Matrix

4.1.1 Coded Data

It should be encoded in accordance to GS1 standard and encoding (FNC1) When needed and at minimum, the Data Matrix barcode must carry the following data:

- GTIN: GS1 Global Trade Item Number. The GS1 application identifier for identifying the GTIN is 01.

  Example:

Application Identifier (AI)	GTIN
01	06280000000000

- Expiration date in YYMMDD format (attribute) as follows in 6 digits:

YY	MM	DD
Last two digits of year number. (Example: 2015 written as 15)	Number of month. (October written as 10)	Number of day. (Example: eighth day of a month written as 08)

The GS1 application identifier for identifying the expiration date is 17.

Example: 8 October 2015 is represented as follows:

Application Identifier (AI)	Expiration Date		
17	15	10	08

- Batch/lot number (attribute). The GS1 application identifier for identifying the batch/lot number is 10.

  Example:

Application Identifier (AI)	Batch/Lot Number
10	X123456789

- SN: the serial number is variable in length up to 20 alphanumeric characters. The GS1 application Identifier for identifying the SN is 21. However, it could be shorter.

  Example:

Application Identifier (AI)	Serialization Number (SN)
21	X123456789XYZ

4.1.2 Application Identifier (AI)

Example:

Application Identifier (AI)	Referred data	Character requirements
01	Global Trade Item Number (GTIN)	AI + 14 numeric digits
10	Batch or lot number	AI + 20 alphanumeric characters
17	Expiration date	AI + 6 numeric digits
21	Serialization Number (SN)	AI + 20 alphanumeric characters

The content and example of the GS1 DataMatrix containing the information above when read by camera-based barcode scanners is as follows:

GTIN:06280000000000

SN: X123456789SFDA

EXPIRY: 151008

BATCH/LOT: 123SFDA

]d2 01 06280000000000 21 X123456789SFDA <GS> 17 151008 10 123SFDA

]d2	01	06280000000000	21	X123456789SFDA	<GS>	17	151008	10	123SFDA
FNC opening character	AI	GTIN	AI	Serial Number	FNC separator	AI	Expiration date	AI	Batch number

4.1.3 FNC1

Serial numbers have alphanumeric characters that can be as long as 20 characters. If the serial number has less than 20 characters then the scan reader normally will not be able to predict when that serial number ends thus will not be able to scan correctly unless it is followed by an FNC after the serial number. Same case applies for batch numbers.

4.2 Printed Information

Options	Data Matrix	Clarification	Labeling on Outer Pack
First option	 GTIN:62800000000000 SN: 1234567890ABCD EXPIRY: YYMMDD BATCH/LOT: ABCD1234	GTIN, SN, lot no., and expiry date are compulsory in the same format. **Expiry date also has to be written** on the outer pack in a clearer format that shows month and year.	Lot: ABCD1234 Exp: May 2016 Mfg: May 2013
Second option	 GTIN: 62800000000000 SN: 1234567890ABCD	An option of printing only the GTIN and SN without the lot number or expiry date **but they should be printed on the outer pack.**	Lot: ABCD 1234 Exp: May 2016 Mfg: May 2013
Third option	 GTIN: 62800000000000 SN: 1234567890ABCD EXPIRY: YYMMDD BATCH/LOT: ABCD1234	GTIN, SN, lot no., and expiry date are compulsory in the same format**. Expiry date also has to be written on the outer pack** in a clearer format that shows month and year.	Exp: May 2016 Mfg: May 2013
Fourth option	 GTIN: 62800000000000 SN: 1234567890ABCD BATCH/LOT: ABCD1234	An option of printing the GTIN, SN and lot number without the expiry date **as long as it is printed on the outer pack**.	Exp: May 2016 Mfg: May 20 13

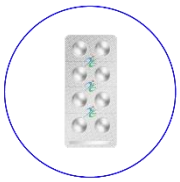
Fifth option	GTIN: 62800000000000 SN: 1234567890ABCD EXPIRY : MMYYYY BATCH/LOT: ABCD1234	GTIN, SN, lot no., and **expiry date are compulsory in the same format.**	Mfg: May 2013

4.3 Aggregation

It is mandatory that companies do the aggregation for packaging stages of the supply chain according to GS1 standards. It's required to be done by the manufacturer on the different packaging level to make it easier for the distributor down to the supply chain to track and report to GHC on each unit of drug movement without having to scan the individual box of medication.

It will also help warehouses to register and track drugs in their system by just scanning the outer barcode and get all the GTIN, expiry, batch and serial numbers without inputting all the information manually which may lead to errors.

4.3.1 Level of Packaging:



- Primary packaging:

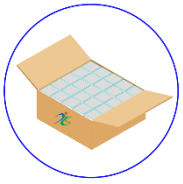
The first level of packaging after production of products. It comes in strips, ampoules... Etc.

- Secondary packaging:

Secondary packaging describes the outer package of a pharmaceutical product. It serves to hold the primary packaging.

- Bundle:

Bundle is a number of the same items/ units wrapped together in a plastic or paper band.



- Sub-cartoon/ Inner-pack:

Sub-cartoon is a number of the same items/ units pack inside a small cartoon and it will not be used as a logistic unit.

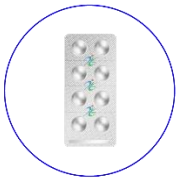
- Cartoon/Case:

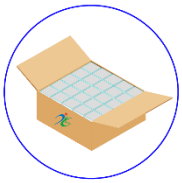
Cartoon/Case is a number of secondary packaging packed in a cartoon or case. It could be of the same drug or a mix of different drugs

- Pallet:

Pallet is a number of cartoons/cases in a pallet used for shipments it could be of the same drug or a mix of different drugs.

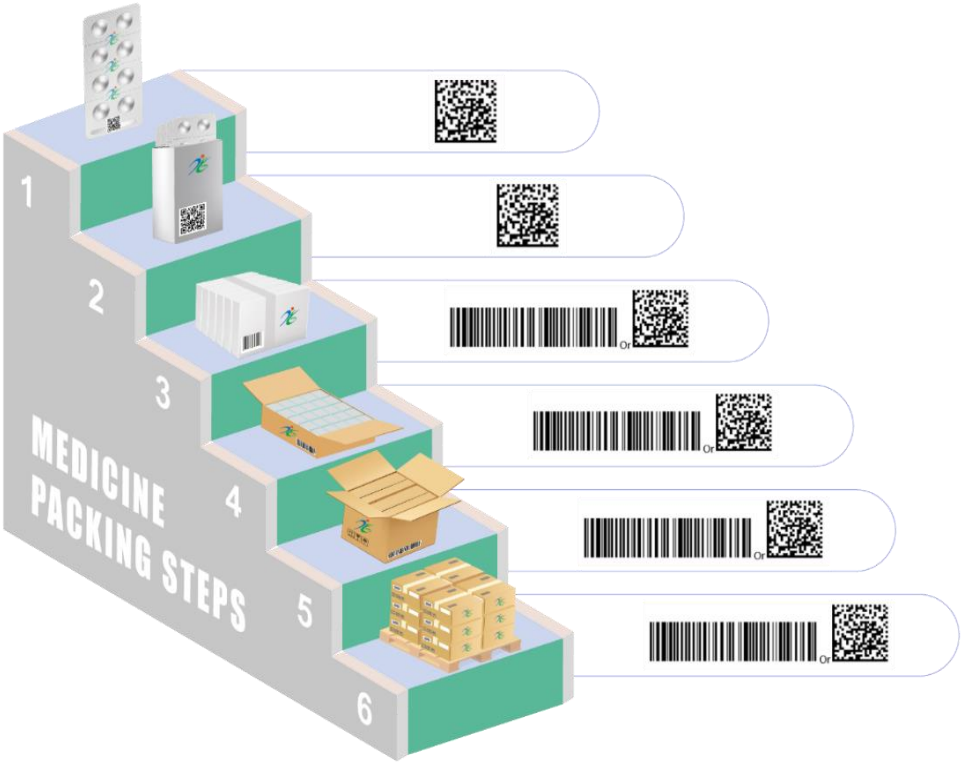
4.3.2 Level of Aggregation

Packaging Level	Packaging Type	Barcoding Requirement	Human Readable Format	Requirement level	Timeline
Primary packaging 		GS1 DataMatrix encoded with: • GTIN 14 • Expiry date • Batch number	Optional	Optional	

Secondary Packaging 		GS1 DataMatrix encoded with: • GTIN 14 • Expiry date • Batch number • Unique Serial number on **each** box	Refer to the printed information table above	Required	Starting from 12/March/ 2017
Bundle 	Homogenous*	• (GS1-128) Linear barcode or GS1 (DataMatrix) encoded with: SSCC code or GTIN*** + SN • And GS1 (DataMatrix) encoded with: ○ GTIN*** ○ Expiry date ○ Batch number	• Expiry date • Batch number • SSCC • GTIN*** + SN	Optional	
Sub-cartoon/ Inner-pack 	Homogenous*	• (GS1-128) Linear barcode or GS1 (DataMatrix) encoded with: SSCC code or GTIN*** + SN • And GS1 (DataMatrix) encoded with: ○ GTIN*** ○ Expiry date ○ Batch number	• Expiry date • Batch number • SSCC • GTIN*** + SN	Optional	
Cartoon/ Case/outer pack 	Homogenous*/ heterogeneous**	(GS1-128) Linear barcode or GS1 DataMatrix encoded with: **SSCC or GTIN*** +SN** And if its homogenous case its optional to include beside SSCC a GS1 (DataMatrix) encoded with: • GTIN*** • Expiry date	• SSCC • GTIN+SN (only for homogenous*)	Required	Starting from 1/October/ 2019

		• Batch number Note: **GTIN*** +SN will be used only with homogenous case/cartoon**			
Pallet 	Homogenous*/ heterogeneous**	(GS1-128) Linear barcode or GS1 DataMatrix encoded with: **SSCC or GTIN*** +SN** And if its homogenous case its optional to include beside SSCC a GS1 (DataMatrix) encoded with: • GTIN*** • Expiry date • Batch number Note: **GTIN*** +SN will be used only with homogenous pallet**	• SSCC • GTIN+SN (only for homogenous*)	Required	Starting from 1/October/ 2019

* Homogenous: the carton or pallet will only contain drugs of the same type.
** Heterogeneous: the carton or pallet will contain drugs of different type.
*** GTIN must be higher level, please refer to GTIN definition.



4.3.3 SSCC encoding

The SSCC should be encoded in a GS1-128 linear barcode or GS1 DataMatrix using AI (00)

Example:

Application Identifier (AI)	SSCC
00	012345678911121314

The identification and symbol marking of logistic units enables a large number of user applications. In particular, the SSCC (Serial Shipping Container Code) provides a link between the physical logistic unit and information pertaining to the logistic unit that is communicated between trading partners.

The SSCC element string AI (00) is used for the identification of logistic units. Each individual logistic unit is allocated a unique number, which remains the same for the life of the logistic unit. When assigning an SSCC, the rule is that an individual SSCC number must not be reallocated again.

In principle, the SSCC provides a unique reference number that can be used as the key to access information regarding the logistic unit in computer files. However, attributes relating to the logistic unit (e.g., ship to information, logistic weights) are also available as standardized element strings.

- GS1-128

The content of the GS1-128 containing the information above when read by camera-based barcode scanners is as follows:

]c1 00 001234567891011123

]c1	00	001234567891011123
FNC Opening Character	Application Identifier (AI)	SSCC

- GS1 DataMatrix

(00) 0 0123456 789101112 3

The content of the GS1 Data Matrix containing the information above when read by camera-based barcode scanners is as follows:

]d2 00 001234567891011123

]d2	00	001234567891011123
FNC Opening Character	Application Identifier (AI)	SSCC

5. WHAT THE INDUSTRY MUST DO FOR BARCODES AND AGGREGATION

- Contact GS1 Saudi Arabia office for more information about acquiring GTINs, GLNs, aggregation standards, and Data Matrix barcodes.
- Prepare your production lines to print and verify the new barcodes.
- The establishment's internal system must store and manage serial numbers meaning that if a product (A) has a quantity of 10000 box the system should store all the 10000 serial numbers for those boxes.
- The establishment's internal system should handle aggregation process and understand aggregation data according to GS1 standards.
- The establishment's internal system should extract and handle aggregation file in accordance with GS1 standards for product shipped to other stakeholders.

6. PRODUCTS THAT REQUIRE BARCODES

- Human drugs that are packaged and ready to be marketed
- Herbal and Health products that are packaged and ready to be marketed will require barcoding in the future.
- Veterinary pharmaceutical products that are packaged and ready to be marketed will require barcoding in the future.

7. PRODUCTS THAT DO NOT REQUIRE BARCODES

- Free samples of pharmaceutical products
- Nonregistered drugs ordered by hospitals for specific patients and in particular quantities
- Drugs cleared for personal use
- Drugs cleared for repackaging purposes

8. APPENDIX A: GS1 DATA MATRIX 2-D BARCODE

8.1 Printing Location

The GS1 Data Matrix barcode must be printed on one side of the secondary packaging—preferably on a flat surface. To facilitate the reading process, it should be placed on the same side where possible.

8.2 Printing Instructions

- Ensure that the surface to be marked is suitable for printing.
- Verify through testing that rubbing does not damage the marking.
- Test the legibility of barcode markings in certain moist conditions.
- Ensure consistent printing quality across packages for information redundancy.

8.3 Readers

The Data Matrix barcode can be read by camera-based barcode scanners but not laser barcode scanners. However, camera-based barcode scanners can read all linear and 2-D barcodes, including Data Matrix.

9. REFERENCES

1. Strength in unity: The promise of global standards in health care http://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf
2. 10 steps to barcode your product http://www.gs1.org/barcodes/implementation
3. GLN Allocation Rules http://www.gs1.org/1/glnrules/
4. GS1 Data Matrix: An introduction and technical overview of the most advanced GS1 application identifiers compliant symbology https://www.gs1.fi/content/download/1057/7252/file/GS1_DataMatrix_Introduction_a nd_technical_overview.pdf
5. GLN in Health care Implementation Guide http://www.gs1.org/docs/gsmp/healthcare/GLN_Healthcare_Imp_Guide.pdf
6. GS1 Saudi Arabia http://gs1.org.sa/
7. GS1 Health care Position Statement on GS1 Data Matrix Implementation http://www.gs1.org/docs/healthcare/GS1_Data_Matrix_Position_Paper.pdf
8. An Introduction to the Serial Shipping Container Code (SSCC) https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=177&language=en-US&PortalId=0&TabId=134
9. GS1 Global Traceability Standard https://www.gs1.org/sites/default/files/docs/traceability/GS1_Global_Traceability_Standard_i2.pdf