مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

Drug Barcoding Specifications

Version O.I

Gulf Health Council

Central Registration

Gulf Central committee
for Drug Registration

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I. 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.

II. Definitions

A. 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

B. 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.

C. 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.

D. 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.

E. 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 does not need for a third party to get the SN.

III. Objectives

- Increase patient safety
- Reduce medication errors
- Detect counterfeits
- Ensure traceability and fast product recalls and withdrawals
- Ensure accurate, real-time information flow among stakeholders

IV. Requirements

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

Coded Data: 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	62800000000000

- Expiration date in YYMMDD format (attribute). 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 length up to 20 alphanumeric characters in length. The GS1 application Identifier to identifying the SN is 21.

  Example:

Application Identifier (AI)	Serialization Number (SN)
21	123456789XYZ

Example of coded data:

GTIN: 08691234567890
SN: 1323424679
Expiration date: 19 January 2007
Batch/lot number: X2512061322
The content of the GS1 DataMatrix containing the information above when read by camera-based barcode scanners is as follows:
01086912345678902113234246791707011910X2512061322

2. Printed Information

Options	Data Matrix	Labeling on Outer Pack	Clarification
First option	GTIN:62800000000000 SN: 1234567890ABCD EXPIRY: YYMMDD BATCH/LOT: ABCD1234	Lot: ABCD1234 Exp: May 2016 Mfg: May 2013	You can print the GTIN, SN, lot no., and exp. on the outer pack.
Second option	GTIN: 62800000000000 SN: 1234567890ABCD	Lot: ABCD 1234 Exp: May 2016 Mfg: May 2013	Print the GTIN, SN and don't print lot no. or exp., because they are printed on the outer pack.
Third option	GTIN: 62800000000000 SN: 1234567890ABCD EXPIRY: YYMMDD BATCH/LOT: ABCD1234	Exp: May 2016 Mfg: May 2013	You can print the GTIN, SN, lot no., and exp. on the outer pack.
Fourth option	GTIN: 62800000000000 SN: 1234567890ABCD BATCH/LOT: ABCD1234	Exp: May 2016 Mfg: May 2013	You can print the GTIN, SN and lot no. without the exp. on the outer pack.
Fifth option	GTIN: 62800000000000 SN: 1234567890ABCD EXPIRY: MMYYYY BATCH/LOT: ABCD1234	Mfg: May 2013	You can print the GTIN, SN, lot no., and exp. on the outer pack.

3. Aggregation

- Aggregation defines the relationship between the parent and child 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.
- It's recommended that companies do the aggregation for packaging stages of the supply chain (contact GS1 for standards).

V. What Industry Must Do for Barcodes

1. Contact the GS1 Saudi Arabia office for more information about acquiring GTINs, GLNs, and Data Matrix barcodes.
2. Prepare your production lines to print and verify the new barcodes.

VI. Products That Require Barcodes

- Human products that are packaged and ready to be marketed
- Veterinary products that are packaged and ready to be marketed will require barcoding in the future

VII. 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

VIII. Appendix A: GS1 Data Matrix 2-D Barcode

A. 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.

B. 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.

C. 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.

IX. References

- Strength in unity: The promise of global standards in health care
  http://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf
- 10 steps to barcode your product
  http://www.gs1.org/barcodes/implementation
- GLN Allocation Rules
  http://www.gs1.org/1/glnrules/
- 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_and_technical_overview.pdf
- GLN in Health care Implementation Guide
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- GS1 Saudi Arabia
  http://gs1.org.sa/
- GS1 Health care Position Statement on GS1 Data Matrix Implementation
  http://www.gs1.org/docs/healthcare/GS1_Data_Matrix_Position_Paper.pdf