

Guidelines on GS1 DataMatrix Barcode and Pharmaceutical Track & Trace System

Ministry of National Health Services, Regulations & Coordination

Islamabad, Pakistan

1. Introduction

These Guidelines are issued to provide stakeholders with detailed technical and operational requirements for implementing GS1 DataMatrix barcodes and a national Track & Trace system for registered pharmaceutical products in Pakistan. They are aligned with GS1 General Specifications and relevant ISO standards and aim to enhance patient safety and supply-chain integrity.

2. Purpose and Scope

- Purpose: To define minimum mandatory data elements, encoding rules, packaging-level requirements, system capabilities, and stakeholder responsibilities for serialization and traceability of pharmaceuticals in Pakistan.
- Scope: These Guidelines apply to all manufacturers, importers, distributors, wholesalers, and retailers of pharmaceutical products intended for the Pakistan market. Primary packaging is exempt at this stage; requirements focus on secondary and tertiary packaging levels.

3. Legal and Regulatory Background

- These Guidelines implement the provisions of S.R.O. 470 (I)/2017 (15 June 2017) issued by the Government of Pakistan requiring 2D barcodes and a Track & Trace System.
- DRAP shall oversee implementation, compliance monitoring, and future modifications to data requirements in line with perceived risk and international best practices.

4. Objectives

- Increase patient safety
- Reduce medication errors
- Detect and prevent counterfeit medicines
- Enable traceability and rapid product recalls or withdrawals
- Ensure real-time, accurate information flow among stakeholders

5. Definitions

GS1	GS1 is a Standards organization that brings efficiency and transparency to the supply chain and track and trace system. GS1 tools help organizations exchange critical data - from manufacturing all the way to the consumer - creating a common language that underpins systems and processes all over the world. (Reference: www.gs1.org)
GS1 DataMatrix	is a matrix (2D or two-dimensional) barcode which may be printed as a square symbol made up of individual dots or squares. 2D Data matrix is a standard for the pharmaceutical manufacturer's distributors and retailers • Graphical representation of digital data in a 2-dimensional format • Readable by any optical equipment • Useful for high storage and error correction
Function 1 Symbol Character (FNC1)	By definition in ISO/IEC 16022 GS1 DataMatrix uses a special start sequence to differentiate GS1 DataMatrix from other ISO/IEC Data Matrix symbols. This is achieved by using the Function 1 Symbol Character (FNC1) in the first position of the data encoded. It enables scanners to process the information according to the GS1 System Rules.
GS1-128	GS1-128 is an application standard of the GS1 implementation using the Code-128 barcode specification.
GTIN	The item number which provides the identification of trade products uniquely worldwide, whose content (structure) is defined by GS1.
Human Readable Interpretation (HRI)	is the information printed adjacent to a barcode that may represent data carried in the barcode.
Healthcare secondary packaging	A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.
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.
Trade item	Any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, or ordered, or invoiced at any point in any supply chain.

6. GS1 DataMatrix and Barcode Symbology Details

- The GS1 DataMatrix uses the Function 1 Symbol Character (FNC1) in the first position of encoded data to denote GS1 format as per ISO/IEC 16022.
- GS1-128 (Code-128) is required for SSCC encoding at tertiary packaging when necessary.
- The DataMatrix offers high data density, error correction, and is readable by standard optical scanners.

7. Packaging Levels and Mandatory Encoding Requirements

7.1 Primary Level Packaging

- Exempt at present; DRAP may revise this in future.

7.2 Secondary Level Packaging

At secondary packaging level, each unit shall bear a GS1 DataMatrix encoding the following application identifiers and data elements:

- (01) GTIN — Product identification (14 digits)
- (17) Expiration date — Format YYMMDD
- (10) Batch / Lot number — Up to 20 characters
- (21) Unique serial number — Up to 20 characters (hexadecimal sequence of 12–20 characters for verification use, see Section 9.3)

7.3 Shipper / Carton (Tertiary) Level Packaging

Two barcode scenarios apply depending on pack homogeneity:

1. Homogeneous pack:

- First barcode (GS1 DataMatrix): (01) GTIN-14, (17) Expiry Date, (10) Batch/Lot Number
- Second barcode (GS1-128): (00) SCCC — unique carton identification

2. Heterogeneous pack:

- Only SCCC (GS1-128) is required to identify the logistics unit.

8. Human-Readable Interpretation (HRI)

The HRI shall be printed adjacent to the DataMatrix or below linear barcodes and shall aid visual verification.

Parentheses used in HRI to demarcate Application Identifiers are for human convenience only and must NOT be encoded into the DataMatrix payload.

The HRI is illustrative and does not substitute the machine-encoded data; the encoded elements specified in Annex I (Form A) shall be present in the DataMatrix.

9. Barcode Composition, Quality and Printing Specifications

- Barcode composition and verification shall comply with relevant TS EN ISO / ISO/IEC standards for linear and 2D barcodes.
- Printing quality: Minimum ISO/IEC grade 'C' for all barcode applications; manufacturers are responsible for print quality and readability.

- Serial number generation: The serial number used for verification shall be a hexadecimal sequence of 12 to 20 characters. It may be generated deterministically or non-deterministically, but must ensure least probability of collision.
- Module size: Code module size may vary between 0.25 mm and 0.615 mm; typical module sizes range from 0.33 to 0.45 mm. Scanners and printing systems must be configured accordingly.
- Quiet zone: Minimum quiet zone of at least three modules is required for reliable reads.
- Character casing: Serial character string may be upper or lower case; ensure consistent application within an organization.
- Durable printing and inks: Select inks and printing processes (e.g., aqueous, pigmented, solvent-based) that resist rubbing and environmental wear; consider use of windows or designated print areas for DataMatrix placement.
- Inline inspection: Inline code scanning inspection during production is recommended to ensure ongoing print quality and compliance.

10. Barcode Placement Rules

- Place barcodes on flat, non-folded surfaces; avoid creases, joins, or areas subject to stacking or abrasion.
- Maintain at least 1 cm separation between existing linear barcodes and DataMatrix symbols when placed on the same plane; where different planes are possible, prefer separation.
- Ensure DataMatrix is not obscured by graphics, seams, or packaging closures.

11. Operational Rules and Data Lifecycle

- System Capabilities: The Track & Trace system shall enable marking/printing, scanning, acceptance/rejection logic.
- Data Capture and Upload: Manufacturers (or authorized subsidiaries) shall upload master data and transaction (event) data to the DRAP Track & Trace System for every supply-chain hop where feasible.
- Parent–Child Relationship: Maintain product hierarchy (parent-child links) for aggregated units to facilitate traceability.
- Sampling and Saleable Unit Marking: Sampling units must be marked using the same standards as saleable units.
- Data Retention: All data submitted to DRAP shall be retained for a minimum of three (3) years after product expiration.
- Consumer Verification: DRAP will enable consumer-facing verification via mobile application that reads DataMatrix and consults DRAP records.

12. Technical Features of the Marking System

- Architecture: Platform-independent CSV/XML for data exchange; secure, scalable, and industry-neutral aggregation and tracking mechanism.
- Interoperability: Compatibility with barcode readers.
- Security and Privacy: Secure authentication, authorization, and audit trails.
- Verification Logic: Business rules to accept/reject scan events, detect duplicates, and flag anomalies.
- Availability: System shall provide high availability and preferably following server-client architecture.

13. Requirements for Stakeholders

13.1 Manufacturers and Importers shall:

- Register with GS1 and acquire GTINs, GLNs and GCPs as applicable.
- Register with DRAP information system and maintain producer records.
- Ensure printing equipment complies with GAMP and 21 CFR Part 11 where applicable.
- Produce master data CSV/XML and transaction/event XML files for submission to DRAP as required.
- Generate and maintain unique serial numbers per unit and ensure compliance with Annex I (Form A).
- Ensure packaging and barcode quality and perform verification prior to dispatch.

13.2 Distributors, Wholesalers and Retailers

- Register with DRAP and acquire GLNs.
- Deploy and maintain systems capable of scanning AIDC data and interfacing with DRAP as required.
- Report anomalous or suspect products to DRAP.

14. Printing Devices and Quality Assurance

- Printing equipment must be capable of printing folded unit packs inside production facilities and comply with relevant regulatory and technical standards.
- Conformance: Each printed 2D DataMatrix must comply with ISO/IEC specifications and pass verification checks.
- Quality assurance: Recommend inline inspection and periodic verification using accredited barcode graders.

15. Implementation Timelines and Phased Rollout

- DRAP will define implementation timelines; a phased approach is recommended starting with secondary packaging marking, followed by serialization at tertiary level and full data submission.
- Manufacturers should plan for up to six (6) years for full serialization of tertiary packaging where required, subject to DRAP timelines.

Annex I — Form A: Data Elements Required for Encoding

Information	Application Identifier	Length / Format
GTIN	(01)	14 digits
Expiration Date	(17)	YYMMDD
Batch / Lot Number	(10)	Up to 20 characters
Serial Number	(21)	Up to 20 characters

Notes:

1. Parentheses around application identifiers in HRI are for display only and must not be encoded in the DataMatrix payload.
2. The serial number generation algorithm must ensure least collision probability.
3. Module size, quiet zone and print quality requirements are detailed in Section 9.