International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 11 Issue 07, July-2022

Healthcare Distribution Alliance - Barcoding Requirement for Serialized Product

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Abstract: **The purpose of this paper is to focus on the barcoding requirements for serialized products as per Healthcare Distribution Alliance (HDA) guidelines. Barcodes are integral part of pharmaceutical products which encoded with critical product attributes for tracking and tracing of product source. In competitive market, manufacturer and other supply chain partners have immense pressure to control increasing healthcare cost and improve patient safety from potential counterfeit drugs. Healthcare industry need stringent law and secure technology to enhance product safety in supply chain. There are many efforts and initiative has been taken by FDA with leading pharmaceutical companies to improve the quality of patient safety and care in global markets. HAD published its first Barcoding guidelines "Numerical and Automatic Identification of Drug Products" in 1993. Under this guidelines HDA directed the barcoding requirements for Saleable unit, Inner/Shipper Case and logistics units (Pallet). Since then, HDA had instructed and revised multiple time its guideline to accommodate product safety and enhance patient healthcare systems. Historically HDA barcoding guidelines has been revised and updated in 2001, 2005, 2011, 2017 and 2022. In USA serialization compliance became effective on 27 November, 2023 where unit label, Case label and pallet label must follow barcoding requirement to encode unique identifier for product traceability in supply chain.**

Keywords: Healthcare Distribution Alliance, Pharmaceutical Barcode, Serialization, Digital Drug traceability,

I. INTRODUCTION

Global healthcare regulatory bodies are trying to implement stringent barcoding requirement in pharmaceutical packages for product security and patient safety. Gradually pharmaceutical serialization compliance is adopting by many countries to streamline themselves in global supply chain. There are two RFID (Radio Frequency Identification) barcode (GS1-DataMatrix and GS1-Databar) is been used in serialization packages. FDA, regulatory body of US and Europe has adopted implementation of GS1-DataMatrix (2D) barcode in unit and case labels as it can contain larger data without expending barcode size and lower cost of implementation.

Serialization is mandate regulatory compliance in many trade markets for drug traceability and authentication. It increases the drug visibility and security in global supply chain. The pharmaceutical serialization required to encode unique identifier in unit/case level packages and temper proof seals with hologram. The main objective of governments and regulatory bodies for implementing serialization with advanced level packaging is to secure the supply chain and mitigate the risk of counterfeit [1]

Criminals and drug counterfeiters deliberately and fraudulently produce fake drug by copying label information and diverting them to supply chain through illegal sources. The World Health Organization (WHO) has estimated that 1 in 10 drugs in low to middle income countries (particularly Southeast Asia and Africa) is falsified or substandard during market circulation.[2]

HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain was the main source of the Drug Quality and Security Act (DQSA), which was signed into law by President Obama on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the U.S. These guidelines are intended to aid supply chain stakeholders in meeting the DSCSA requirements.[3] Innovative barcode technology is the key source of improving the administration phase of medication given to patient to ensure the 5 rights of medication administration – the correct drug, dose, time, route, and patient.[4](Naidu & Alicia, 2019)

DSCSA (Drug Supply Chain Security Act) requires pharmaceutical manufacturers must need to affix or imprint unique identifier in each product packages and homogeneous case. The unique identifier with Lot number and expiration date must be encoded into the 2D barcode to make Standardized numerical identifier [SNI. The "Standardized Numerical identifier" represents a set of numerical or alphanumerical characters used to identify each product and case uniquely and that would be combination of GTIN (Global Trade Item Number) and uniquely defined serial number up to 20-digit length for that product. FDA's bar code rule, 21 C.F.R. § 201.25,14(14) requires an encoded, standardized 2D barcode on human prescription drugs which will contain GTIN, Lot No., Expiry Date and unique serial number. These drug products must meet GS1, health Industry Business Communication Council (HIBCC) standard or standard format approved by FDA. The DSCSA also recommend that GTIN must not be used against NDC and NDC must be printed separately in human readable form on product and Case label. NDC number is not interchangeable with GTIN as per GS1 (General Specification 1) international standard and combination of NDC and Serial number will not make it unique identifier so DSCSA also recommend to use GTIN which contain NDC number for drug sold within united states. FDA strongly recommended to print human-readable version of product identifier and with batch and expiry date in drug packages. In some situation when Radio frequency scanner can not scan or read the GS1 2D data-matrix or GS1

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Linear barcode then supply chain partner can use human readable portion for validating product authenticity. FDA also mandated to print NDC number in one of three hyphenated, human-readable formats, i.e. “4-4-2”, “5-3-2”, or “5-4-1”

Figure 1.

The first 4-to-5-digit segment is for labeler code which represent identification of Brand owner. Next 3 to 4 digits represent product code and its attributes and final 1 to 2 digit is for individual packaging size of product.

Table 1.

NDC Format	GS1-US	Labeler	Product	SKU/Product	Mod-10 Check
5-4-1	3	NNNNN	NNNN	N	N
4-4-2	3	NNNN	NNNN	NN	N
5-3-2	3	NNNNN	NNN	NN	N

From the NDC examples:

- 5-4-1 Format: NDC 01234-5678-9
- 4-4-2 Format: NDC 0123-4567-89
- 5-3-2 Format: NDC 01234-567-89

DSCSA regulation mandated to include the Unique serial number identifier on each product package and homogenous case. In final guidance FDA stated that it is acceptable to present the NDC within the GTIN in Machine-readable 2D bar code the DSCSA requires and that it may be presented optionally in the human-readable portion of the product identifier. The product identifier represented as “a standardized graphic in both a human-readable format and on a machine-readable data carrier called 2D DataMatrix barcode [5]. GS1 guidelines mandate to include the GTIN AI(01) + the serial number AI(21) + the lot number AI(10) + the expiration date AI(17) to create the DSCSA-compliant product identifier encoded in a 2D Data Matrix bar code. The encoded data in 2D barcode should use as followings

<FNC1> + AI(01) + GTIN + AI(21) + Serial Number + <FNC1> + AI(10) + Lot Number + <FNC1>+ AI(17)

Expiration Date

The followings are attribute of 2D DataMatrix barcode

- The 2D Data Matrix bar code when encoded with data or imprinted upon on packages shall include GTIN, Serial number, Batch and Lot no. on both product as well as homogenous case.

Figure 2.

GTIN 003456478765257
SN 123456789012
Lot AB001
EXP 2024-12-31

(01)003456478765257
(21) 123456789012
(10) AB001
(17)2024-12-31

Above: ISO/IEC Data Matrix symbols encoding “Healthcare Distribution Alliance” at a cell size (“X-dimension”) of 30 mils. DSCSA regulation requires to include lot number (Batch number) in 2D barcode and human readable form as well. The application identifier (10) uses to represent lot number and the lot number can be maximum 20 digit numerical or alphanumerical as per GS1 standard guidelines. FDA recommended the following abbreviations of “Lot Number” in human readable form.

➔ *Lot*	➔ *Lot No.*	➔ *LOT*

HDA strongly recommend that following for special character must be avoided to include in Bat Lot number as it may cause issue in supply chain for interoperability, readability and product traceability

“ *Quotation mark*	. *Full Stop*
- *Hyphen/Minus*	_ *Low Line*

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The products expiration date is another critical information which needs to include in product packages as per DSCSA guidelines. Product expiration date encoded with application identifier (17) in human readable form in six numeric number to represent date in YYMMDD (Year, Year, Month, Month, Day, Day) format. In current situation some manufacturers do not include exact day of the month instead they encode "00" which represent last day of the month.
GS1 strongly recommend to use exact day of the month and will not allow to use "00" represent as day of the month from 1st January, 2025. FDA published final guidelines to use product expiry date in following human readable format.

Table 2

➔ *EXP.* ➔ *EXP* ➔ *EXPIRY.*	➔ *EXP DATE* ➔ *Exp. Date.*

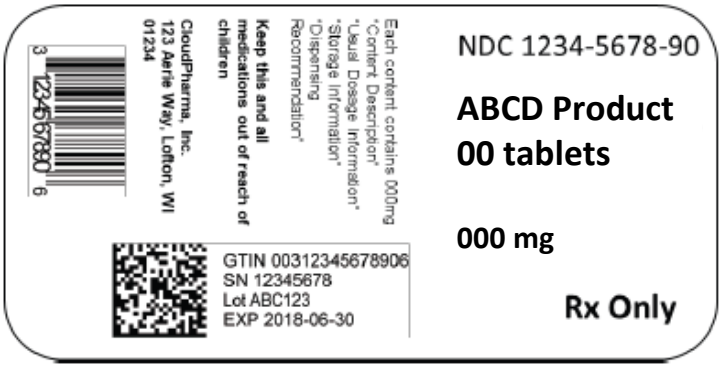
In the Product Identifier Final Guidance, FDA recommends using one of the following abbreviations for expiration date:

Table 3.

Expiration Date	Non-HRI Text	YYMMDD Encodation
January 31, 2021	JAN 31, 2021	210131
January 31, 2021	31 JAN 2021	210131
December 2021	DEC 2021	211231
December 2021	12/2021	211231
December 15, 2021	2021/12/15 or 2021 DEC 15	211215
December 31, 2021 (space constraint)	2021DEC or 2021-12	211231

GS1 (General Specification 1) [6]. Barcode is very critical for AIDC process in pharmaceutical industries. It is very important that barcode should contain correct encoded information and must be scanned, read and decoded in any location. Manufacture must ensure that right barcode as per regulatory compliance printed in right label of product. [7]. HDA recommends to encode all fixed length data element first then variable length elements. It is also significantly noticed that encoding GTIN/NDC + unique serial number first will avoid the practical limit of length of some data scanning devices.

Figure 3.



When GS1 2D DataMatrix barcode gets scanned, following data string decoded without the parentheses:
]d2(01)00312345678906(10)ABC123(17)180630<FNC1>(21)123456789012

Product unique identifier in barcode address some important traceability in many countries. [8] Serialized barcode are integral part of serialization process which require supply chain partners to invest capital to get or upgrade equipment for serialized barcode reading compatibility. Stakeholders in supply chain must change their existing labels to contain serialized barcode as per DSCSA's regulatory compliance. [9] The pharmaceutical barcodes are critical elements to mitigate the potential threat of counterfeiting drugs.
Regulatory agency like DSCSA implemented stringent regulations, enforced sever punishment and heavy penalties for counterfeiting medicine and diverting into supply chain [10]. The DSCSA has mandated to print product identifier in 2D Data

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
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Matrix bar code on each saleable unit and homogenous shipper case (encoding unique identifier in inner case is option unless pack is an individual saleable unit or trading partners in supply chain opt to serialize inner case. If inner case is labeled as serialized, guidelines recommend to include GS1 2D DataMatrix and Lot no. with expiry date of product packed inside inner case. It also must print AI(01) GTIN + AI(21) Serial Number + AI(17) Expiration Date + AI(10) Lot Number in human readable format on inner case label. The DSCSA guideline also recommend to add bundle label product is shrink wrapped. It is also noticed in supply chain that some systems, cameras or scanners faces difficulty reading through shrink wrap unless the bundle is placed in a good position or a stretch bundle is used. Additionally supply chain partners recommend to make the 2D bar code visible from the top in shrink wrap as a best practice. Homogeneous cases should distinctly identify the product and the (optional) quantity contained in the case. Information should be mentioned accurately for Handling, storing and picking of case and automatic identification systems to be able to determine case contents quickly. Label readability is very important in warehouse to determine right product for picking and dispatching to mitigate the risk of delivering wrong product to supply chain partners. Drug Enforcement Administration (DEA) regulations must be followed when labeling scheduled drugs.

DSCSA guidelines also recommend marking the following attributes on product pack label affixed/printed on each trade-item case. Trade item name should be printed 0.5 inch or larger in height if possible. Product strength with storing condition and temperature, NDC number in three hyphenated segment, manufacturer and distributor name, 2D DataMatrix encoded with GTIN, Serial number, Lot number, expiry date and case quantity (optional), GS1-128 Linear barcode for GTIN and serial number combination and another GS1-128 Linear barcode for Lot number, expiry date and quantity [11]. Manufacture can also include their own barcode but it must be labelled as “for internal use” or brackets so that it should not create any confusion in supply chain for scanning correct barcode for serialization authentication.

Figure 4.

HDA recommend that corner wrap shipper case serialized label for homogenous case should be 4 inches by 10 inches. The X-dimension of the GS1-128 symbols is 20.0 mils. GS1 DataMatrix symbol X-dimension is 30.0 mils.
Primary GTIN + Serial Number is 0.75” tall; secondary EXP + LOT + QTY is 0.50” tall. Bar code HRI below the GS1-128 symbols is 12 point. EXP/LOT/QTY text above top secondary data symbol also is 12 point In the example shown above, the data used results in a 22x22 GS1 DataMatrix, therefore 0.66”x0.66”, plus a mandatory quiet zone. All symbols encode FNC1 in the first position and FNC1 as the mandatory field delimiter where required.

Figure 5.

Homogeneous partial case of product is case which does not contain full case quantity specified in product configuration in logistics. This helps manufacturer and distributor to identify partial case and distinguished from full quantity shipper case. Partial case label design is the responsibility of brand owner, with no change of brand ownership, partial case is not yet covered by

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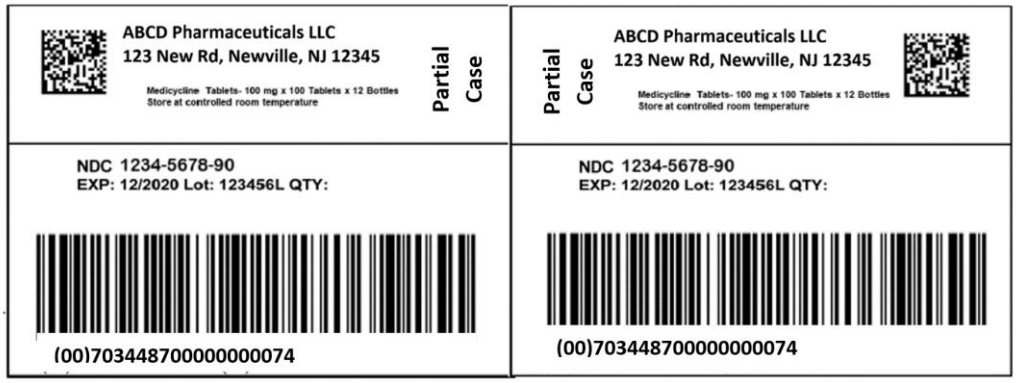
DSCSA. Manufacturers and repackagers may wish to affix serialized labels to the homogeneous partial cases to aid in inventory control and management.

Figure 6.



The logistics unit or SSCC label should be affixed to pallets. Pallets are made by keeping shipper case in arranged manner and then shrink wrapped for securing cases from damages. SSCC labels are affix no closer than 1.25 inches (32 millimeters) from any package edge. Avoid placing the label toward the center of the sides of rectangular corrugated packages to prevent undue exposure and resultant abrasion damage. In any circumstances if a supply chain partner applies two SSCC encoded label then both labels must have same SSCC number There is no expectation for the serial reference within a SSCC to mirror the serial number(s) a part of product identification information encoded in a bar code label and/or RFID tag. The manufacturer can affix a label contain product ID and another label for SSCC. The identification keys encoded in these labels are intended for different purposes, so there is not inherent need for the serial number with the product ID to match the serial reference of the SSCC. This prevents ambiguity and confusion when the containers are read. Pharmaceutical products generally consist three level of packaging. The pallet (Tertiary) level is a logistics unit which is considered as final unit used for transportation in supply chain. Secondary pack which also called as Shipper Case in pharmaceutical supply chain terminology, mostly used for managing stock at pharmacy level. Final and lowest hierarchy of package is product which is also considered as primary product [12]. The first level of product in packaging hierarchy for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be the packaging in direct contact with the product [13]. GS1 and regulatory bodies must consider the complexity and investment required to adopt barcoding guidelines as it may impact financial status of small pharmaceutical manufacturers [14]. The Barcode grading is also very critical part in pharmaceutical industry. Barcode grading is established based on various barcoding standard such as ISO/IEC and ANSI. GS1 has published guidelines to create Datamatrix barcode based on ISO/IEC recognized and use it as per standard implementation. [15] FDA also recommend GS1 specified barcode requirement for manufacturer and repackagers. FDA mandate to affix 2D datamatrix barcode on primary packaging of prescribed drug only. The 2D datamatrix barcode is suitable for product which does not have sufficient space on package label to print contain liner barcode contain larger data [16].

Figure 7.

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ISSN: 2278-0181
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CONCLUSION

Barcode is an integral part of serialization processes. The DSCSA mandated that manufacturer must affix 2D DataMatrix symbology barcode in products and homogenous case labels to make product globally compliant as per serialization requirement in supply chain. The DSCSA also mandated to print human-readable form adjacent to GS1-2D DataMatrix barcode that conforms to the standards developed by a widely recognized international standards development organization. The barcodes encoded serialization data makes supply chain process harmonize in international trade where data readability through radio frequency devices become easier and more robust. The barcodes in serialization label also helps to mitigate the risk of counterfeiting as it contains unique product identifier. The DSCSA requires that a product identifier be a "standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product. Further more drug packaging should have temper evident installed to make product more secure in supply chain. DSCSA has mandated that serialization data must be shared by manufacturer with wholesaler and distributor in electronic interoperable manner where barcode on pharmaceutical supply chain will play an important role to mitigate the risk of counterfeit drug [17]. Barcode in labelling can be important in preventing medication errors and patient health risk. The barcode should be placed carefully on the drug because any incorrect information may lead confusion and delay in supply chain and can cause of batch recall and further investigation [18]

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