

**PARSING THE
DRUG SUPPLY CHAIN SECURITY ACT
(DSCSA) BARCODE**



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What is the Drug Supply Chain Security Act (DSCSA)?



First enacted in 2013 to combat drug counterfeiting, the DSCSA is a comprehensive regulatory framework for identification, tracking, and tracing medications as they move through the US supply chain. The DSCSA requirements have been enacted in stages over the last 10 years, with the final stage effective in November 2023.

Key to the tracking and tracing mandates, is the bar coded Unique Identifier (UI), which must contain certain drug data in a specifically constructed format and bar code.

The DSCSA Barcode

- DSCSA Unique Identifier (UI) barcode symbology is Data Matrix
 - Data Matrix is a two-dimensional barcode (commonly called 2D barcode)
 - 2D barcodes can store up to 2,335 alphanumeric characters



Data Elements of the DSCSA Barcode



- The UI contains the following information about that particular drug package, such as a bottle of pills:
 - 1) Global Trade Identification Number (GTIN), which in turn, also usually also contains that drug's 10-Digit NDC Number and the UPC code of that drug package. The GTIN for most US drugs start with the numbers "003" .
 - 2) A unique Serial Number assigned by the drug manufacturer specifically for that particular drug bottle or other package – a bottle serial number for a particular bottle of pills, for example (bottle serial number
 - 3) Manufacturer's expiration date for that particular drug bottle or other package;
 - 4) Manufacturer's lot number for that particular drug bottle or other package;
 - 5) A total of 4 specific 2-digit GS1 Code Application Identifiers (AI) that appear before each of the above data elements contained in the UI. These AI numbers serve as data separators that identify the type of data element following each AI.

The Application Identifiers in the DSCSA Barcode



The 4 specific 2-digit Application Identifiers (AI) appear immediately before each of the above 4 data elements contained in the UI. These AI numbers serve as data separators that identify the type of data element following each AI.

- a) “01” is the AI that appears immediately before the GTIN;
- b) “21” is the AI that appears immediately before the Serial Number for that package;
- c) “17” is the AI that appears immediately before the Manufacturer Expiration Date; and
- d) “10” is the AI that appears immediately before the Manufacturer’s Lot Number.

Barcode Requirements of the DSCSA Product Identifier (PI)

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Dosage:
See accompanying product literature.

Store at 20° to 25°C (68° to 77°F);
excursions permitted between 15° to 30°C
(59° to 86°F) [see USP Controlled Room
Temperature].
Protect from light and moisture.

Keep out of reach of children.

Marketed by :
Ajanta Pharma USA Inc.
Bridgewater, NJ 08807.
Made in India.

Code No. : GUJ/DRUGS/G/25/2080
3020692

NDC 27241-001-50 500 Tablets

risperidONE
Tablets, USP

1 mg

R_x Only

Each film coated tablet contains
Risperidone USP 1 mg

ajanta

LOT : DJ11102
EXP. : 05/31/2026
GTIN : 00327241001505
Sr. No. : 301975526534



N 3 2724100150 5

Barcode Requirements of the DSCSA Product Identifier (PI)

- Data Fields Included within the DSCSA Barcode include:

- 1) Global Trade Item Number (GTIN)
 - (Often contains the UPC and NDC)
- 2) Serial Number
- 3) Manufacturer's Expiration Date
- 4) Manufacturer's Lot Number
- 5) Four (4) GS1 Standard Application Identifiers (AI)
 - 2-Digit Number Codes (*example highlighted below*)
 - Used as a “prefix” for each data field



Scanned Barcode Example (*See Next Page for Breakdown*)

0100312345678906**21**12345678**17**180630**10**ABC123

Barcode Requirements of the DSCSA Product Identifier (PI)

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 - 2-Digit Number Codes (*example highlighted below*)
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Scanned Barcode Example (*See Next Page for Breakdown*)

0100312345678906**21**12345678**17**180630**10**ABC123

Example

- Bar Code Scanned:
 - Printed Bar Code Data (Scan to Notepad):
010037071011311721302000650732051721113010Z905812
 - Sectioned: (01) 00370710113117 (21) 30200065073205 (17) 211130 (10) Z905812

- Notes
 - Sections can be in alternate orders, but GTIN is almost always first
 - GTIN and Expiration Date character counts are a set length

BREAKDOWN



GTIN (Always 14 Numbers)

AI Prefix Code: 01
00370710113117
NDC = 7071011311

Serial Number (1-20 Alphanumeric Characters)

AI Prefix Code: 21
30200065073205

Expiration Date (Always 6 Numbers = YYMMDD)

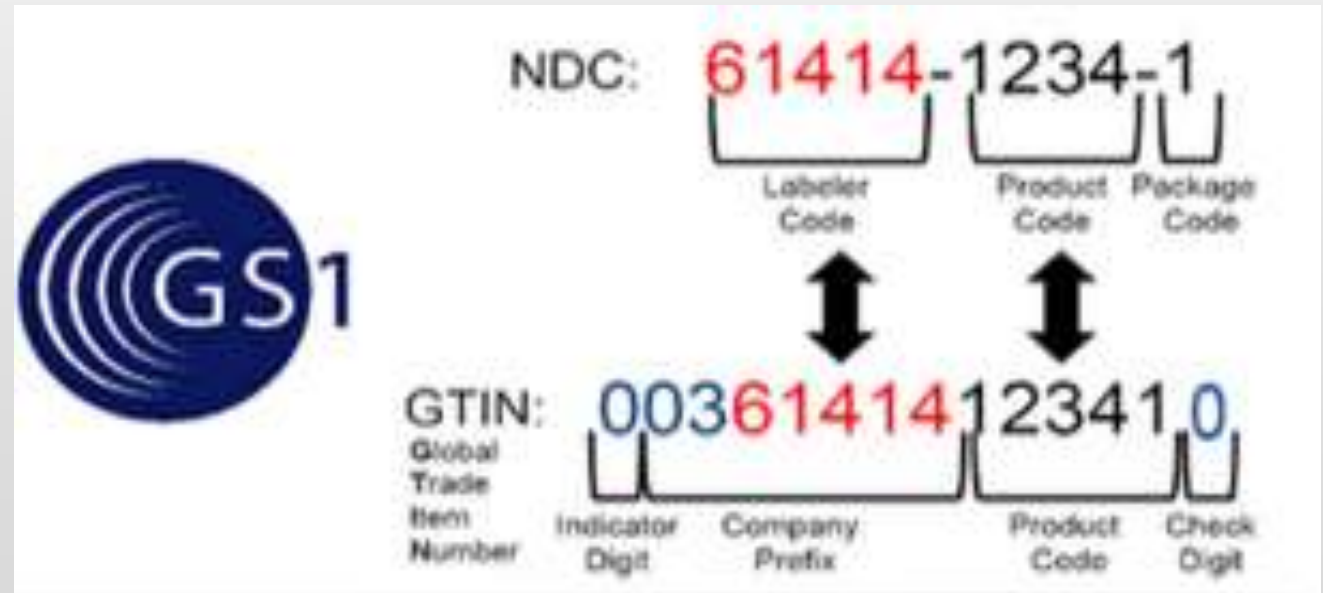
AI Prefix Code: 17
211130 = 11/30/2021 = November 30th 2021

Lot Number (1-20 Alphanumeric Characters)

AI Prefix Code: 10
Z905812

GTIN

- GS1 Code Application Identifier (AI) “01” always precedes GTIN
- Global Trade Item Number – Unique 14 Digit Product ID
- GTIN-14 Structure - Always 14 Numerical Digits
- Assigned by NDC owner
- Recognized globally
- Valid and unique
- Numbers only



Serial Number

- GS1 Code Application Identifier (AI) “21” always precedes Serial Number
- 1-20 Characters
- Can be alphanumeric
- Number assigned to the smallest package size of that Lot or Batch
- For example, if you had one case with ten bottles of aspirin inside
 - Case Lot Number: ABC123
 - Bottle 1 Serial Number: Z71
 - Bottle 2 Serial Number: F150



Manufacturer Expiration Date

- GS1 Code Application Identifier (AI) “17” always precedes Mfg. Expiration Date
- GS1 Code AI(17)
- Numbers only – 6 Digits
- YYMMDD date format.

| Expiration Date | Non-HRI Text | YYMMDD Encodation |
|------------------|--------------|-------------------|
| January 31, 2018 | JAN 31, 2018 | 180131 |
| January 31, 2018 | 31 JAN 2018 | 180131 |
| December 2018 | DEC 2018 | 181231 |
| December 2018 | 12/2018 | 181231 |

Lot Number

- GS1 Code Application Identifier (AI) “10” always precedes the Lot Number
- 1-20 characters
- Can be alphanumeric
- Represents the batch or lot number.
- For example, 1 case with 10 bottles of aspirin in it...
 - Case Lot Number: ABC123
 - Bottle 1 Serial Number: Z710
 - Bottle 2 Serial Number: F150
 - And so on . . .



Putting It All Together

UNDER THE DSCSA

Product Identifier = [SNI] + product expiration date + product lot number

NDC/GTIN + product's unique serial number³⁶

(01) 00361414123410 (21) 100000000369 (17) 190131 (10) 12345678

(indicator digit, company prefix, product code, check digit) (serial number up to 20 characters) (batch or lot number up to 20 characters)

| | |
|-----------------------------------|----------------|
| GTIN Number [GS1 AI(01)]: | 00361414123410 |
| Serial Number [GS1 AI(21)]: | 100000000369 |
| Expiration Date [GS1 AI(17)]: | 190131 |
| Batch or Lot Number [GS1 AI(10)]: | 12345678 |

NOTE: FDA refers to the GTIN + Serial Number as a Standardized Numerical Identifier (SNI)

Impact on Hospital Unit Dose Packaging

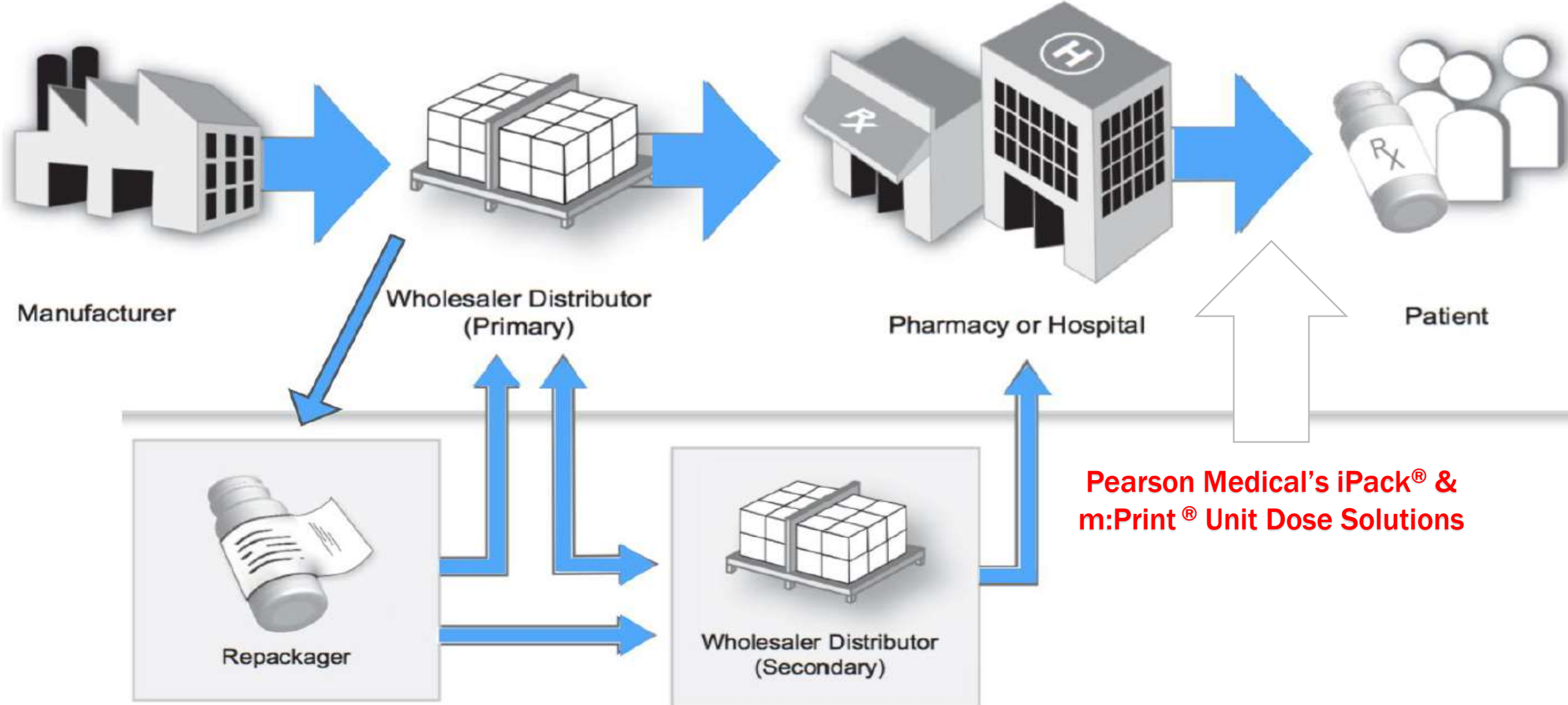


Overall, the DSCSA Product Identifier (PI) bar code contains more unit dose labeling information in this new 2D bar code including:

- GTIN (previously UPC)
- Unique “Bottle” Serial Number
- Manufacturer Expiration Date
- Manufacturer Lot Number

PHARMACIES CAN USE UNIT DOSE PACKAGING AND LABELING SOFTWARE THAT CAN EXTRACT THAT INFORMATION TO PREVENT UNIT DOSE PACKAGING LABEL ERRORS

Pharmacy Supply Chain



FOR MORE INFORMATION ON DSCSA



Contact a Pharmacy Automation Consultant at Pearson Medical to find out more about DSCSA and how our iPack® Rx Unit Dose Packager and m:Print® Bar Code Labeling Software can help you put the DSCSA to work for your pharmacy

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