

The Global Language of Business

GS1 Pharmaceutical Image Implementation Guideline

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1 Introduction

The purpose of this document is to provide a method of image naming; associated data, and transport methods needed to increase efficiencies and minimise costs. The harmonisation of required data and exchange practices reduces the individual mapping from multiple sources to a single process, thus avoiding errors. The image naming utilising a global standardised convention allows for a higher level of security against inadvertent over-writing.

This document is designed to be used by both manufacturers and end users; as well as set a framework for any third party providers that may service either trade partner.

2 Pharmaceutical images

The requirements outlined in this section are for:

Pharmaceutical images: Medication; solid form.

Practical application of these images include, but are not limited to:

- Order Assembly
- Dispensing
- Robotic anti-counterfeiting
- Visual validation
- Emergency response
- Reverse identification
- Product selection verification via physical attribute

2.1 File naming

A non-intelligent unique naming that identifies who the image is from, what type of image it is and a unique reference to link to additional information/content within a data system.

The use of the GS1 GDTI (Global Document Type Identifier) ensures an interoperability globally, and uniqueness identical to the GTIN.



Note: identifying that the best course of action is a unique; non-intelligent naming structure does not mean that a structured format is not allowed, it is merely allowing the manufacturers a margin of flexibility with regards to the naming structure to better integrate with a system they may currently be employing.

Uniqueness:

A globally unique naming structure should be developed to ensure cross functionality within an organisation's document management system, as well as increase the level of stability within an image collection point. Points that should be considered are the following:

Does the naming structure allow for multiple images of the same base elements without impacting current or future image storage practices?

Will the naming structure work with existing systems?

Non-intelligent Structure:

With a non-intelligent naming structure, there will be less chance of improper naming practices, and a smaller time gap for standard integration.

2.1.1 GDTI naming

From the GS1 Global web site:

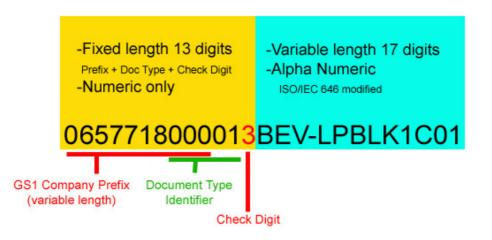


The GDTI is the Identification Key for a document type combined with an optional serial number and used to access database information that is required for document control purposes. The GDTI is assigned for the life time of the document type and may be barcoded using GS1 Application Identifier (253) *Global Document Type Identifier (GDTI)*.

The GDTI is constructed as:

GS1 Company Prefix > < Doc type									Check digit	Serial number (optional)			
N ₁	N_2	N ₃	N4	N ₅	N ₆	N ₇	N ₈	N9	N ₁₀	N ₁₁	N ₁₂	N ₁₃	X_1 variable X $_{17}$ **

**Please note that current GS1 standards identify that the serial component of the GDTI be solely numeric, however due to modifications currently in process, the document as written has been to reflect the proposed change to the GDTI structure.



The GDTI is composed of a document type and an optional serial number (the check digit applies only to the barcode representation). At its simplest, the document type represents a set of documents with similar attributes and the document type together with the serial number represents an instance of a document with those attributes.

The first 12 digits of the GDTI are assigned in exactly the same way as for the GTIN or the GLN: the company prefix and a document reference are concatenated to make a 12-digit number. Apart from the basic format, there is absolutely no correlation between the GDTI and any other GS1 identification key.

2.2 Image specifications

See <u>Product Image Specification Standard</u>: Still Shot Single GTIN



3 Required images

This section outlines the format of the pharmaceutical and the suggested image facings **Front** (in order of importance):

- Largest surface area;
- Company logo or brand;
- Alpha characters (first character alphabetic order)
- Numeric characters

Back:

Directly opposite the front

Alternate:

Another side (other than the front or back) which contains markings

3.1 Pill

Images for a pill include:

- Front
- Back
- Alternate (optional)
 Where additional characteristics are identified

3.2 Caplets/Capsules

Images for a pill include:

- Front
- Back
- Alternate (optional)
 Where additional characteristics are identified

3.3 Transdermal patches

Images for a transdermal patch include:

- Front
- Back



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Images for an oral/buccal strip include:

Front

