

## BARCODING ON PHARMACEUTICAL PRODUCTS : **GETTING IT RIGHT**

The challenge of today's healthcare industries globally, demand traceability, primarily as a deterrent against counterfeiting apart from other benefits.

This has grown in the last few years to become a legislative compliance requirement, and spreading fast across many Countries. Now INDIA initiating this legislation strongly for all exports to begin with. The preferred data carrier tool to achieve this was 2D barcoding and chosen over other comparable technologies including RFID for numerous reasons. The 2D Datamatrix enables identification of a product covering its article number, batch of origin, date of manufacture and if required even a serial number.

The Datamatrix ECC 200 is the most suitable format given its very robust nature and small footprint. The ECC 200 provides redundancy through error checking and correction which is particularly relevant for scanning the symbol under challenging circumstances, particularly online.

Amongst the Countries who have pioneered in adopting barcoding on pharma products for traceability, very successfully, is the French Pharmaceutical industry. This has become a benchmark for other countries in the world to follow, given its success. The legislation in French, CIP-13, requires every pharmaceutical item to incorporate a 2D Data Matrix barcode comprising of product code, batch number and expiry date.

The gathering momentum globally requires that all pharmaceutical manufacturers gear up to the challenges of this upcoming legislative requirement to and be able to print and verify this barcode symbols on their products. The printing techniques to generate these 2D Datamatrix barcodes could cover thermal inkjet, thermal transfer, print-and-apply and, drop-on- demand systems depending on the particular application requirements.

In view of the criticality of the task on hand, it therefore becomes the bound duty of pharmaceutical manufacturers to be able to assure good barcode quality, since much depends on this right up to the point of consumption. Therefore maintaining acceptable barcode quality is an important task and a legal requirement. Just using a hand held reader to check the readability of the code is very insufficient because its reading quality is not defined. Therefore specialized testing equipment and assessment procedure are already laid down, to be adopted, in conformance to ISO/IEC standards that have been created for assessing and defining barcode quality.

This specialized measuring system for 2D Datamatrix barcodes and verifiers are specified under ISO IEC 15415. The global standards body – GS1 which is also the issuing agency for the linear EAN/UPC family of barcodes, developed "Calibration Conformance Standards Text Chart" for the Datamatrix barcodes as well. This makes it a very definitive parameter check of the data quality generated by the barcode verifiers.

Any Pharmaceutical company has to therefore use the data structure of GS1 general specifications in handling the Datamatrix barcodes for their products.

In printing of the Datamatrix 2D barcodes there are potential areas of problems and challenges that need to be carefully considered. Important amongst this is the structure of the symbol identified by a perimeter where scanners begin their attempt to read the encoded data. This finder pattern is “L”-shaped and the opposite two adjacent sides consist of a dark and light clock-pattern. Some of the critical elements of ISO/IEC 15415 in assessing the quality of the printed Datamatrix code include:

- Axial non-uniformity
- Fixed pattern damage
- Grid non-uniformity
- Modulation
- Symbol contrast
- Decode
- Unused error correction
- Reflectance margin
- Quiet zones
- Transition ratios

It is very important not to confuse scanning with verification and this is a very critical link, within control and scope of the pharmaceutical manufacturer. No scanning system will be able to reliably assess and measure barcode quality as defined by ISO/IEC with repeatability and consistency, to be able to therefore assure scannability in any other scanning environment further down the supply chain.

It is therefore important to measure the barcode quality and simply put we can't control what we can't measure. This has been seen as a global phenomenon even with linear barcodes and more and more, larger retailers and distributors globally are imposing fines on suppliers when they deliver goods with poor or low quality barcodes. This includes the likes of TESCO, WALMART, WOOLWORTH, and more, in retail supply chain operations. Obviously the barcode quality assumes greater criticality in a health and pharmaceutical environment.

Therefore most effective method of supervising the Datamatrix barcode quality would be to have stand alone verifiers which allow a comprehensive assessment on every single aspect of the Datamatrix quality. Any on-line scanning system would be more motivated from a data collection perspective and can never do the job of clearly defined barcode verifier systems.

In selection of a barcode verifier care must be taken that it meets the standards of ISO/IEC 15415 and ISO/IEC 16022. Secondly the verifier must be capable of consistent performance in any environment. The verifier's camera pixel size and wave length on light should be in conformance to the symbology specification and the GS1 requirements respectively.

An important element of Datamatrix verification also includes operation training and calibration as per standards. Care and attention to these above parameters will ensure that manufacturers get the right product and knowledge to implement a successful Datamatrix printing operation for their facility. This is going to stay and grow, and getting it right is critical for all.

- Siva Nagarajan  
Director, Sandilyam Automation Systems (Pvt) Limited  
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