

ANNEX

STANDARDS ON DATA CAPTURE OF ACTUAL COMMERCIAL SAMPLES

1. Set the scene to ensure clear photographs can be taken

- Use camera with at least 10 megapixels
- Use a plain background and sufficient indirect lighting
- Avoid reflection (e.g., disable flash)
- Prevent blurry photos (e.g., auto focus, stable support, use of zoom if necessary)
- Include a graduated ruler next to the actual commercial sample in frame (preferably in centimeter)
- Level camera close to and directly above the sample (no slanted views)

2. Photograph ALL SIDES of the packaging by capturing key information of the following:

- Unit Carton (secondary packaging)
 - i. Product Name
 - ii. Dosage Form and Strength
 - iii. Pharmacologic Property
 - iv. Formulation/Composition
 - v. Indication(s)
 - vi. Warning(s) (if applicable)
 - vii. Storage Condition(s)
 - viii. Pack Size
 - ix. Name and Address of Marketing Authorization Holder and Manufacturer
 - x. Rx Symbol and Caution Statement (for prescription products)
 - xi. ADR Reporting Statement
 - xii. Registration Number
 - xiii. Batch/Lot Number
 - xiv. Expiration and Manufacturing Dates
 - xv. Detailed views of key features, including any authentication marks (e.g., hologram, logo, barcode, etc.)
- Primary Packaging *excluding* blister pack, foil strip, and small containers
 - i. Product Name
 - ii. Dosage form and Strength
 - iii. Pharmacologic property
 - iv. Formulation/Composition
 - v. Indication(s)
 - vi. Warning(s) (if applicable)
 - vii. Storage condition(s)
 - viii. Net content
 - ix. Name and Address of Marketing Authorization Holder and Manufacturer
 - x. Rx Symbol and Caution Statement (for prescription products)
 - xi. ADR Reporting Statement (if without accompanying unit carton)
 - xii. Registration Number
 - xiii. Batch/Lot Number
 - xiv. Expiration and Manufacturing Dates
- Blister Pack/Foil Strips
 - i. Product Name
 - ii. Name and/or Logo of the Marketing Authorization Holder
 - iii. Rx Symbol (for prescription product)

- iv. Batch/ Lot No. and expiration date
- Primary label for small containers
 - i. Product Name
 - ii. Dosage Form and Strength
 - iii. Net Content
 - iv. Name and/or Logo of Marketing Authorization Holder
 - v. Rx Symbol (if applicable)
 - vi. Registration Number
 - vii. Storage Condition(s)
 - viii. Batch/Lot Number
 - ix. Expiration Date and Date of Manufacture
- Package Insert and Patient Information Leaflet
 - i. Scanned full insert/leaflet (colored and resolution at least 400 DPI)

3. Check all of the information if captured exhaustively and are readable.

4. Save the captured files in a JPEG or PNG format.

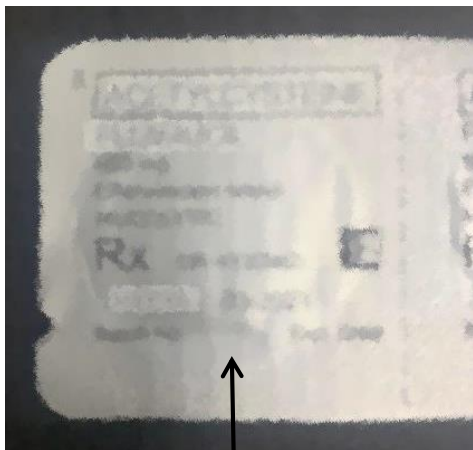
5. Submit the captured files to the FDA.

EXAMPLES

I. CORRECT Data Capture



II. INCORRECT Data Capture



Blurry Information, cannot be read



Light reflected from Camera Flash