EDA’s Requirements for BA/BE & Dissolution Studies

Key Regulatory Guidance: EDA’s Requirements for Bioavailability, Bioequivalence & Dissolution Studies (EDREX: GL.CAPP.001 v1/2015)
Issue Date: 7 June 2015
Effective for Licensed Centers (if applicable): Applies to centers licensed by Egypt’s drug authority to carry out bioequivalence (BE), bioavailability (BA), and dissolution rate (in vitro) studies.

Why This Guideline Matters

This regulation establishes clear standards for centers in Egypt that perform bioequivalence, bioavailability, and dissolution studies. For registration holders, CROs, and regulatory affairs officers, it provides a roadmap of what is required to ensure studies are acceptable, reproducible, and compliant with EDA expectations. It impacts generic product approvals, labeling, and market entry in Egypt.

What It Covers

Here are the principal components of the guideline:

Scope & Definitions

Apply to licensed centers that conduct bioavailability, bioequivalence, and dissolution studies.
Defines key terms: bioavailability, bioequivalence, biowaiver.

Organizational & Operational Requirements

The center must hold enough both the test and reference products to conduct studies.
For modified-release dosage forms, studies in both fasting and fed states are required (except enteric/delayed-release where only fasting may suffice) with studies reported as separate files.
Dissolution (in vitro) parts: must be done at various pH values (1.2, 4.5, 6.8) plus a suitable medium (FDA / USP or other recognized pharmacopeias) unless alternative justified.

Notifying EDA & Study Initiation

Centers must notify the EDA’s Protocol Evaluation & Monitoring Unit for Bioavailability/Bioequivalence Studies in advance—no less than 3 working days and no more than 2 weeks before start of each study.
Before starting, the center must submit certain details: product name, dosage form, active ingredient, manufacturer/license holder, study design and whether fed/fasting, etc.

Volunteer / Ethical & Health Requirements

List of volunteers, volunteer identification (civil ID), demographic data, signed informed consent in Arabic, IRB (Ethics Committee) approval.
Health screening required: complete blood picture, liver & kidney function, serology (HIV, HCV), drug abuse tests, etc.
Adverse event monitoring during study; ability to handle serious events.

Study Protocol & Conduct

Protocol must include test/reference product data, randomization, washout periods, sample collection schedules, phases/stages (especially if multi-stage), inclusion/exclusion criteria, dosing administration, etc.
Sampling, analysis, data management, labeling of samples, storage conditions (e.g., deep freezers at –80°C for biological samples) are specified.

Reporting & Retention

Final study report plus raw data, documentation of all study materials, reference and test product packaging.
Retention of biological samples (after analysis) and retention of all study records for no less than 5 years after approval by EDA.

General Compliance and Quality

GCP (Good Clinical Practice) requirements apply. Centers must follow ethical and procedural standards.
Staff roles must be clear: Director, Quality Assurance, Technical/Analytical heads etc., must be present or officially delegated.
Practical Tips for Regulatory Teams
Checklist approach: Use internal checklists to ensure your center meets all requirements before initiating a study. Missing even one component may lead to rejection or delays.
Documentation hygiene: Ensure everything is properly signed, dated, and stored. Raw data integrity is critical.
Time notifications: Be proactive in notifying EDA—don't leave notifications to the last minute.
Sample handling & storage: Make sure your cold chain/storage capacities meet the guideline, especially for biological sample preservation.
Volunteer recruitment & ethics: Don't underestimate the importance of clear informed consents and screening—critical for both regulatory acceptance and subject safety.
Conclusion
For regulatory professionals in Egypt, EDREX: GL.CAPP.001 is an essential reference. It codifies what the EDA expects from centers performing bioavailability, bioequivalence, and dissolution studies. Adherence not only ensures regulatory compliance but also facilitates smoother, faster reviews of generic drug submissions and product registrations.
Staying current with such guidelines, training team members on them, and integrating these standards into operational SOPs can reduce risk of non-compliance and improve the quality of submitted studies.