

Investigational Product (IP) Manual: Sample Document

1. Title Page

Document Title: Investigational Product Manual for XYZ Drug

Protocol Number: XYZ-2025-001

Version: 1.0

Date: May 20, 2025

Sponsor: ABC Pharmaceuticals

2. Table of Contents

- Product Description
- Packaging and Labeling
- Storage and Stability
- Accountability and Record Keeping
- Dispensing Procedures
- Return and Disposal
- Emergency Unblinding Procedures
- Contact Information

3. Product Description

Name: XYZ Drug

Formulation: Oral tablet, 50 mg

Appearance: White, round, film-coated tablet

Manufacturer: ABC Pharmaceuticals

Indication: Investigational use for type 2 diabetes

4. Packaging and Labeling

XYZ Drug will be packaged in HDPE bottles, each containing 30 tablets.

Each bottle will carry a label stating:

- Protocol number
- Investigational use only statement

- Storage conditions
- Batch number and expiration date

5. Storage and Stability

Storage Conditions:

- Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C–30°C.

Stability:

- Shelf life is 24 months under recommended storage conditions.

6. Accountability and Record Keeping

Sites are required to maintain accurate records of:

- Receipt of IP
- Dispensing to subjects
- Return/destruction of unused IP

All records must be signed, dated, and stored securely.

7. Dispensing Procedures

- IP will be dispensed only to participants who meet all eligibility criteria.
- Dispensed by designated site pharmacist or authorized personnel.
- Documented in subject's medication log.

8. Return and Disposal

- Unused or expired IP must be returned to the sponsor or destroyed per site SOPs.
- Documentation of return or destruction must be maintained.

9. Emergency Unblinding Procedures

In the event of a medical emergency, the blind may be broken by contacting the designated

Medical Monitor.

All unblinding incidents must be documented and reported immediately.

10. Contact Information

Sponsor Contact: Clinical Operations Manager, ABC Pharmaceuticals

Phone: +1-800-555-XYZD

Email: clinicaltrials@abcpharma.com