



## INSPECTION AGENDA – DRUGSTORE

### Inspection Activity

#### I. Opening Meeting

- Introductions / Inspection scope/Attendance record

#### II. Ocular inspection of Premises / Storage facilities and Products

- Storage and sanitary conditions
- Segregated area for expired, damaged, recalled or returned products
- Equipment – Bioref / dedicated refrigerator, generator Set (if selling time and temperature sensitive pharmaceutical products (TTSPPs))
- Dispensing apparatus including ice packs for dispensing of TTSPPs
- Product compliance to registration and labeling requirements – may collect product

#### B Document and Records Review

- License to Operate
- Pharmacist's credentials
- Organizational structure with duties and responsibilities of personnel
- Records of training, competency evaluation of personnel
- Attendance to FDA licensing seminar or other relevant trainings
- Risk Management Plan
- Standard Operating Procedures (SOPs)
- Invoices issued by suppliers (lot #, exp. Date and transport temp requirement)
- Stock reconciliation records
- Prescription book – both full and partially filled prescriptions must be recorded in Rx book
- Senior Citizens and PWD records
- Generic menu cards / MDRP (EO 821 & EO 104 / IEC materials) / GMAP / EDPMS
- Temperature Monitoring records (bioref/ refrigerator if with TTSPPs and room)
- Calibration Certificates of temperature monitoring device/s and/or bioref
- Franchise agreement (if applicable)

#### IV. Report writing

- Consolidation of findings; when necessary

#### V. Exit Meeting

- Attendance record /Discussion of findings or deficiencies /violation