



LICENSING AND ENFORCEMENT DIVISION

CHECKLIST FOR AN INSPECTION REPORT FOR AN INDUSTRIAL CLINIC

1.0 Licensee:

2.0 Name of Clinic:

3.0 Address:

4.0 Phone Number(s):

5.0 Email address (es):

6.0 Inspection date:

7.0 Name of inspectors:

8.0 Class of Clinic:

9.0 Type of inspection **10.0** ROUTINE/INVESTIGATIVE.....

11.0 Doctor on cover: **12.0** Licensed: **YES/NO**

13.0 Doctor's Visiting Times:

14.0 Doctor/Nurse in charge on the day:

15.0 Other staff members.....

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(Other Nurses, Dispensary Assistants, etc.)

16.0 Time inspection started.....

17.0 Equipment used (*capture the equipment number where applicable*):

17.1 Inspection Tablet.....

17.2 Data Logger.....

17.3 Measuring Tape.....

17.4 Raman Spectroscopy.....

17.5 Other.....(specify)

18.0 Inspection Element	Notes	Inspector's Notes
18.1 Licenses	1. Were both the persons and the premises licence displayed conspicuously 2. Are both licenses valid	
18.2 Premises	Are the premises clean and tidy?	
18.3 Natural Lighting	Visibility within the distance of a meter when lights are switched off.	
18.4 Artificial Lighting	Visibility within the distance of a meter when lights are switched on.	
18.5 Storage of medicines	Protection from heat, light and moisture? Is there adequate shelving? Is there temperature control and monitoring? Out of reach of the public? Any Medicines on the floor?	
18.6 Labelling	Are the pre-packs labelled clearly? (<i>capture the batch number, expiry date and clinic details</i>)	
18.7 Working Space	Is the space adequate for dispensing and compounding? Measurements of the actual dimensions of the working space in the dispensary and calculate the total area (<i>minimum 10 square meter</i>)	

18.8 Security	Measures in place to protect medicines e.g., Metal grills, alarm system, burglar bars, security guard (<i>take note of the times of availability</i>), etc. (<i>take note of the premises` operating hours</i>)	
18.9 Measuring cylinders	At least one (1) 50ml or 100ml for internal preparations At least one (1) 50ml or 100ml for external preparations Labelling to indicate use	
18.10 Shelving	Washable and painted	
18.11 Walls	Painted and washable	
18.12 Floor	Smooth and impervious	
18.13 Counting trays	At least two (2) counting trays.	
18.14 Measuring Balance(<i>optional</i>)	Record the type of balance	
18.15 Refrigerator	1. Model colour, Identification number 2. Is it functional for storing cold chain medicines? 3. Cleanliness and free of mold? 4. Temperature monitoring device (<i>note the temperature at the time of inspection</i>)? 5. Are there records for temperature monitoring being filed?	
18.16	Identification Number	

Thermometer	Used, calibration status	
18.17 MCAZ Data logger	Identification number Time recording started	
18.18 Power Supply	Backup power supply being used. Ice packs used during after hours	
18.19 Hand wash facilities	Double stainless steel sink or single stainless steel sink with separate wash hand basin.	
18.20 Water	Running hot and cold water	
18.21 Control of medicines	Unregistered medicines/ medical devices	
18.22 Storage of unregistered medicines	Dispensary, shelves, boxes, office, etc.	
18.23 Packaging of unregistered medicines	Medicines or medical devices sold in their original packaging or not?	
18.24 Importation	Authorization letters for the unregistered medicines Do the unregistered medicines match those on the authorization letters?	
18.25 Proof of clearance for Importation	Unregistered medicines / medical devices by ZIMRA and MCAZ	
18.26 Purchase	Invoices to account for purchase of the unregistered medicines / medical devices	
18.27 Origins of the source	Licensed by MCAZ <i>(If the source is unlicensed collect evidence of sell/ dispensing of</i>	

	<i>the medicines)</i>	
18.28 Registers	Human allopathic medicines register Complementary medicines register Premises and Persons register	
18.29 Saleable stock	Expired medicines / medical devices. <i>(note the location of the medicines)</i>	
18.30 Stock management system	Traceability of a particular medicine to a particular patient through use of batch number, expiry date, manufacturer of medicine (manual/electronic) Sufficient patient details captured during dispensing PP and PIM medicines	
18.31 Evidence of sell	Expired medicines <i>(take photographs/ copies of dispensing records. Sales receipt, etc.)</i>	
18.32 Reference Texts	BNF and or Martindale EDLIZ Antiretroviral Therapy Guidelines. Any other referenced texts	
18.33 Legislation	Medicines and Allied Substances Control Act (Chapter 15:03) Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991 Dangerous Drugs Act (Chapter 15:02) Dangerous Drugs Regulations,	

18.34 Retention for record keeping	Are records being kept for 5 years/ or more?	
18.35 Recording system	Microfilm, computer, photocopy or patient profile cards or other approved Capturing of repeat prescriptions Back up provided; type of back up	
18.36 Storage of medicines in the absence of the doctor	Storage arrangement of medicines (<i>if applicable</i>)	
18.37 Dangerous Drug (DD) Cupboard	Fixed and lockable (<i>if note take clear pictures of the records</i>)	
18.38 DD registers	Bound books (<i>if not, collect copies or clear pictures of the records</i>) Are transaction being recorded within 24 hours Stock tallying with the recorded quantities. If not what are the discrepancies (<i>collect copies or clear pictures of the records</i>) Any cancellations and obliterations (<i>If yes collect copies or clear pictures of the records</i>)	

18.39 Toilet facilities	Available within the proximity Good working order	
18.40 Other abnormalities noted.	Are there any repeat shortcomings noted in the last inspection? - Poor supervision - Unregistered medicines - Purchasing from unlicensed sources - Selling medicines to unlicensed premises - Expired medicines - Poor recording and stock taking of DDs or Part 1A Psychotropic Substances - Incomplete set of statutes - Inadequate equipment - Failure to notify importation	
18.41 MCAZ Data loggers final reading	Record the readings from the data logger Time recording ended	

19.0 INSPECTOR'S COMMENTS (WHERE APPLICABLE – USE PROVIDED SPACE, REFERENCE RELEVANT COLUMN FROM ABOVE).

Column number	Comments

20.0 Time Inspection Ended.....

21.0 I the supervisor of these premises agree with the findings made during this inspection.

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Signature

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Date