

DEPARTMENT OF HEALTH
DIRECTORATE: MEDICINES CONTROL AND REGISTRATION

MODULE: CLINICS AND HEALTH INSTITUTIONS

FILE NO:

CLINIC DETAILS:

NAME
AND
ADDRESS
OF
CLINIC

(PRINT NAME PLEASE)

AUTHORISED PERSON:

REGISTRATION
NUMBER

SIGNATURE:

TELEPHONE NUMBER

RENEWAL: PERMIT NUMBER

NEW:

MEDICINE SUPPLIERS:

INSPECTION DETAILS:

MEDICINES CONTROL
OFFICER:

INSPECTION DATE:

TIME COMMENCED:TIME COMPLETED.....

REPORT AFRIKAANS/ENGLISH (CIRCLE PREFERENCE)

PRESCRIPTION RECORDS: COMPUTERISED/PATIENT CLINICAL CARD,OTHER SPECIFY

RE-INSPECTION: 3/6/12/18 MONTHS

MEDICINES OR SUBSTANCES DESTROYED OR REMOVED FOR DESTRUCTION DURING INSPECTION:
(SCHEDULE 7):

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THERMOLABILE PRODUCTS WERE NOT STORED IN ACCORDANCE WITH LABEL INSTRUCTIONS:

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THE FOLLOWING EXPIRED MEDICINES WERE FOUND:

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REMARKS:

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	CODE	COMPLIES	DEFAULT	N A
Does the authorised person hold a valid registration certificate issued by the Statutory Controlling Body	98001			
Is the manipulation, preparation or compounding of any medicinal or chemical substance for sale or supply as a medicine performed by the authorised person PERSONALLY?	98002			
Does the authorised person ensure that the conditions under which medicines are kept or sold, minimise the risk of error or contamination in the preparation, dispensing, sale or supply of such medicine.	98003			
Is the processing of substances for non-medical use effectively separated from the dispensing of medicinal products?	98004			
Does any person other than an authorised person employed in this clinic: Prepare a medicine?	98005			
Keep or possess a medicine?	98006			
Supply or deliver a medicine for the purpose of sale?	98007			
Can the authorised person guarantee that all medicines under his/her control are: Able to be kept under lock and key?	98008			
Are in fact locked up when the authorised person is not present?	98009			

	CODE	COMPLIES	DEFAULT	N A
Can the authorised person supply evidence that all medications under his /her control is subject to meaningful stock control or reconciliation?	98010			
Is the compounding and dispensing of medicinal products subject to an adequate control system?	98011			
Are all medicines stored out of direct reach of the general public?	98012			
Are all medicines stored out of the direct reach of unqualified personnel when the authorised person is absent from the premises?	98013			
Are items of expired stock physically separated from dispensary stock?	98014			
Are expiry dates recorded and/or is a flagging system in use?	98015			
Are medicines in a clean condition and clearly labelled?	98016			
Are medicines effectively screened from direct sunlight?	98017			
Are thermolabile medicines stored correctly? (List on front page)	98018			
Is the ambient temperature in the dispensary and storage areas monitored regularly?	98019			
Does the dispensary have a suitable and effective means of heating and ventilation?	98020			

	CODE	COMPLIES	DEFAULT	N A
Is there sufficient space in the dispensary to ensure an efficient flow of work?	98021			
Are all working surfaces, cupboards and shelves in the dispensary finished with a smooth, impervious washable material and maintained in good repair?	98022			
Is the dispensing bench of adequate size?	98023			
Are dispensary stocks arranged in an orderly and systematic fashion?	98024			
Is shelving adequate?	98025			
Is a sink with an adequate supply of hot and cold water available in the dispensary?	98026			
Are walls, floors, ceilings and shelves kept clean?	98027			
Does the dispensary have a suitable and effective means of lighting?	98028			
Is a suitable means of counting tablets and capsules available to avoid both direct contact with the operator's hands and cross-contamination?	98029			
Is a refrigerator unit capable of storing products within a selected temperature range of 0-10 C available, and is the efficiency of the unit checked regularly?	98034			
Is a suitable range of both clear and amber liquid, tablet and capsule containers available?	98036			

	CODE	COMPLIES	DEFAULT	N A
Is there a suitable range of containers for dispensing of creams and ointments?	98037			
Are containers used for dispensing, appropriate to the particular product dispensed, particularly the need to protect the contents from the adverse effects of atmospheric moisture, sunlight, transportation and handling by the patient?	98038			
Is there a suitable range of labels for the above-mentioned containers?	98039			
Are labels of dispensed medicine typewritten?	98040			
Does the label of a dispensed medicine bear the name of the medicine or supplier?	98041			
Does the label of the dispensed medicine bear the name of the patient?	98042			
Does the label of a dispensed medicine bear the directions for use	98043			
Does the label of a dispensed medicine bear the name and address of the seller?	98044			
Does the label of a dispensed medicine bear a reference number?	98045			
Were examples of dispensed medicine available to the inspector for verification of the above labelling requirements?	98046	YES	NO	

	CODE	COMPLIES	DEFAULT	N A
Are unscheduled medicines sold without being entered into a prescription book or other permanent record?	98047			
Are scheduled medicines sold without being entered into a prescription book or other permanent record?	98048			
Are patient profiles being kept?	98049			
Is the prescription book or record kept on the premises where the prescriptions are dispensed?	98050			
Are prescriptions for all medicines being kept for 3 years after the last date of sale of the prescription?	98051			
Does the prescription book or record contain the date on which the prescription was dispensed?	98052			
Does the prescription book or record contain the form of preparation and quantity of the medicine dispensed?	98053			
Does the prescription book or record contain the name and address of the patient?	98054			
Was an example of such a prescription book or record examined by the inspector to verify compliance with legal requirements?	98055	YES	NO	
Is smoking prohibited in all areas where medicines are dispensed?	98056			

	CODE	COMPLIES	DEFAULT	N A
Are toilet facilities appropriately located, designed, equipped and kept clean?	98057			
Are toilet areas used for the purpose of storing stock or as a source of water for the preparation of medicinal products?	98058			
Is water of a suitable quality used for the preparation of medicines (especially in rural areas)?	98059			
Are unregistered medicines sold by this clinic in contravention of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965)	98060			
Do all raw materials used in the compounding and dispensing of medicines, comply with official pharmacopoeial standards?	98061			
Have any medicines been repacked from original (registered) containers?	98062			
If so, are these medicines packed into containers that ensure the stability of these medicines?	98063			
Is there documentary evidence that the repackaging procedure is properly executed and under the supervision of the authorised person?	98064			
Is the schedule status reference number indicated on the containers of these repacked medicines?	98065			

	CODE	COMPLIES	DEFAULT	N A
Are these prepacked medicines labelled with the name of a particular patient?	98066			
Are these prepacked medicines labelled with a batch number?	98067			
Are these prepacked medicines labelled with an expiry date?	98068			
Has the prepacking process been documented i.e. are batch manufacturing documents available?	98069			
Is the clinic in possession of the latest edition of MIMS or equivalent eg. Daily Drug Use, SA Medicines Formulary,	98070			
Are patients counselled on the correct use of dispensed medicine?	98071			
Are package inserts provided with dispensed medicines where possible?	98072			
Are Schedule 3 medicines supplied to a patient for a period in excess of six months without further medical examination?	98073			
Are issues of professional samples recorded and labelled in the prescribed manner?	98074			
Are prescriptions issued by other institutions, dispensed at this institution?	98075			
Are any medicines stored in areas NOT examined during this inspection?	98076	YES	NO	

	CODE	COMPLIES	DEFAULT	N A
Were any samples taken by the officer during this inspection? (Attach details to this report)	98077	YES	NO	
Are injectables and related apparatus handled so as to prevent a break in sterility?	98078			
Were possibly microbially contaminated material or testing equipment etc observed in areas where medicines are dispensed or stored?	98079			
Are disposable syringes and needles used only once?	98080			
Does the authorised person, keep an open shop?	98081			
Are prescriptions handwritten by the authorised person?	98082			
Does the authorised person ensure that the cold chain for thermo-labile medicines is maintained.?	98083			
Was any expired stock found on dispensary shelves? (List on front page all contraventions)	98084			
Were any veterinary products found in the dispensary shelves? (List on front page all contraventions)	98085			
List names of wholesalers and other organisations where medicines are being purchased from?	98086			

	CODE	COMPLIES	DEFAULT	N A
Does the ordering procedure indicate the permit number and signature of the authorised person?	98087			
Are medicines being purchased from the sources as listed as in the permit application form?	98088			
Are other medicines held in stock/ being used than those which the permit authorises?	98089			
Is the authorised person in control of after hours services?	98090			
When prescriptions are repeated by an authorised person, what evidence is there that the supervising medical practitioner is involved?	98091			
Determine the magnitude of the dispensing procedures in units per day (office use)	98092			

Comments/Recommendation