

**STANDARD ON PHARMACY**

Name of Facility:

Address:

*If comply tick (√) Yes, if not tick (√) No. Please add comment for any explanation.*

PROVISION	ITEM	YES	NO	COMMENT
	<b>INFRASTRUCTURE &amp; EQUIPMENT</b>			
	<b>Location</b>			
R.243(1)	Outpatient pharmacy near or adjoining outpatient department			
R.243(2)	Inpatient pharmacy clean room @ area accessible to nursing unit			
R.244(1)	Adequate space and relevant equipment for all pharmacy operations			
	<b>Signs and labels</b>			
R.60	Proper signage and labelling system			
	<b>Waiting room</b>			
R.244(5)	Waiting room and pharmacy office may be provided			
	<b>Dispensing unit</b>			
R.244(2)(a)	Dispensing counter			
R.244(2)(b)(i)	Work counter with impermeable surface			
R.244(2)(b)(ii)	Corrosion-resistant sink			
R.244(2)(b)(iii)	Storage unit (may be moveable with drawers)			
R.244(2)(b)(iv)	Pharmaceutical refrigerator with thermometer and freezing compartment			
R.244(2)(b)(v)	Locked storage for dangerous drug and other controlled drug			
R.244(2)(b)(vi)	Separate storage room for inflammable chemicals and reagents			
	<b>Compounding Unit (if available)</b>			
R.244(2)(b)(i)	Work counter with impermeable surface			
R.244(2)(b)(ii)	Corrosion-resistant sink			
R.244(2)(b)(iii)	Storage unit			
R.244(2)(b)(iv)	Pharmaceutical refrigerator with thermometer and freezing compartment			
R.244(2)(b)(v)	Locked storage for dangerous drug and other controlled drug			
R.244(2)(b)(vi)	Separate storage room for inflammable chemicals and reagents			

PROVISION	ITEM	YES	NO	COMMENT
	<b>Manufacturing area</b>			
R.244(3)	Comply with Good Manufacturing Practices (GMP)			
R.244(3)	Separate areas for preparation of cytotoxic drug or radioactive material preparation			
R.244(4)	Sufficient storage facilities and accordance with Good Storage Practices issued by a competent authority			
	<b>Overall findings</b>			
S.16(1)(a)	Complies with the building layout plan, design construction and specification to which the approval to establish or maintain relates			
S.16(1)(b)	Equipment, apparatus, instrument, material, article, sample or substance or any other thing found in the premises, or any matter connected therewith			
R.122(2)	Infrastructure and all equipment are kept in good repair and operating condition			
	<b>STANDARD &amp; REQUIREMENT (DOCUMENTATION)</b>			
	<b>Organization &amp; Management</b>			
R.240(1)	Head of pharmaceutical services			
R.240(2)	• with $\geq 50$ beds - licensed pharmacist			
R.240(3) & (4)	• with $< 50$ beds - licensed pharmacist / RMP			
R.240(5)	In house drugs manufacturing required licensed pharmacists			
R.248	Establishment of a Pharmacy and Therapeutic Committee			
	<b>Personnel</b>			
R.242	Adequate number of trained and experience staff			
R.16(4)	Adequate qualified staff to operate the department			
R.240	Pharmacist ( <i>compulsory if <math>\geq 50</math> bedded</i> )			
	<b>Policies and standard operating procedures</b>			
R.22	Relevant written policies, standards, procedures and guidelines are available and accessible to all personnel			
R.249(1)	Written policies and procedures for control and accountability, drug distribution, storage and assurance of quality of all drugs and biological products			
R.248	Policies on evaluation, selection, procurement, storage, distribution, use, safety procedures and other matters related to drugs			
R.21(2)(a)&(b)	Written policy available to all staff & review every 5 years			

PROVISION	ITEM	YES	NO	COMMENT
	<b>Records, registers, returns and books</b>			
R.34	Staff register			
	<b>Labelling of medications</b>			
R.245(1)	Floor stock are adequately labelled (name, strength of medication & expiry date)			
R.245(2),(3)	Relabeling containers if required, only if contents is certain			
R.245(4)	No containers with no label			
R.245(5)	Prescribed medications are properly labelled (Generic or trade)			
R.246 & 247	Expired, discontinued and contaminated drug returned to the pharmacy for proper disposal			
	<b>Program and activities on quality</b>			
S.74(1),(2)	Information on quality programme and activities			
	<b>Overall findings</b>			
S.16(1)(c)	Complies with standards or requirements: books, records, policies, standard operating procedures, clinical practice guidelines or the management or related matters			

<b>Comments:</b>			
<b>Recommendation:</b>			
<b>Prepared by:</b>		<b>Verified by:</b>	
<b>(Name &amp; Stamp)</b>		<b>(Name &amp; Stamp)</b>	
<b>Date :</b>		<b>Date:</b>	