CONFIDENTIAL

MANUFACTURING PHARMACIES INSPECTION QUESTIONNAIRE TO ESTABLISH THE NATURE, EXTENT AND STANDARD OF PHARMACEUTICAL SERVICES

South African Pharmacy Council

Registered Office
SAPC Building
591 Belvedere Street
Arcadia, Pretoria,0083

Postal Address
Private Bag X40040
Arcadia, 0007

Customer Care Line
0861 7272 00

Fax
(27)12-321 1492 /1479

E-mail
customercare@sapc.za.org

Website
www.sapc.za.org

PHARMACY NAME					
Y NUMBER	Y				
CASE NUMBER					
INSPECTION TYPE	Monitoring	Training	New Premises	Disciplinary	Follow-up

PLEASE NOTE:
The confidentiality of this document may be withdrawn should the information furnished lead to further investigation(s)

Please refer this questionnaire for special attention: YES NO

TABLE OF CONTENTS

(A) INSPECTION DETAILS 3
(B) PHARMACY DETAILS 3
(C) PHARMACY STAFFING 4
(D) REGISTRATION DETAILS 6
(E) PREMISES AND LAYOUT (in all applicable areas) 7
(F) STORAGE (in all applicable areas) 8
(G) CONTROL OF MEDICINES, SCHEDULED SUBSTANCES AND ACTIVE PHARMACEUTICAL INGREDIENTS/MEDICINES 10
(H) SCHEDULE 5 AND 6 MEDICINES, SCHEDULED SUBSTANCES AND ACTIVE PHARMACEUTICAL INGREDIENTS/MEDICINES 12
(I) THERMOLABILE MEDICINES 13
(J) WRITTEN STANDARD OPERATING PROCEDURES AS REQUIRED BY GMP 14
(K) REFERENCES 16
(L) GENERAL 17
(M) RECOMMENDATIONS IN RESPECT OF TRAINING 18
(N) SIGNATURES 19

NOTE: Throughout this questionnaire all questions carry a specific weighting and the questions in sections (B) and (C) marked with an ** carry a weighting of 3.

WEIGHTING KEY	
1.	**Not at all important but necessary to document**
2.	**Low importance**
3.	**Slight importance**
4.	**Neutral importance**
5.	**Moderate important**
6.	**Very important**
7.	**Extremely important**

Responsible Pharmacist or Pharmacist Initials/signature

Encircle or mark applicable number/block with an 'X'

(A) INSPECTION DETAILS

NOTE: Throughout this questionnaire legislative requirements are indicated with an *

1.0 Date of inspection	D D / M M / Y Y Y Y									
2.1 Name of inspector *(in block capitals)*					2.2 Inspector P number					
3.1 Type of inspection	Monitoring	Training	New Premises	Disciplinary	Follow-up	3.2 Inspection start time	H	H	M	M

(B) PHARMACY DETAILS

4.0 Name of pharmacy *(in block capitals)*[1]*																		0	3
5.0 Pharmacy registration number	Y															OFFICE USE ONLY	Pharmacy details confirmed	Inspection cycle	
6.1 Licence number: DoH														DOH										0	3
6.2 Type of authorised site activity (e.g. manufacturer; packer, testing laboratory, import, export *(if applicable)***																								0	3
7.1 Licence number: MCC														MCC										0	3
7.2 Type of authorised site activity (e.g. manufacturer; packer, testing laboratory, import, export *(if applicable)***																								0	3
8.1 Telephone number(s)				-				-					8.2 Ext.												
9.0 Cellphone number																									
10.0 Fax number				-				-																	

11.0 Pharmacy and/or Responsible Pharmacist e-mail address if not the same	11.1 Pharmacy e-mail address	11.2 Responsible Pharmacist e-mail address
12.1 Pharmacy: Registered postal address		12.2 Postal code
13.1 Pharmacy: Registered physical address**		13.2 Street code

14.0 Does the pharmacy keep stock?	Yes		No					
15.0 If no, who does the distribution and warehousing (supply details Y no, licence no and the copy of the service agreement)								
16.0 In which province is the pharmacy situated?	Eastern Cape		Free State		Gauteng		Kwazulu-Natal	
	Mpumalanga		Northern Cape		Limpopo		North West	
	Western Cape							

[1] As per the displayed recording certificate and licence issued by the Department of Health

Responsible Pharmacist or Pharmacist Initials/signature

Encircle or mark applicable number/block with an 'X'

17.0 Where is the pharmacy situated? (for statistical purposes)	City centre [2]		City suburb[3]		Town[4]		Township [5]		Rural[6]		Others		
18.0 Where is the pharmacy situated (Others please specify)													
19.0 Pharmacy GPS Co-ordinates	19.1 X (Latitude):						19.2 Y (Longitude):						

(C) PHARMACY STAFFING

20.1 Name of pharmacy owner as registered *(in block capitals)*[7]				0	3
20.2 Company Registration number as per CIPC documents (if applicable)**				0	3
21.1 Name and P number of responsible pharmacist as registered**		21.2 P number		0	3
22.1 Name and P number of pharmacist in charge during inspection**		22.2 P number		0	3
23.0 Name of (prospective) tutor(s) if applicable		23.1 P number			
		23.2 P number			
		23.3 P number			

24.0 How many full-time pharmacists are in the permanent employ of the pharmacy? *(at least 5 hours per day) (Fill in name and number on the table attached as schedule A).*		
25.0 How many part-time pharmacists are in the permanent employ of the pharmacy? *(less than 5 hours per day) (Fill in name and number under comments).*		
26.0 How many pharmacist interns are undergoing practical training in the pharmacy? *(Fill in details as required in the table attached as schedule A).*		
27.0 How many registered pharmacist's assistants (basic) work in the pharmacy? *(Fill in details as required in the table attached as schedule A).*		
28.0 How many registered pharmacist's assistants (post-basic) work in the pharmacy? *(Fill in name and number on the table attached as schedule A).*		
29.0 How many registered pharmacist's assistants (learner basic) are undergoing practical training in the pharmacy? *(Fill in details as required in the table attached as schedule A).*		
30.0 How many registered pharmacist's assistants (learner post-basic) are undergoing practical training in the pharmacy?		
31.0 How many registered pharmacy technical assistants trainees are undergoing practical training in the pharmacy? *(Fill in details as required in the table attached as schedule A).*		
32.0 How many registered pharmacy technicians trainees are undergoing practical training in the pharmacy? *(Fill in details as required in the table attached as schedule A*).		
33.0 How many registered pharmacy technicians work in the pharmacy? *(Fill in details as required in the table attached as schedule A)*		
34.0 Are there any unregistered persons performing acts falling within the scope of practice of pharmacists and/or pharmacy support personnel who would require training in order to register as pharmacist's assistants with the Council? [8]	0	3

[2] Refers to the central business district area.
[3] A residential area within the boundaries of a town or city.
[4] Usually a town or part of a town.
[5] 'township' in South Africa referred to an urban residential area created for migrant labour, usually beyond the town or city limits. Generally, every town/city has one or several townships associated with it.
[6] Any area that is not classified *urban*. Rural areas are subdivided into tribal areas and commercial farms.
[7] As per the SAPC recording certificate and DOH licence.
[8] Inspector to explain the legal requirement

Responsible Pharmacist or Pharmacist Initials/signature

PHARMACY STAFFING [9]					
Name and Surname(as per registration card)	**SAPC Registration number(as per registration card)**	**Id number/ Passport number**	**Primary Registration type (Pharmacist, Pharmacist intern, Basic or Post basic Pharmacists assistant, etc)**	**Secondary Registration type (e.g. Tutor, Responsible Pharmacist, etc)**	**Pharmacy support personnel per tutor**

[9] Inspector must record the names and other details of all personnel in the pharmacy that are concerned with the handling of pharmaceuticals and delivery of pharmaceutical services as indicated on the table.

(D) REGISTRATION DETAILS

	N/A	Does not comply	Complies	Weight
35.0 The name of the responsible pharmacist is displayed conspicuously at the main entrance of the pharmacy.		0	3	**3**
36.0 The name of the pharmacist(s) on duty is/are displayed conspicuously		0	3	**3**
37.0 The pharmacist(s) on duty is/are wearing a nametag or badge indicating his/her name and designation for the purpose of identification of such person(s) to the public.		0	3	**3**
38.0 The pharmacy is under the continuous personal supervision of a pharmacist.[10]		0	3	**3**
39.0 A currently valid **registration card(s)** is available for the pharmacist(s) *(refer questions 21, 22, 24 and 25).*	N/A	0	3	**7**
40.0 A currently valid **registration card(s)** is available for the pharmacy support personnel *(refer questions 26-30).*	N/A	0	3	**7**
41.0 A currently valid, original and signed certificate issued by the South African pharmacy Council, for the recording of the pharmacy is available.		0	3	**3**
42.0 A valid original licence issued by the Director-General (in terms of section 22 of the Pharmacy Act) is displayed conspicuously in the pharmacy for the purpose of identification of such to the public.[11]	N/A	0	3	**3**
43.0 When last did the pharmacy have a GMP inspection by the MCC?	**CCYYMMDD**			

Comments and/or corrective action

[10] Inspector must note the name of the pharmacist.
[11] Not Applicable (N/A) only in case of Pre-May 2003 pharmacies

(E) PREMISES AND LAYOUT (in all applicable areas)

	N/A	**Does not comply**	Partially complies	Complies	**Weight**
44.0 The premises are clean.		0		3	**5**
45.0 The premises are orderly and tidy.		0		3	**5**
46.0 There is a facility for washing hands		0		3	**5**
47.0 The floor surface in the dispensing area is of impermeable material.		0		3	**5**
48.0 All working surfaces are finished with a smooth impermeable and washable material which is easy to maintain in a hygienic condition.		0		3	**5**
49.0 Countertops are finished with a smooth impermeable and washable material which is easy to maintain in a hygienic condition.		0		3	**5**
50.0 Shelves are finished with a smooth, impermeable and washable material which is easy to maintain in a hygienic condition.		0		3	**5**
51.0 Walls are finished with a smooth impermeable and washable material which is easy to maintain in a hygienic condition.		0		3	**5**
52.0 There are no open drain channels.		0	1	3	**5**
53.0 There is sufficient lighting.		0	1	3	**5**
54.0 Forklift machines (if used) do not have combustion engines.		0	1	3	**5**
55.0 The temperature in the pharmacy is below 25 degrees Celsius *(as checked with a thermometer)*		0	1	3	**5**
56.0 The temperature in the pharmacy is controlled 24 hours a day as demonstrated by a maximum/minimum thermometer.		0	1	3	**5**
57.0 The temperature in the pharmacy is recorded daily.		0	1	3	**5**
58.0 The air conditioning system in the pharmacy is in good working condition to keep the temperature below 25 degrees Celsius		0	1	3	**5**
59.0 There is at least one fire extinguisher or fire hose in the pharmacy.		0		3	**5**
60.0 The electrical equipment is regularly maintained and safe.		0	1	3	**5**
61.0 The workflow in the pharmacy is efficient.		0	1	3	**5**
62.0 There is sufficient security to prevent unauthorised access to medicines, scheduled substances and active pharmaceutical ingredients/medicines.		0	1	3	**5**
63.0 The pharmacy is designated as a non-smoking area		0	1	3	**5**
64.0 The pharmacy is designated as a non-eating		0	1	3	**5**

Comments and/or corrective action required for all items marked 'does not comply' or only 'partially complies'

Responsible Pharmacist or Pharmacist Initials/signature

(F) STORAGE (in all applicable areas)

		N/A	Does not comply	Partially complies	Complies	Weight
65.0	Medicines, scheduled substances and active pharmaceutical ingredients/medicines, are stored according to a system.	N/A	0	1	3	**3**
66.0	Storage area is large enough to allow for orderly arrangement of stock and proper stock rotation.		0	1	3	**3**
67.0	The store is kept locked at all times when not in use.		0	1	3	**3**
68.0	There are no cracks, holes or sign of water damage in the facility.		0	1	3	**3**
69.0	The ceiling is in a good condition.		0	1	3	**3**
70.0	The floor is swept daily in accordance with SOP.		0	1	3	**3**
71.0	Shelves are dusted daily in accordance with SOP.		0	1	3	**3**
72.0	Walls are clean in accordance with SOP.		0	1	3	**3**
73.0	The storage area is tidy in accordance with SOP.		0	1	3	**3**
74.0	Pest control is conducted regularly in accordance with SOP		0	1	3	**3**
75.0	Storage areas are situated so that products are protected from potentially harmful influences.		0	1	3	**3**
76.0	All goods are stored off the floor, in accordance with SOP.		0	1	3	**3**
77.0	Supplies are stored neatly on shelves on boxes, in accordance with SOP.		0	1	3	**3**
78.0	Raw materials known to be at risk for cross-contamination are stored separately.	No stock	0	1	3	**3**
79.0	Proper care and control is exercised over hazardous substances *(e.g. caustic soda, insecticides etc.)* which are stored separately and safely.	No stock	0	1	3	**3**
80.0	Proper care and control is exercised over flammable substances *(e.g. ether, methylated spirits etc.)* which are stored separately and safely.	No stock	0	1	3	**3**
81.0	A system is in place to ensure effective stock rotation *(refer also SOP section).*	No stock	0	1	3	**3**
82.0	There are no expired medicines, scheduled substances and active pharmaceutical ingredients/medicines, on the shelves *(as observed)*.	No stock	0	1	3	**3**
83.0	Expired stock is clearly separated and prevented from re-entry into the system.	No stock	0	1	3	**3**
84.0	Damaged and/or contaminated stock is clearly separated and prevented from entry into the system.	No stock	0	1	3	**3**
85.0	Expired stock is destroyed in a safe manner *(e.g. returned to supplier or waste disposal company) (refer also SOP section and Regulation 27 of Act 101 of 1965)*.	No stock	0	1	3	**3**
86.0	Damaged and/or contaminated stock is destroyed in a safe manner *(e.g. returned to supplier or waste disposal company) (refer also SOP section and Regulation 27 of Act 101 of 1965)*.	No stock	0	1	3	**3**
87.0	The pharmacy has suitable refuse receptacles (*with closing lids where applicable*).	No stock	0	1	3	**3**
88.0	There is a separate and secure receiving area which is under cover.		0	1	3	**3**
89.0	There is a separate and secure dispatch area which is under cover.		0	1	3	**3**
90.0	All the areas (dispatch, receiving, quality control, etc) are clearly defined and effectively separated.		0	1	3	**3**
91.0	Stock is checked on receipt for quantity, quality, damaged containers, type, storage conditions and expiry dates and appropriate action taken in accordance with SOP.		0	1	3	**3**
92.0	A list of product types requiring special storage or handling instructions is available and consulted on receipt of stock *(refer also SOP section)*.		0	1	3	**3**
93.0	There is a system for the correct handling of the various types of goods returned. *(refer also SOP section).*		0	1	3	**3**
94.0	Pre-packing performed on the premises is in accordance with the applicable GPP and GMP guidelines.	N/A	0	1	3	**3**
95.0	If pre-packing is taking place, the site licenced to do prepacking as per the conditions on the MCC license.	N/A	0	2	3	**3**

Responsible Pharmacist or Pharmacist Initials/signature

Encircle or mark applicable number/block with an 'X'

Comments and/or corrective action required for all items marked 'does not comply' or 'partially complies'

Responsible Pharmacist or Pharmacist Initials/signature

(G) CONTROL OF MEDICINES, SCHEDULED SUBSTANCES AND ACTIVE PHARMACEUTICAL INGREDIENTS/MEDICINES

		N/A	Does not comply	Partially complies	Complies	Weight
96.0	An effective stock control system is in place that ensures that there is no damaged, expired stock. (*refer to relevant SOP)*.	No stock	0	1	3	**7**
97.0	A computerised programme is used for stock control.[12]	No			Yes	
98.0	All medicines, scheduled substances and active pharmaceutical ingredients/medicines, sold for human use, comply with Regulation 8 of Act 101 of 1965 i.e. labelling requirements for human medicine.	Do not supply/ N/A	0	1	3	**7**
99.0	All veterinary medicines, scheduled substances and active pharmaceutical ingredients/medicines, sold, comply with Regulation 48 of Act 101 of 1965 i.e. labelling requirements for veterinary medicines, scheduled substances and active pharmaceutical ingredients/medicines,	*Do not supply/ N/A*	0	1	3	**7**
100.0	An up-to-date list of pharmacies registered with the SAPC is available.		0	1	3	**7**
101.0	Copies of permits of all Section 22A (15) permit holders are available (*previously Section 22A (12*)).	N/A	0	1	3	**7**
102.0	Medicine lists for permit holders are available and consulted.	*N/ A*	0	1	3	**7**
103.0	There is an up-to-date list of Veterinarians registered with the South African Veterinary Council.	N/A	0	1	3	**7**
104.0	There is an up-to-date list of dispensing doctors registered with the Health Professions Council of South Africa (*dispensing licence as from 2.05.2004*).	N/A	0	1	3	**7**
105.0	There is a recording system that enables the chain of supply (*specific batch numbers*) to be traced.		0	1	3	**7**
106.0	There is an up-to-date register of all **specified S5 purchases and sales** as required in Regulation 30 of Act 101 of 1965.		0	1	3	**7**
107.0	Records are kept for a minimum of 5 years after the date of sale of medicines, scheduled substances and active pharmaceutical ingredients/medicines as required by Act 101 of 1965.	Not stock ed	0	1	3	**7**
108.0	Records of all sales of medicines, scheduled substances and active pharmaceutical ingredients/medicines are kept in a safe place and are easily retrievable.		0	1	3	**7**
109.0	A control system is implemented that enables detection and correction of a delay in the delivery process.		0	1	3	**7**
110.0	Medicines, scheduled substances and active pharmaceutical ingredients/medicines, are supplied only on valid sales orders *(as confirmed by pharmacist in charge during inspection)*.		0	1	3	**7**
111.0	Medicines, scheduled substances and active pharmaceutical ingredients/medicines, are packaged and stored in accordance with registration requirements throughout the delivery process.	N/A	0	1	3	**7**
112.0	Control is exercised so that products are not subjected to unacceptable degrees of heat, cold, sunlight or any other adverse influences during the transportation process.	N/A	0	1	3	**7**
113.0	Does the pharmacy deliver medicines, scheduled substances and active pharmaceutical ingredients/medicines by mail?		Yes		No	
114.0	Does the pharmacy deliver medicines, scheduled substances and active pharmaceutical ingredients/medicines, by courier?		Yes		No	
115.0	Does the pharmacy deliver medicines, scheduled substances and active pharmaceutical ingredients/medicines, by delivery person?		Yes		No	
116.0	Does the pharmacy deliver medicines, scheduled substances and active pharmaceutical ingredients/medicines, by any other means *(e.g. train etc.)*?		Yes		No	
117.0	*If question 116 was answered 'yes',* PLEASE SPECIFY by which means:[13]					

[12] ***For Information only***
[13] ***For Information only***

Responsible Pharmacist or Pharmacist Initials/signature

Encircle or mark applicable number/block with an 'X'

Comments and/or corrective action required for all items marked 'does not comply' or 'partially complies'

Responsible Pharmacist or Pharmacist Initials/signature

(H) SCHEDULE 5 AND 6 MEDICINES, SCHEDULED SUBSTANCES AND ACTIVE PHARMACEUTICAL INGREDIENTS/MEDICINES

	N/A	Does not comply	Partially complies	Complies	Weight
118.0 Are specified S5 and S6 medicines, scheduled substances and active pharmaceutical ingredients/medicines, ordered, stored or supplied at any time?	No			Yes	
119.0 There is a system in place for the correct handling by the pharmacist of specified S5 and S6 medicines, scheduled substances and active pharmaceutical ingredients/medicines *(refer also SOP section)*.	Not stocked	0	1	3	**7**
120.0 S6 medicines, scheduled substances and active pharmaceutical ingredients/medicines are locked away and the key is under the control of the pharmacist.	Not stocked	0	1	3	**7**
121.0 There is an up-to-date register of all S6 medicine **purchases and sales** as required in Section 22A (6) (p) and regulation 30 of the general regulations of Act 101 of 1965.	Not stocked	0	1	3	**7**
122.0 The S6 substances register was balanced on the last day of March, June, September and December of each year.	Not stocked	0	1	3	**7**
123.0 There is an up-to-date register of all specified S5 medicine **purchases and sales** as required in Section 22A (6) (p) and regulation 30 of the general regulations of Act 101 of 1965.	N/A	0	1	3	**7**
124.0 The specified S5 substances register was balanced on the last day of March, June, September and December of each year.	Not stocked	0	1	3	**7**
125.0 Are medicines and scheduled substances exported to other countries?	No			Yes	
126.0 The necessary export documents for S5 and S6 substances are obtained.	No export	0	1	3	**7**
127.0 The relevant permit numbers of the export documents for S5 and S6 substances are recorded in the S5 and S6 substances register.	No export	0	1	3	**7**
128.0 Are medicines and scheduled substances imported from other countries?	No			Yes	
129.0 The necessary import documents for S5 and S6 substances are obtained.	No import	0	1	3	**7**

Comments and/or corrective action required for all items marked 'does not comply' or 'partially complies'

Responsible Pharmacist or Pharmacist Initials/signature

(I) THERMOLABILE MEDICINES

	N/A	Does not comply	Partially complies	Complies	Weight
130.0 Are thermolabile medicines purchased, stored or supplied at any time?[14]	No			Yes	
131.0 All thermolabile medicines are stored in a refrigerator/cold room as per the storage conditions.	Not stocked	0	1	3	**6**
132.0 Only medicines, scheduled substances and active pharmaceutical ingredients/medicines are stored in the refrigerator/cold room.	Not stocked	0	1	3	**6**
133.0 Medicines, scheduled substances and active pharmaceutical ingredients/medicines, are stored in the refrigerator/cold room according to a system.	Not stocked	0	1	3	**6**
134.0 The refrigerator/cold room is suitable and in good working order.	N/A	0	1	3	**6**
135.0 The refrigerator is connected to a standby generator or other emergency power system to ensure uninterrupted power supply in case of power (current) failure.	N/A	0	1	3	**6**
136.0 The refrigerator is fitted with a warning system to indicate that refrigeration has failed or temperatures are above or below 2°C and 8°C[15]		0	1	3	**6**
137.0 Only authorised personnel reset the alarm and a visual signal in case of refrigerator failure.	N/A	0	1	3	**6**
138.0 The temperature of the refrigerator/cold room is between 2°C and 8°C *(as checked with a thermometer).*	N/A	0	1	3	**6**
139.0 The temperature of the refrigerator/cold room is controlled 24 hours a day by a WHO approved dial thermometer or alcohol thermometer as demonstrated by the use of either chart recorders, or electronic recorders to continuously record the temperatures.[16]	N/A	0	1	3	**6**
140.0 There is a warning system to indicate if storage temperatures have varied beyond the specified limits.	N/A	0	1	3	**6**
141.0 Thermolabile medicines, scheduled substances and active pharmaceutical ingredients/medicines, are stored/dispatched maintaining the cold chain.	Not stocked	0	1	3	**6**

Comments and/or corrective action required for all items marked 'does not comply' or 'partially complies'

[14] ***For Information only***

[15] This refers to continuous temperature monitoring to alert the pharmacist immediately even when they are off-site of the variations in temperatures.

[16] Expanded Programme on Immunisation (EPI) provisions applies

Responsible Pharmacist or Pharmacist Initials/signature

(J) WRITTEN STANDARD OPERATING PROCEDURES AS REQUIRED BY GMP

There are written standard operating procedures for:	*N/A*	Does not comply	Partially complies	Complies	Weight
142.0 good housekeeping (*cleaning procedures etc*.).		0	1	3	**3**
143.0 pest (*insects, rodents etc*.) elimination.		0	1	3	**3**
144.0 receipt of stock.		0	1	3	**3**
145.0 effective stock rotation (*FEEFO – First entry, expiry, first out*).		0	1	3	**3**
146.0 disposal or removal of S1 – S6 expired, damaged and/or contaminated stock as required in Regulation 27 of Act 101 of 1965.		0	1	3	**3**
147.0 product types requiring special storage or handling instructions.		0	1	3	**3**
148.0 separation and handling of goods returned.		0	1	3	**3**
149.0 recall of medicine.		0	1	3	**3**
150.0 delivery of medicines, scheduled substances and active pharmaceutical ingredients.	N/A	0	1	3	**3**
151.0 procedures to be followed regarding the handling of keys, money, etc for a locum or relief pharmacist(s) (where applicable).	N/A	0	1	3	**3**
152.0 cold chain management (*including procedures to be followed in the event of a power failure*).	N/A	0	1	3	**3**
153.0 pre-packing (*including quality assurance procedures*).	N/A	0	1	3	**3**
154.0 handling of product complaints.		0	1	3	**3**
155.0 advertising of medicines.		0	1	3	**3**
156.0 reporting of adverse drug reactions.		0	1	3	**3**

Comments and/or corrective action required for all items marked 'does not comply' or 'partially complies'

Responsible Pharmacist or Pharmacist Initials/signature

WRITTEN STANDARD OPERATING PROCEDURES (Continued)

There are written standard operating procedures for:	*N/A*	Does not comply	Partially complies	Complies	Weight
157.0 daily routine and working hours.		0	1	3	**3**
158.0 enquiry or complaint procedure		0	1	3	**3**
159.0 stock-taking.		0	1	3	**3**
160.0 obsolete or unusable stock.		0	1	3	**3**
161.0 storage of medicine.		0	1	3	**3**
162.0 procurement of medicine.		0	1	3	**3**
163.0 handling of S5 and S6 medicines, scheduled substances and active pharmaceutical ingredients/medicines.		0	1	3	**3**
164.0 SOPs are reviewed/updated on a regular basis and are adapted to the operations of the specific pharmacy, and staff trained on the SOP's.		0	1	3	**3**

Comments and/or corrective action required for all items marked 'does not comply' or 'partially complies'

Responsible Pharmacist or Pharmacist Initials/signature

(K) REFERENCES

The pharmacy has copies of, or electronic access to: **[17]	*N/A*	Does not comply	Partially complies	Complies	Weight
165.0 - one of the last 5 editions of the Martindale.		0	1	3	**3**
166.0 - the latest edition of the Good Pharmacy Practice (GPP) Manual.		0	1	3	**3**
167.0 - the latest edition of MIMS.		0	1	3	**3**
168.0 - a comprehensive textbook on complementary medicine.		0	1	3	**3**
169.0 - the latest edition of Daily Drug Use (Tincture Press Publications) or other Drug Interactions reference source.		0	1	3	**3**
170.0 - the latest edition of either MDR or SAMF.		0	1	3	**3**
171.0 - a recent and comprehensive textbook on Pharmacology (*not older than 10 years*).		0	1	3	**3**
172.0 - a medical dictionary.		0	1	3	**3**
173.0 - a paediatric Dosing Reference Guide.		0	1	3	**3**
174.0 - Pharmacopoeia [BP, USP, EP [where applicable].		0	1	3	**3**
175.0 - NDOH- Adult Standard Treatment Guidelines for Hospital.	N/A	0	1	3	**3**
176.0 - NDOH-Paediatric Standard Treatment Guidelines for Hospital.	N/A	0	1	3	**3**
177.0 - NDOH-Primary Health Care Standard Treatment Guidelines.	N/A	0	1	3	**3**
178.0 - a guideline for non-substitutable list of medicines.		0	1	3	**3**
179.0 - a copy of the Pharmacy Act, 1974 (Act 53 of 1974) as amended		0	1	3	**3**
180.0 - a copy of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended.		**0**	**1**	**3**	**3**

****Official exemption may be applied for at the SAPC.**

Comments and/or corrective action required for all items marked 'does not comply' or 'partially complies'

[17] ***In case of electronic access the Responsible Pharmacist/Pharmacist in charge must produce valid subscription evidence.***

Responsible Pharmacist or Pharmacist Initials/signature

Encircle or mark applicable number/block with an 'X'

(L) GENERAL

	N/A	Does not comply	Partially complies	Complies	Weight
181.0 Medicines are advertised in accordance to GPP standards, code of conduct and Regulation 45 of Act 101 of 1965.		0		3	**1**
182.0 There is a pharmacist assigned to handle all ethical product enquiries.		0		3	**1**

Comments and/or corrective action required for all items marked 'does not comply' or 'partially complies'

Responsible Pharmacist or Pharmacist Initials/signature

(M) RECOMMENDATIONS IN RESPECT OF TRAINING

NB: RECOMMENDATIONS MUST ALSO BE MADE IN THE CASE OF MONITORING INSPECTIONS.

The inspector must, through his/her observations, take notice of all aspects of pharmacy practice, to give an objective evaluation of the training facilities in the pharmacy and the ability of a prospective tutor to train pharmacy support personnel effectively.

183.0 A pharmacy support personnel was trained within the last 3 years.	No	Yes
184.0 Would the pharmacist accept responsibility as a tutor for the training of a pharmacy support personnel?	No	Yes
185.0 Is there evidence that the prospective tutor participates in continuing education/professional development?	No	Yes
186.0 Is there disciplinary action pending against the prospective tutor?	No	Yes
187.0 Is there evidence that the prospective tutor/pharmacist upholds the principles of GPP/GMP/GDP?	No	Yes

! Recommendations made by the inspector with respect to training do not constitute approval for training by the Council.
Final approval of the pharmacy premises and tutor is made by the Council.

Comments and/or corrective action required for all items marked 'no' or 'see comments'

Responsible Pharmacist or Pharmacist Initials/signature

(N) SIGNATURES

I, THE UNDERSIGNED, AM FAMILIAR WITH THE CONTENTS OF THIS INSPECTION REPORT. THE RECOMMENDED CORRECTIVE ACTION TO BE TAKEN IN INSTANCES WHERE A QUESTION WAS ANSWERED AS EITHER 'DOES NOT COMPLY' OR 'PARTIALLY COMPLIES' HAS BEEN EXPLAINED AND WRITTEN IN THIS REPORT, IN EVERY SUCH INSTANCE.										
188.0 Signature of **pharmacist in charge during inspection:**										
189.1 Name and P number of above **pharmacist in charge during inspection** *(in block capitals) (refer question 22)*:										
	189.2 **P**									
190.0 Signature of **inspector:**										
191.0 Duration of inspection: *(refer inspection start time on page 2)*		191.1 Duration (no. of hours)		191.2 Inspection end time	H	H	M	M		

FURTHER COMMENTS

Responsible Pharmacist or Pharmacist Initials/signature