

Prepared by

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**Self inspection / audit of Drug sale unit
(Retail and / or Wholesale units)**

Abbreviations: RSDL: Retail Sale Drugs License WSDL: Whole Sale Drugs License RP: Regd. Pharmacist EP: Experience Person	RMP: Regd. Medical Practitioner DCO: Drugs Control Officer NSQ: not of std. quality CS: Civil Surgeon TB: Tuberculosis
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Self inspection / audit of the drug sale units (RSDL and or WSDL) is suggested for the assessment of the working of the firm, whether the firm is working as per the Drugs and Cosmetics Act 1940 and Rules framed thereunder or not.

Self inspection / audit should be conducted periodically by the Prop. / Partners / Directors and / or Regd. Pharmacist or Experience Person of the firm and improvement or rectification should be done immediately as per the observations during self inspection / audit. Here is the checklist for self inspection / audit for RSDL and or WSDL:

<p>Checklist for Self inspection / audit of Drug sale unit Retail and / or Wholesale units</p>
<p>Date</p>
<p>Done by</p>

Sr. No.	Checklist points	Observations
1	Distt.	
2	Name of the firm	
3	Address of the firm	

4	License No. of the firm	
5	License granted on	Dated
6	Validity of the license	Dated.....
7	License Retention fee submitted (If due) (Submit license retention fee within time)	Yes / No
8	Proof of license Retention fee submission kept (Proof of License retention fee must be kept in record)	Yes / No
9	Constitution of the firm	Proprietorship / Partnership / Pvt. Ltd. / Ltd firm
10	Any change in constitution	Yes / No

11	Have you applied for new license due to change in constitution in time (If constitution changed) (Apply for change in constitution within 90 days)	Yes / No / NA
12	Name(s) of Prop. / Partners / Directors of the firm	
13	Name of the responsible person of the firm	
14	Have you changed the premises without obtaining fresh license (Obtain fresh license before changing the premises)	Yes / No
15	File regarding correspondence with Drug department is maintained (Maintain file of correspondence drug department. e.g. Letters, Notices and circular etc.)	Yes / No
16	Whether licenses of the firm ever suspended or partially cancelled (Obey Drugs and Cosmetics Rules)	Yes / No
17	Whether sign board of name of the firm displayed (Display sign board with name of the firm)	Yes / No
18	Whether “Chemist and Druggist” written on the sign board (“Chemist and Druggist” must be written on sign board)	Yes / No
19	Whether Drug License displayed at a prominent place (Display drug license at the prominent place)	Yes / No
20	Name of Regd. Pharmacist (RP / EP)	

	of the firm	
21	Regn. Number of RP	
22	Validity of Regn. of RP (Validity of Regn. Certificate of RP must be up to date)	
23	Whether Regn. Certificate of RP displayed (You should display Regn. Certificate of RP)	Yes / No
24	Joining date of RP	
25	Whether any change in RP	Yes / No
26	Resignation date of RP (If resigned)	
27	Whether new RP appointed (If resigned)	Yes / No
28	Whether information of change in RP has been given to department within one month	Yes / No
29	If yes, date of appointment of new RP	
30	Name of new RP	

31	Regn. Number of RP	
32	Validity of Regn. of RP	
33	Whether Gap is there between resigning and joining of new RP, if any	No, if yesdays
34	If yes, sale /purchase of drugs between gap period (No sale / purchase of drug be done in the absence of RP)	Yes / No
35	Whether dust free environment is maintained in the premises (Keep your premises neat and clean)	Yes / No
36	Whether purchase record of drugs is maintained properly (Maintain purchase record of every drug properly)	Yes / No
37	Whether purchase record is maintained in chronological order (Maintain purchase record in chronological order)	Yes / No
38	Whether drugs are purchased from licensed dealers (Always purchase the drugs from licenses dealers only)	Yes / No
39	Whether purchase invoices bear all the mandatory details (Purchase invoice should	Yes / No

	have all mandatory details of drug)	
40	Whether drugs are being sold under the personal supervision of RP (Sale of drugs must be in the personal supervision of RP only)	Yes / No
41	Whether drugs are being sold on the prescription of RMP (Sell the drugs on the prescription of a RMP)	Yes / No
42	Whether substituting the prescription of RMP (Do not substitute the prescription of RMP)	Yes / No
43	Selling of drugs on price more than MRP (Do not sell the drugs on the price more than MRP)	Yes / No
44	Sale records of drugs maintained (Maintain sale record of the drugs)	Yes / No
45	Sale records maintained in legible manner (Maintain sale record of the drugs in legible manner)	Yes / No
46	Name and address of prescriber mentioned (Mention name and address of prescriber)	Yes / No
47	Name and address of patients mentioned (Mention name and address of patient)	Yes / No
48	Sale record is having all other mandatory details ? (sale record of drugs should have all mandatory details)	Yes / No
49	Sale invoice signed by RP (sale invoices must be signed by RP)	Yes / No
50	Schedule-H1 register maintained (Maintain Schedule-H1 register)	Yes / No

51	Full time electricity supply (Full time electricity supply must be ensured to maintain desired temperature of the drugs)	Yes / No
52	If not, Generator maintained (Full time electricity supply must be ensured to maintain desired temperature of the drugs)	Yes / No
53	Direct Sun light on the drugs (Drugs should not be exposed to direct sunlight)	Yes / No
54	Refrigerator maintained	Yes / No
55	Whether adequate gap is there	Yes / No

	between wall and refrigerator (maintain adequate gap between wall and refrigerator)	
56	Refrigerator is in working condition (Refrigerator must be in working condition)	Yes / No
57	Temperature of refrigerator is maintained (Temperature of refrigerator must be maintained)	Yes / No
58	Stocking the drugs in refrigerator which do not require storage of refrigerator (Do not stock drugs in refrigerator which do not require storage of refrigerator)	Yes / No
59	Stocking the drugs in refrigerator which require storage of refrigerator (Stock drugs in refrigerator which require storage of refrigerator)	Yes / No
60	Whether food items are stored in refrigerator ? (Do not stock food items in refrigerator)	Yes / No

61	Whether oily injections are stored in refrigerator ? (Do not stock oily injections in refrigerator)	Yes / No
62	Switching off the refrigerator in the night (Do not switch off the refrigerator in the night and maintain desired temperature of the drugs)	Yes / No
63	Air conditioner / Cooler (Do not install cooler, however air conditioner is advisable to maintain the temperature of drugs)	
64	Stocking the drugs in its original containers (Always stock the drug in the original container of that drug)	Yes / No
65	Stocking the drugs in racks (Retail) raised platforms (Wholesale) (Stock the drugs in racks or raised platforms)	Yes / No
66	Stocking the drugs on floor (Do not stock the drugs directly on the floor)	Yes / No
67	Homeopathic medicines stocked separately (Stock the homeopathic medicines separately)	Yes / No
68	“Homeopathic medicines” written on the rack (write “Homeopathic medicines” on the rack)	Yes / No

69	Ayurvedic medicines stocked separately (Stock the Ayurvedic medicines separately)	Yes / No
70	“Ayurvedic medicines” written on the rack (write “Ayurvedic medicines” on the rack)	Yes / No

71	Veterinary drugs stocked separately (Stock the Veterinary drugs separately)	Yes / No
72	“Veterinary drugs Not for human use” written on the rack (write “Veterinary drugs Not for human use” on the rack)	Yes / No
73	Expiry drugs found stocked	Yes / No
74	If yes, expiry drugs kept separately (Stock Expired drugs separately away from the trade stock)	Yes / No
75	“Expired dated drugs Not for Sale” written on the rack (Write “Expired dated drugs Not for Sale” written on the rack)	Yes / No
76	Correspondence with dealers regarding expired drugs (Correspondence with dealers regarding expired drugs must be done)	Yes / No
77	Sch-X drugs found stocked (License must be taken before dealing in Schedule-X drugs)	Yes / No
78	“Physician samples not for sale” found stocked (Do not stock and sell “Physician samples not for sale”)	Yes / No
79	“Hospital supply drugs not for sale” found stocked (Do not stock and sell “Hospital supply drugs not for sale”)	Yes / No
80	Misuse of Intoxicating drugs (Never sell intoxicating drugs without prescription of a RMP, it may be misused)	Yes / No

81	Vet. Oxytocin Injection found stocked (Stock and sell Vet. Oxytocin Injection in single blister pack only)	Yes / No
82	Diclofenac Injection for veterinary use found stocked (Do not Stock and sell Diclofenac Injection for veterinary use and it should not more than 10ml vial)	Yes / No

83	MTP Kit (MTP kit is to be used under the supervision of a service provider and in a medical facility as specified under MTP Act 2002 and MTP Rules 2003)	
84	Sildenafil Tablets (Sildenafil tablets are to be sold on the prescription of Urologist / Psychiatrist Endocrinologist / Venereologist / Dermatologist only)	
85	Are Infant food displayed (Infant food should not be displayed)	Yes / No
86	‘Banned Nail Polish Remover’ found stocked (Do not stock and sell ‘Banned Nail Polish Remover’)	Yes / No
87	“Banned drugs” found stocked (Never stock and sell ‘Banned drugs’)	Yes / No
88	Whether you sell TB drugs	Yes / No
89	If Yes, whether you are reporting about TB patient to Civil Surgeon. (You should report details of the TB patient to CS)	Yes / No
90	“Without invoice drugs” found stocked (Purchase of drugs with invoice only)	Yes / No

91	Whether Essential Narcotics Drugs stocked ?	Yes / No
92	If yes, whether you have obtained license on Form-24 ? (Obtain license on Form-24 before stocking and selling of Essential Narcotics Drugs)	Yes / No
93	Dustbin kept for “Clean India Project” (Keep a dustbin and keep India Clean)	Yes / No
94	Date of last inspection done by Drugs Control Officer	
95	Whether samples have been withdrawn by DCO	Yes / No
96	What was the result of sampled drug	Standard / NSQ
97	Copy of last inspection kept (Copy of inspection report must be kept)	Yes / No
98	Hydroxychloroquine is in Schedule-H1 now (Maintain schedule-H1 record for this drug)	To download the notification, click here.
99	2ply, 3ply surgical masks, N95 masks and hand sanitizers are under Essential	To download the notification, click here.

	Commodities Act 1955 up to 30-06-2020	
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100	Retail prices of 2ply, 3ply surgical mask and Hand sanitizer are fixed upto 30-06-2020	2ply surgical mask- not more than Rs. 8/- per piece 3ply surgical mask- not more than Rs. 10/- per piece Hand sanitizer – Rs. 100/- per bottle of 200ml To download the notification, click here.
101	Is sale license is required for stocking and selling of hand sanitizer ?	Yes
102	Is sale license is required for stocking and selling of hand cleanser / Rub / wash ?	No
103	Door step delivery of drugs	Govt of India has issued notification No. G.S.R. 220 (E) dt. 26-03-2020 regarding the door step delivery of drugs. To download the notification, click here.
104	Sale of some drugs without prescription of RMP and without supervision of Registered Pharmacist.	Drugs which are not covered under Schedule H, H1, G, X, nRx, can be sold without prescription of RMP and without supervision of Registered Pharmacist.
105	Whether you have installed CC Camera at your premises ?	Yes / No

Sign
Date
Name