PROFORMA FOR INSPECTION OF AYURVEDIC PHARMACIES AS PER THE PROVISION OF GOOD MANUFACTURING PRACTICES.

1. Name and address of pharmacy: _____
   _____
   _____

2. Manufacturing Lic. No. _____

3. Date of Renewal _____

4. Any other address for Correspondence ----------
   ----

5. Name of Proprietor _____
   _____
   _____

6. Date of Establishment of unit _____

7. Total covered area of pharmacy complex (Sq.feet) _____

8. Location of Pharmacy– Please specify whether: -

Sr. no.	Provision	Status Yes	No
a	Chances of contamination from open sewerage/ drain/public lavatory or obnoxious odour of fumes produced by another factory		
b	Premises compatible with other manufacturing operations in same building		
c	Adequately provided with working space to avoid risk of mix up between different drugs		
d	Premises designed, constructed and maintained to prevent entry of insects.		
e	Walls, floors, ceilings of premises smooth		

9. BUILDING OF PHARMACY –

A) Map of office building -: (Please attach as annexure I)

B) Furnish information regarding office

Sr. No	Office	Length	Width	Height

Please specify whether:-

Sr. no.	Provision	Status Yes	No
a	Permit production of drugs under hygienic condition		
b	Provision of light and ventilation.		
c	Floor and walls having dampness.		
d	Provided with proper drainage system.		
e	Sanitary fitting and electrical fixtures proper and safe.		
f	Bhatti section covered with tin roof, proper ventilation.		
g	Fire safety measures and proper exits provided.		

10. WATER SUPPLY: Please specify whether:-

Sr. no.	Provision	Status Yes	No
a	Adequate provision of water for washing the premises.		
b	Water used of pure and of potable quality.		

11.DISPOSAL OF WASTES: Please specify whether:-

Sr. No.	Provision	Status Yes	No
a	Waste water and residues produced during manufacturing processes prejudicial to the workers or public health		
b	If yes, then whether the NOC from Pollution Control Board obtained.		

12. CONTAINER CLEANING:- Please specify whether:-

Sr. No.	Provision	Status Yes	No
a	Adequate arrangements for Washing, cleaning and drying of containers being used in premises.		

13. STORES;- Please specify whether:-

Sr. No.	Provision	Status Yes	No
	A) Raw-Material stores		
a	Stores having proper ventilation & free from dampness.		
b	Quality of raw material having dampness and insects infestation.		
c	Raw material stores properly labeled.		
d	Labeled drugs indicates source of Supply, status of material.		
	B) Packing Material Stores		
e	Containers used properly cleaned and dried before packing the products.		
	C) Finished goods Stores		
f	Quality control lab. and experts checked the correctness of finished goods.		

g	Medicines prepared have been labeled and packed as per the drug and Cosmetic Act-1945 i.e.(list of ingredients with quantity indication, dose, net weight of packed medicines, batch no. Manufacturing license number, date of manufacturing, best before use)		

Furnish Information regarding dimensions of stores in feet:-

Sr. No	Store	Length	Width	Height
A)	**Raw-Material stores**			
a	Metallic Origin			
b	Mineral Origin			
c	Animal source			
d	Fresh Herbs			
e	Dry Herbs or plant parts			
f	Excipients etc.			
g	Volatile oils/perfumes and flavours			
h	Plant concentrates extracts and exudates/resins			
B)	**Packing Material Stores**			
i	Packing Material Stores			
C)	**Finished goods Stores**			
j	Finished goods Stores			

14. (I) Detail of medicine manufactured during last three years as per the table given below. (Attach Annexure)

Sr.No	Year	Group of medicine	Name of medicine	Batch No.	Quantity

14. (II) Sale of Medicines in open market during last 3 years as per the table given below.(Attach Annexure)

Sr.No	Year	Group of medicine	Name of medicine	Batch No.	Quantity

14. (III) Sale of medicine for Govt. supply during last 3 years as per the table given below. (Attach Annexure)

Sr.No	Year	Group of medicine	Name of medicine	Batch No.	Quantity

15. (A) List of Medicines being manufactured at the time of Inspection. Please attach annexure.
(B) List of medicines not being prepared according to the formula approved. Please attach annexure

16. WORKING SPACE: - Please specify whether:-
Working space sufficient for orderly placement of equipments and for carrying out various processes. Yes No

17. HEALTH CLOTHING SANITATION AND HYGIENCE OF WORKING:- Please specify whether:-

Sr. No.	Provision	Status Yes	No
a	Workers employed free from contagious disease		
b	Proper uniform provided to workers		
c	Provision for clean towel, soap provided		
d	Lavatories provided for men/women separately located at places distant from processing rooms		
e	Workers provided with change rooms, if Yes, then furnish information.		

18. MEDICAL SERVICES:- Please specify whether:-

Sr. No.	Provision	Status Yes	No
a	Adequate facility for first aid provided.		
b	Medical examination of workers conducted at the time of employment.		
c	Periodical check-up by a physical once a year conducted		
d	Record of periodical check-up by a Physician maintained.		

19. (I) MACHINERY AND EQUIPMENTS:- Please specify whether:-

Sr. No.	Provision	Status Yes	No
a	Equipment's properly installed and maintained.		
b	Proper standard operational procedures (SOPS) for cleaning, maintaining and performance of every machine maintained.		

19. (II). INFORMATION REGARDING MACHINERY AND EQUIPMENTS:-
Please attach annexure as per table below:-

Sr. No.	Category/Group of medicines	Available space(size)	Machinery and Equipments

20. BATCH MANUFACTURING RECORDS:- Please specify whether:-

Sr. No.	Provision	Status Yes	No
a	Manufacturing record of each Batch maintained		
b	Daily observation registered regarding details of manufacturing processes i.e. stage by stage process of manufacturing processes maintained.		

c	Classical tests like taste/ colour/Physical characteristics during various stages of manufacturing conducted.		
d	Chemical tests as may have been necessary conducted.		
e	Raw material approved by the the laboratory.		
f	Finished drug approved by the Drug Testing Laboratory.		
g	Quality control in laboratory, If any.		
h	Raw material register maintained.		
i	Finished material register maintained.		
j	Provision of library/manual.		

21. DISTRIBUTION RECORD:- Please specify whether:-
Record of sale and distribution of each batch of medicine maintained. Yes No

22. RECORD OF MARKET COMPLAINTS:- Please specify whether:-

Sr. No.	Provision	Status Yes	No
a	Record of market complaints regarding product sold on a separate Register maintained.		
b	Manufacturer submitted the record of such complaint to the Licensing authority once in a period Of six months.		

23. QUALITY CONTROL:- Please specify whether:-

Sr. No.	Provision	Status Yes	No
a	Provision of Govt. approved Testing laboratory. (Name of approved DTL)……		
b	Quality control section provided in own premises.		
c	If yes, then furnish dimensions. L……W…….H……		
d	Standards of identity, purity and Strength followed as given in		
e	Quality control section having One officer with degree qualification In Ayurveda as per Schedule-II CCIM Act,1970 alongwith the registration No.		
f	Bachelor of Pharmacy, Pharmacogonosy and Chemistry associated with quality control Section.		

24. REQUIREMENT FOR STERILE PRODUCTS :- Please specify whether:-
Provisions for sterile products exists Yes No

25. ELECTRICITY DETAILS:- _____
_____

26. HERBAL GARDEN:-(if any) furnish information. _____

27. Name and qualification of Supervisory Technical Officers for manufacturing purpose under Drug and Cosmetic Act-1945. Please attach annexure as per table below.

Sr. No.	Name	Qualification	Section

28. LIST OF SKILLED WORKERS:-Section wise/Ministerial Staff.Please attach annexure as per table below.

Sr. No.	Name	Qualification	Section

29. LIST OF UNSKILLED WORKERS:-Please attach annexure.
(a) Whether attendance register of workers Maintained. Yes No
(b) Whether unit deployed less than ten workers In the premises. Yes No
(c) If no, then registration under rule No. 99 of Factory Act-1948 _____

30. CERTIFICATION OF WEIGHING EQUIPMENTS.:- Please attach copies

31.(a) LIST OF TOTAL NUMBER OF LICENSED MEDICINES:- As per group/categories. Please attach annexure.

31. (b).List of total number of licensed medicines not being manufactured with reason thereof. Please attach annexure.

32. TAX DETAIL FOR PAST THREE YEARS:- Please attach copies

Signature of Owner

REMARKS OF THE COMMITTEE