

## **1) APPLICATION FOR APPROVAL OF PLAN LAYOUT.**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	List of Directors with address	1 copy
4	Copy of Power of attorney to sign the documents.	1 copy
5	Copy of Plan approval	1 copy
6	Noc/Consent from SSI, Pollution.	1 copy
7	Copy of Memorandum of Articles	1 copy

## **2) APPLICATION FOR GRANT OR RENEWAL OF DRUG MANUFACTURING LICENCE.[For Application in Form 24/ 27]**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter alongwith payment of application fee.	1 copy
2	Self Assesed check list of documents	1 copy
3	Form 24 & 27 (Maximum 10 Products should apply under each form)	1 copy
4	Product List.	2 copies
5	List of Excipients.	1 copy
6	Similar Product.	1 copy
7	Draft Label.	1 copy
8	Method of Analysis.	1 copy
9	Additional Information Form.	1 copy
10	Copy of Memorandum of Articles	1 copy
11	List of Directors with address	1 copy
12	Copy of Power of attorney to sign the documents.	1 copy
13	Copy of Plan approval	1 copy
14	Noc/Consent from SSI, Pollution.	1 copy

**3) APPLICATION FOR GRANT OR RENEWAL OF AYURVEDIC  
MANUFACTURING LICENCE. [For Application in Form 24-D]**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter alongwith payment of application fee.	1 copy
2	Self Assesed check list of documents	1 copy
3	Form 24-D (Maximum 10 Products should apply under each form)	1 copy
4	Product List.	2 copies
5	List of Excipients.	1 copy
6	Similar Product.	1 copy
7	Draft Label.	1 copy
8	Method of Analysis.	1 copy
9	Copy of Memorandum of Articles	1 copy
10	List of Directors with address	1 copy
11	Copy of Power of attorney to sign the documents.	1 copy
12	Copy of Plan approval	1 copy
13	Noc/Consent from SSI, Pollution.	1 copy

**4) APPLICATON FOR GRANT OR RENEWAL OF COSMETICS  
MANUFACTURING LICENCE. [For Application in Form 31]**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter alongwith payment of application fee.	1 copy
2	Self Assesed check list of documents	1 copy
3	Form 31(Maximum 10 Products should apply under each form)	1 copy
4	Copy of approved technical persons	1 copy
5	Product List.	2 copies
6	List of Excipients.	1 copy
7	Similar Product.	1 copy
8	Draft Label.	1 copy
9	Method of Analysis.	1 copy
10	Additional Information Form.	1 copy
11	Copy of Memorandum of Articles	1 copy
12	List of Directors with address	1 copy
13	Copy of Power of attorney to sign the documents.	1 copy
14	Copy of Plan approval	1 copy
15	Noc/Consent from SSI, Pollution.	1 copy

**5) APPLICATION FOR GRANT & RENEWAL OF RETAIL SALE LICENSE /  
WHOLESALE LICENCE.**  
**(FORM 19)**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	Form – 19.	1 copy
4	Copy of Ownership of premises/Agreement of leave & Licence/Lease Agreement. /Rent receipt.	1 copy
5	Copy of Memorandum and Articles of Association.	1 copy
6	List of Directors	1 copy
7	Copy of Plan of Premises/Lay out of location.	1 copy
8	Certificates of Competent Person/ Super wiser in charge. a) Copy of Offer of Appointment. b) Copy of Consent/Acceptance Letter. c) Copy of Experience Certificate. d) Copy of Degree Certificate. e) Copy of Marks Statement. f) Affidavit of pharmacist.	1 copy
9	Copy of Power of attorney to sign the documents.	1 copy
10	Photo Identity proof	1 copy

**6) APPLICATION FOR GRANT OR RENEWAL OF MANUFACTURING LOAN  
LICENCE. [For Application in Form 24-A /27-A]**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter along with payment of application fee	1 copy
2	Self Assesed check list of documents	1 copy
3	Form 24-A & 27-A (Maximum 10 Products should apply under each form)	1 copy
4	Manufacturing Loan no. 1, 2 & 3. (original)	1 copy
5	Copy of Selling licence	1 copy
6	Product List.	2 copies
7	List of Excipients.	1 copy
8	Similar Product.	1 copy
9	Draft Label.	1 copy
10	Method of Analysis.	1 copy
11	Additional Information Form.	1 copy
12	Copy of Memorandum of Articles	1 copy
13	List of Directors with address	1 copy
14	Copy of Power of attorney to sign the documents.	1 copy

## **7. APPLICATION FOR TEST LICENCE.**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	List of Excipients	1 copy
4	Form 30	1 copy
5	Pharmacopoeial reference	1 copy
6	Manufacturing licence copy	1 copy
7	Power of Attorney to sing. Documents	1 Copy
8	Method of analysis	2

## **8) APPLICATION FOR NDPS LICENCE.**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter along with payment of application fee	1 copy
2	Self Assesed check list of documents	1 copy
3	Form NDPS I/NDPS II	1 copy
4	Approval of product permission	1 copy
5	Pharmacopoeial reference	1 copy
6	Manufacturing licence copy	1 copy
7	Power of Attorney to sing. Documents	1 copy
8	Approval of plant layout of premise	1 copy

## **9) ADDITIONAL PRODUCTS**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter along payment of application fee	1 copy
2	Self Assesed check list of documents	1 copy
3	Product list	2 copies
4	List of Excipients	1 copy
5	Draft Label	1 copy
6	Method of analysis a) Finished products b) Active Raw material	1 copy
7	Reference of pharmacopoeia if finished product or raw material is official in any pharmacopoeia	1 copy
8	Copy of DCGI approval if applicable.	1 copy
9	Similar product	1 copy
10	Additional information form	1 copy for one product
11	Self Declaration in prescribed format for export product only.	1 copy
12	Manufacturing licence copy	1 copy
13	List of approved technical persons	1 copy
14	Copy of Power of Attorney to sing the documents	1 copy

### **10)FREE SALE CERTIFICATE**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	Copy of manufacturing licence along with approved product list	1 copy
4	Copies of draft of Free Sale Certificates in attached format	2 copies
5	Certificate of production & sales details from Chartered Accountant (original)	1 copy
6	Copy of power of attorney to sing the documents	1 copy

### **11)MANUFACTURING & MARKETING CERTIFICATE**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	Copy of manufacturing licence along with approved product list of applied products.	1 copy
4	Performa A	1 copies
5	Production & sales details from Chartered Accountant (original)	1 copy
6	Copy of Manufacturing & Marketing Certificate in attached format	2 copy
7	Copy of power of attorney to sing the documents	1 copy

### **12)NO CONVICTION CERTIFICATE**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	Copy of manufacturing licence along with approved product list of applied products.	1 copy
4	Performa A	1 copy
5	Copies of draft of No Conviction Certificate in attached format.	2 copies
6	List of Directors	1 copy
7	Copy of power of attorney to sing the documents	1 copy

**13) APPLICATION FOR GRANT OF NEUTRAL CODE. (FOR EXPORT)**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	Copy of manufacturing licence	
4	Copy of evidence asking for export under neutral code	1 copy
5	Copy of Power of attorney to sign the documents.	1 copy

**14) APPLICATION FOR APPROVAL OF COPPS.**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	Copy of Mfg. Licence.	1 copy
4	Copy of WHO –GMP Certificate	1 copy
5	List of approved product at a time of WHO Certificate issued.	1 copy
6	Copy of Power of attorney to sign the documents.	1 copy

**15) APPLICATION FOR THE UNIT WHO- GMP CERTIFICATE**

<b>Sr. No.</b>	<b>Papers</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	List of products.	1 copy
3	Copy of Site Master File.	1 copy

**16) APPLICATION FOR SCHEDULE M. GMP CERTIFICATE**

<b>Sr. No.</b>	<b>Papers</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	Copy of Site Master File.	1 copy
4	Copy of power of attorney to sing the documents	1 copy

**17) APPLICATION FOR APPROVAL OF TECHNICAL STAFF.**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	Copy of Mfg. Licence.	1 copy
4	Copy of Performa A	1 copy
5	Copy of Offer letter and Appointment letter	1 copy
5	Copy of Consent Letter	1 copy
6	Copy of Joining Letter	1 copy
7	Copy of Degree Certificate	1 copy
8	Copy of Mark Sheet	1 copy
9	Experience Certificate and previous job reliving certificate	1 copy
10	Copy of Power of Attorney to sign the documents	1 copy

**18) APPLICATION FOR APPROVAL OF APPROVED PUBLIC TESTING LABORATORY**

<b>Sr. No.</b>	<b>Documents</b>	<b>No. of copies</b>
1	Covering letter	1 copy
2	Self Assesed check list of documents	1 copy
3	Copy of Mfg. Licence.	1 copy
4	Copy of consent letter from public testing laboratory	1 copy
5	Copy of Public Testing Laboratory (Licence Copy)	1 copy

**\* PROFORMA 'A'**

Additional information to be submitted along with application for Performance Certificate:

1. Name of the Manufacturer and Address.
2. Details of Licence/s and their Validity- and names of the drugs manufactured in own premises.
3. Reasons for Performance Certificate-
4. Whether Own Testing Facilities are provided-
5. Names of approved technical staff (section wise)-
6. Whether the Licence/s was/were suspended during last two years, if so, details thereof
7. Names of the drugs to be mentioned in tender-Certificate signed by the Chartered Accountant in respect of Manufacture and sale of those drugs during last two years.
8. Whether the permission to manufacture the said drugs was/were withdrawn during last two years- if so, give details.
9. Whether drugs manufactured by you was/were reported to be Not of Standard Quality during – last two years, if so give details.

***Signature and name of applicant  
Name of the Firm***

**PROFORMA B**

Name of the manufacturer and Address:

**CERTIFICATE OF THE CHARTERED ACCOUNTANT**

Name of the Drug	Batch No.	Total production for the	Batch wise details of
Quantity		Period for Which the	Sales Total
Period of		Certificate is applied	sold and
		For	Sale
(1)	(2)	(3)	(4)

SEAL

Signature of the Chartered Accountant.

Date: