**Prescribed format of Patent & Proprietory Drugs**

Name of firm:

Address:

Manufacturing Licence No:

Name of the product:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sl. No. | Malayalam Name | Sanskrit name | Scientific name | Part used | Quantity of raw material used | Ref. Text | Page No. | Chapter | Year of publication | Name of publisher | Name of commentator | Ref.Yoga |
|  |  |  |  |  | Batch size | Packingsize |  |  |  |  |  |  |  |
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**APPLICATION FOR PATENT & PROPRIETORY MEDICINES**

1. **Application for Approval of Form change Classical Drugs with same indication**
2. Application with 5 Court Fee Stamp
3. Questionnaire for additional medicine
4. Chellan of Rs 3000/- for first ten products,

 after that Rs.2000/- per each product

1. Copy of License
2. Copy of GMP
3. Formula prepared in the prescribed 14 column format two copies (in which one copy should be with the signature of the licensee & Manufacturing Technical Staff)
4. Approved lab test report
5. Samples of drug
6. API reference of ingredients (If the drug is not specified in API, reference pages of other books in I Schedule can be submitted
7. **Application for Approval of Form change Classical Drugs with new indication**
8. Application with 5 Court Fee Stamp
9. Questionnaire for additional medicine
10. Chellan of Rs 3000/- for first ten products,

 after that Rs.2000/- per each product

1. Copy of License
2. Copy of GMP
3. Formula prepared in the prescribed 14 column format two copies (in which one copy should be with the signature of the licensee & Manufacturing Technical Staff)
4. Approved lab test report
5. Samples of drug
6. API reference of ingredients (If the drug is not specified in API, reference pages of other books in I Schedule can be submitted
7. Pilot Study report
8. **Application for Patent Drugs with clinical indications.**

1. Application with 5 Court Fee Stamp
2. Questionnaire for additional medicine
3. Chellan of Rs 3000/- for first ten products,

 after that Rs.2000/- per each product

1. Copy of License
2. Copy of GMP
3. Formula prepared in the prescribed 14 column format two copies (in which one copy should be with the signature of the licensee & Manufacturing Technical Staff)
4. Approved lab test report
5. Samples of drug
6. API reference of ingredients (If the drug is not specified in API, reference pages of other books in I Schedule can be submitted
7. Pilot Study report
8. Safety Study report should be submitted for the drugs included with Schedule E drugs
9. **Application for Patent Drugs with indications as Balya Poshak, Soundaryaprasadhak**
10. Application with 5 Court Fee Stamp
11. Questionnaire for additional medicine
12. Chellan of Rs 3000/- for first ten products,

 after that Rs.2000/- per each product

1. Copy of License
2. Copy of GMP
3. Formula prepared in the prescribed 14 column format
4. Approved lab test report
5. Samples of drug
6. API reference of ingredients (If the drug is not specified in API, reference pages of other books in I Schedule can be submitted
7. Safety Study report should be submitted for the drugs included with Schedule E drugs
8. **Application for Medicinal Plants Extracts**
9. **Application for Aqueous Extracts with indication as per text**
10. Application with 5 Court Fee Stamp
11. Questionnaire for additional medicine
12. Chellan of Rs 3000/- for first ten products,

 after that Rs.2000/- per each product

1. Copy of License
2. Copy of GMP
3. Formula prepared in the prescribed 14 column format
4. Approved lab test report
5. Samples of drug
6. API reference of ingredients (If the drug is not specified in API, reference pages of other books in I Schedule can be submitted
7. **Application for Aqueous Extracts with new indication**
8. Application with 5 Court Fee Stamp
9. Questionnaire for additional medicine
10. Chellan of Rs 3000/- for first ten products,

 after that Rs.2000/- per each product

1. Copy of License
2. Copy of GMP
3. Formula prepared in the prescribed 14 column format two copies (in which one copy should be with the signature of the licensee & Manufacturing Technical Staff)
4. Approved lab test report
5. Samples of drug
6. API reference of ingredients (If the drug is not specified in API, reference pages of other books in I Schedule can be submitted
7. Pilot Study report
8. **Application for Hydro-Alcohol Extract with indication as per text**
9. Application with 5 Court Fee Stamp
10. Questionnaire for additional medicine
11. Chellan of Rs 3000/- for first ten products,

 after that Rs.2000/- per each product

1. Copy of License
2. Copy of GMP
3. Formula prepared in the prescribed 14 column format
4. Approved lab test report
5. Samples of drug
6. API reference of ingredients (If the drug is not specified in API, reference pages of other books in I Schedule can be submitted
7. **Application for Hydro-Alcohol Extract with new indication**

Application with 5 Court Fee Stamp

Questionnaire for additional medicine

Chellan of Rs 3000/- for first ten products,

after that Rs.2000/- per each product

Copy of License

Copy of GMP

Formula prepared in the prescribed 14 column format two copies (in which one copy should be with the signature of the licensee & Manufacturing Technical Staff)

Approved lab test report

Samples of drug

API reference of ingredients (If the drug is not specified in API, reference pages of other books in I Schedule can be submitted

Pilot Study report

1. **Application for Extracts other than Hydro Alcohol**

Application with 5 Court Fee Stamp

Questionnaire for additional medicine

Chellan of Rs 3000/- for first ten products,

after that Rs.2000/- per each product

Copy of License

Copy of GMP

Formula prepared in the prescribed 14 column

format two copies (in which one copy should be with the signature of the licensee & Manufacturing Technical Staff)

Approved lab test report

Samples of drug

API reference of ingredients (If the drug is not specified in API, reference pages of other books in I Schedule can be submitted

Pilot Study report

Safety Study report should be submitted for the drugs included with Schedule E drugs

**APPLICATION FOR CLASSICAL MEDICINES**

1. Application with 5 Court Fee Stamp
2. Questionnaire for additional medicine
3. Copy of License
4. Copy of GMP
5. Formula prepared in the prescribed format two copies (in which one copy should be with the signature of the licensee & Manufacturing Technical Staff)

**Prescribed format of Patent & Proprietory Drugs**

Name of firm:

Address:

Manufacturing Licence No:

Name of the product:

|  |  |  |  |
| --- | --- | --- | --- |
| Sl.No. | Yogam | Reference book | Reference page |
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