**FEES FOR A PHARMACEUTICAL MANUFACTURING LICENCE**

**Local manufacturers**

1. **Fees for operating licences and certificate of suitability of premises**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Application for a licence** | **Application for renewal of** |
|  |  |  |  |  |  | **licence** |
|  |  |  |  |  |  |  |  |
|  |  |  |  | **Application** | **Certificate of** | **Application** | **Certificate of** |
|  | **Licence Category** | **for operating** | **Suitability of** | **for operating** | **Suitability of** |
|  |  |  |  | **licence** | **premises** | **licence** | **premises** |
|  |  |  |  |  |  |
| i | Licence to manufacture |  |  |  |  |
|  | external preparations or | 420,000/= | 350,000/= | 350,000/= | 350,000/= |
|  | oral liquid preparations |  |  |  |  |
|  |  |  |  |  |  |
| ii | Licence to manufacture |  |  |  |  |
|  | external | preparations | 480,000/= | 400,000/= | 400,000/= | 400,000/= |
|  | and oral preparation |  |  |  |  |
|  |  |  |  |  |  |  |  |
| iii | Licence | to | manufacture |  |  |  |  |
|  | sterile preparations, the |  |  |  |  |
|  | preparations | in para- | 700,000/- | 700,000/= | 600,000/= | 600,000/= |
|  | graphs (i), (ii) and other |  |  |  |  |
|  | types of dosage forms |  |  |  |  |
|  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| iv | Approval of primary |  |  |  |  |
|  | packaging for the local | 350,000/= | 300,000/= | 300,000/= | 300,000/= |
|  | manufacturer |  |  |  |  |
|  |  |  |  |  |  |
| v | Approval of secondary |  |  |  |  |
|  | packaging for the local | 300,000/= | 250,000/= | 250,000/= | 250,000/= |
|  | manufacturer |  |  |  |  |
|  |  |  |  |  |  |

**(b) Inspection fees for the categories in paragraph (a)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | 1 | Inspection of facilities for manufacturing drugs in |  | **70,000/=** |
|  | paragraph (a) categories (iv) and (v) |  |
|  |  |  |  |
|  |  |  |  |  |
|  | 2 | Inspection of facilities for manufacturing drugs in |  | **130,000/=** |
|  | paragraph (a) | categories (i) (ii) and (iii) |  |
|  |  |  |  |
|  |  |  |  |  |
| **(c) Re-inspection fees for the categories in paragraph (a)** |  |  |
|  |  |  |  |  |  |
|  | 1 | Re-inspection | of facilities for manufacturing drugs in |  | **200,000/=** |
|  | paragraph (a) | categories (iv) and (v) |  |
|  |  |  |  |
|  |  |  |  |  |
|  | 2 | Re- inspection of facilities manufacturing drugs in |  | **500,000/=** |
|  | paragraph (a) | categories (i), (ii) and (iii) |  |
|  |  |  |  |
|  |  |  |  |
| **(d) Application to amend the conditions of manufacturing licence** |
|  |  |  |  |  |
|  |  | Application to amend the conditions of manufacturing licence |  |  |
|  | 1 | with site inspection for manufacturers in paragraph (a) | **250,000/=** |
|  |  | categories (i) , (ii) and (iii) |  |  |
|  |  |  |  |  |
|  |  | Application to amend the conditions of a manufacturing |  |  |
|  | 2 | licence with site inspection for manufacturers paragraph (a), | **150,000/=** |
|  |  | categories (iv) and (v) |  |  |
|  |  |  |  |  |
|  | 3 | Application to amend the conditions of a manufacturing | **100,000/=** |
|  | licence for all categories without inspection |
|  |  |  |  |
|  |  |  |  |  |  |