**Company Registration Form**

**Form A1**

**Kurdistan Medical Control Agency (KMCA),**

**Erbil, Kurdistan region,**

**Iraq,**

**2013**



**Applicant Company:**

|  |  |
| --- | --- |
| Applicant company  | Name:Main Address: Telephone no.:Fax:Email:Website:  |
| Applicant company category | Wholesaler [ ] Distributor [ ] Legal manufacturer representative [ ] Others (specify) [ ]  |

**Responsible Pharmacist:**

|  |  |
| --- | --- |
| Full name |  |
| Present residency |  |
| Job titles |  |
| Business address | Main Address :Telephone no.:Fax : Website : Email :  |
| Date and number of registration at Kurdistan Pharmacist Syndicate |  |

1. **General information:**

|  |  |
| --- | --- |
| 1: 1 - Manufacturer name |  |
| 1:2 - Manufacturer address | Main AddressTelephone no.FaxWebsiteEmail |
| 1:3 - Manufacturer category | Manufacturer [ ] Re-Packager and/or Re-Labeler [ ] Others (specify) [ ]  |
| 1:4 - Year of Foundation  |  { } year  |
| 1:5- Number and Date of Registration in the country of origin. |  |

**2- Affiliates:**

If the company is owned by another company or belong to a group pf companies, describe your position within the structure.

**3- Regulatory issues:**

|  |  |
| --- | --- |
| 3:1- Number and date of the last inspection report by regulatory authority in charge in the country of origin **(attach a legalized copy)**. |  |
| 3:2- Regulatory authority at the country of origin. | NameMain Address Telephone no.FaxWebsiteEmail |
| 3:3- Does regulatory authority at the country of origin organizes periodic inspection?  | Yes [ ] No [ ]  |
| 3:4- Periodicity of the inspection  | [ ] yearsOthers (specify) |
| 3:5- Good manufacturing practice (GMP), indicate the GMP standards (WHO, EU, FDA, or others) with which the company complies. |  |
| 3:6- Manufacturing license for pharmaceutical products, list the pharmaceutical dosage forms you are licensed to manufacture by the national regulatory authority (attach a copy of the manufacturing licenses.)  |  |

**4: Manufacturing**

 **4.1- Manufacturing site:**

|  |  |
| --- | --- |
| A - Pharmaceutical preparations ( Attach list of these preparations )  |  |
| B - Source of Raw materials  4.1.1 Self Manufacturing  4.1.2 Under license  4.1.3 Other sources  | Yes [ ]  No [ ] Yes [ ]  No [ ] Yes [ ]   |
| C - Sources of packaging materials  4.1.4 Self Manufacturing  4.1.5 Under license  4.1.6 Other sources  | Yes [ ]  No [ ] Yes [ ]  No [ ] Yes [ ]   |
| D - Availability of suitable storage conditions according to Good Storage Practice ( GSP) for : 4.1.7 Raw materials  4.1.8 Final Products  4.1.9 Rejected Products  |  Yes [ ]  No [ ] Yes [ ]  No [ ] Yes [ ]  No [ ]  |
| E- Availability of system for batches registration and follow up the suitability of the final product within the shelf life  | Yes [ ]  No [ ]  |

**4:2 Key Personnel**

|  |  |  |
| --- | --- | --- |
| **Title** | **Qualifications and degrees** | **Background and experience** |
| Marketing manager |  |  |
| Technical manager |  |  |
| Production manager |  |  |
| Quality control manager |  |  |
| Quality assurance manager |  |  |
| Others |  |  |

|  |  |
| --- | --- |
| **Total number of key personnel** |  |

**4:3 Ventilation Systems**

|  |  |
| --- | --- |
| Indicate whether the manufacturingareas are equipped with controlled ventilation. | Yes [ ]  No [ ]  |
| If “No” explain reasons**.** |  |

**4:4 Contract manufacture**

|  |  |
| --- | --- |
| Do you under take contract manufacture for other companies? | Yes [ ]  No [ ]  |
| If yes indicate the type of products |  |

**4:5 Research and development activities**

|  |  |
| --- | --- |
|  a- Does Manufacturer company contains Research & Development department  | Yes [ ] No [ ]  |
| b- Number and qualification of personal working in this department  | **Qualification** | **Numbers** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  c- Do you cooperate with universities or Research centers  | Yes [ ]  No [ ]  If yes, what type of activities?  |

**4:6 Quality control laboratories**

|  |  |
| --- | --- |
| a- Does manufacturer company contains quality control laboratories? | Yes [ ]  No [ ]  |
| b- Number and qualification of key personnel working in these laboratories. | **Qualification** | **Number** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| c- Instrumentation: \* Chemical laboratories \* Biological laboratories |  In house Contracted lab |

**4:7 Beta-Lactam, highly sensitizing compounds, hormones, cytotoxic products:**

|  |  |
| --- | --- |
| a- Do you manufacture penicillins or other beta-lactam, or highly sensitizing compounds, or hormones, or cytotoxic products**?** | Yes [ ]  No [ ]  |
| b- If yes does this production take place in a separate building, provided with its own dedicated air-handling system? | Yes [ ]  No [ ]  |

**4:8 Complaints and recalls**

|  |  |
| --- | --- |
| a- Do you have a recall procedure, which enables you to recall any product effectively and promptly within 24 hours from the distribution points or markets? | Yes [ ]  No [ ]  |

**4:9 Tests:**

|  |  |
| --- | --- |
| a- Type of tests performed on starting materials  ( raw materials )  |  |
| b- Type of tests performed on intermediate(in process) materials  |  |
| c - Type of tests on finished product  |  |

The undersigned here declares that all the information contained herein is correct to the best of my knowledge and belief.

 **Signature of responsible person Name of responsible person**

 **(Of the Manufacturer) (Of the Manufacturer)**

 **Date Manufacturer stamp**