**Technical Specification for the Development and Commercial Production of a Pharmaceutical Product**

1. **General Information about the Customer** (to be completed for both development and commercial production)
   1. Full name of the Customer Company:
   2. Contact person of the Customer:
      1. Full Name:
      2. Contact Phone:
      3. E-mail:
      4. Mailing Address:
2. **Information about the Pharmaceutical Product** (to be completed for both development and commercial production)
   1. INN or group name:
   2. Brand name of the drug: Место для ввода текста.
   3. Form of release:

Hard gelatin capsules № \_\_\_\_\_\_

Cellulose capsules №\_\_\_\_\_\_

Round biconvex tablets, diameter\_\_\_\_\_\_\_ mm

Round biconvex coated tablets, diameter \_\_\_\_\_\_\_ mm

Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. Composition:

For each dosage  
 Active substance –

Auxiliary substances –

* 1. Dosage(s):
  2. Pharmacological group:
  3. Technology for producing the pharmaceutical product:
  4. Are there any manufacturing restrictions?

highly toxic drug

hormonal drug

coloring drug/active substance

hydrophilicity

explosiveness

* 1. What is the status of the drug in the Russian Federation?

reproduced  reference (original)

* + 1. If the drug is reproduced, what is the reference (original) drug in the Russian Federation
  1. Are there any patent restrictions regarding the composition and technology for obtaining the drug:
  2. Storage conditions of the drug:
  3. Shelf life of the drug:

1. **Information about the active pharmaceutical substance** (to be filled for both development and commercial production)
   1. INN or group name: Место для ввода текста.
   2. Type of active pharmaceutical substance (powder, liquid, etc.)
   3. Trade name of active pharmaceutical substance:
   4. Manufacturer, country:
   5. Registration status of the active pharmaceutical substance in the Russian Federation:

included in the state registry of the Ministry of Health of the Russian Federation

registered as part of the drug registration for the pharmaceutical product

no

* 1. Are there any patent restrictions regarding the composition and technology of obtaining the active pharmaceutical substance

yes  no

* 1. Availability of MSDS (safety data sheet):  yes  no
  2. Hazard class (specify if yes):
  3. Hazard class (specify if yes):
  4. Cleaning (decontamination) recommendations:
  5. Environmental hazard:
  6. Therapeutic dose:
  7. Maximum daily dose:
  8. Storage conditions of the active pharmaceutical substance:
  9. Shelf life of the active pharmaceutical substance:

1. **Information about the packaging of the pharmaceutical product** (to be filled for both development and commercial production)
   1. **Primary packaging:**
      1. Type (blister, jar) –
      2. Packaging (number of capsules or tablets in a blister (jar)-
   2. **Secondary packaging:**
      1. Type *(corrugated box):*
      2. Packaging (number of blisters/jars in a box):
2. **Scope of work** (to be filled for both development and commercial production)

|  |  |  |  |
| --- | --- | --- | --- |
| **Work** | **Yes** | **No** | **Requirements** |
| * 1. **Literature review** |  |  |  |
| * 1. **Patent search** |  |  |  |
| * 1. **Pharmaceutical development** | | | |
| * + 1. Study of the compatibility of pharmaceutical components with each other and with equipment materials and primary packaging |  |  |  |
| * + 1. Development of the formulation (preformulation) |  |  |  |
| * + 1. Physicochemical and biological properties |  |  |  |
| * + 1. Development of the manufacturing process |  |  |  |
| * + 1. Microbiological indicators |  |  |  |
| * 1. **Analytical part** | | | |
| * + 1. Stress testing of the active pharmaceutical substance |  |  |  |
| * + 1. Stress testing of the pharmaceutical formulation |  |  |  |
| * + 1. Development of analytical methods |  |  |  |
| * + 1. Validation of analytical methods |  |  |  |
| * + 1. Comparative test of the dissolution kinetics of laboratory samples |  |  |  |
| * + 1. Comparative test of the dissolution kinetics of the finished product |  |  |  |
| * 1. **Laboratory production** | | | |
| * + 1. Production of the first laboratory batch within the framework of technology development and for preliminary stability studies |  |  |  |
| * + 1. Production of placebo |  |  |  |
| * 1. **Study of the stability of laboratory samples** | | | |
| * + 1. Development of a stability program |  |  |  |
| * + 1. atural storage (25°C/65%RH) |  |  |  |
| * + 1. Accelerated aging (40°C/75%RH) |  |  |  |
| * + 1. Intermediate (30°C/65%RH) |  |  |  |
| * + 1. Photostability |  |  |  |
| * 1. **Scale-up** | | | |
| * + 1. Production of three pilot industrial batches |  |  |  |
| * + 1. Packaging of three pilot industrial batches in primary packaging |  |  |  |
| * + 1. Quality control of three pilot industrial batches (validation) |  |  |  |
| * 1. **Process validation** |  |  |  |
| * 1. **Study of the stability of the finished product** |  |  |  |
| * + 1. Development of a stability program |  |  |  |
| * + 1. Natural storage (25°C/65%RH) |  |  |  |
| * + 1. Accelerated aging (40°C/75%RH) |  |  |  |
| * + 1. Intermediate (30°C/65%RH) |  |  |  |
| * + 1. Long-term storage |  |  |  |
| * 1. **Cleaning of equipment** | | | |
| * + 1. Development of a cleaning method for equipment |  |  |  |
| * + 1. Validation of the cleaning method for equipment |  |  |  |
| * 1. **Development of a registration dossier for the drug** |  |  |  |
| * 1. **Preparation of documents for registration at the regulatory authority** |  |  |  |
| * 1. **Transfer** | | | |
| * + 1. Technology transfer |  |  |  |
| * + 1. Transfer of analytical methods |  |  |  |
| * + 1. Validation of industrial technology |  |  |  |
| * + 1. Production of the first "pilot" batch in the shop as part of technology transfer |  |  |  |
| * 1. **Safety and efficacy studies** | | | |
| * + 1. Preclinical |  |  |  |
| * + 1. Clinical |  |  |  |

1. **List of Material Assets (TMC) for Work Execution** (to be filled for both development and commercial production)

|  |  |  |
| --- | --- | --- |
| **Name of TMC** | **Customer** | **Contractor** |
| * 1. Active Pharmaceutical Substance |  | ☐ |
| * 1. Auxiliary substances |  |  |
| * 1. Reagents for Analysis |  | ☐ |
| * 1. Standards, chromatographic columns, and other consumables for incoming control of the active pharmaceutical substance |  | ☐ |
| * 1. Standards, chromatographic columns, and other consumables for incoming control of excipients |  | ☐ |
| * 1. Standards, chromatographic columns, and other consumables for quality control of the pharmaceutical formulation |  | ☐ |
| * 1. Primary packaging |  |  |
| * 1. Secondary packaging (cardboard boxes without labeling (blanks) for stability) |  |  |
| * 1. Analytical or technological equipment (if necessary) |  | ☐ |

1. **Information about the commercial release of the pharmaceutical product** (to be filled only for commercial production)
   1. Start dates for commercial production of the product-
   2. Requirements for seasonality of production (1st - 4th quarter of the year) based on the characteristics of the active pharmaceutical substance, pharmaceutical product, or production technology  yes  no
   3. If yes, what
   4. Projected production volume

|  |  |  |  |
| --- | --- | --- | --- |
| Name | 1st year | 2nd year | 3rd year |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **Project Implementation** (to be filled for both development and commercial production)
   1. Supply scheme for the active pharmaceutical substance:

:  Contract manufacturing  purchased by the Contractor  mixed

* 1. Supply scheme for auxiliary substances

Contract manufacturing  purchased by the Contractor  mixed

* 1. Supply scheme:

HPLC columns  Contract manufacturing  purchased by the Contractor

reagents  Contract manufacturing  purchased by the Contractor

standard samples  Contract manufacturing  purchased by the Contractor

* 1. Supply scheme:

Packages

Contract manufacturing  purchased by the Contractor based on submitted approved layouts

Films

Contract manufacturing  purchased by the Contractor

Foils

Contract manufacturing  purchased by the Contractor based on submitted approved layouts

Instructions

Contract manufacturing  purchased by the Contractor based on submitted approved layouts

Corrugated box

Contract manufacturing  purchased by the Contractor

* 1. Acquisition of equipment (analytical or technological)

by and at the expense of  Customer  Contractor  not required

* 1. Trademark registration®  Customer  Contractor  not required
  2. Quality control of commercial batches of the product

Customer  Contractor

* 1. Introduction of the product into civil circulation  Customer  Contractor
  2. Testing of the first three batches  Customer  Contractor
  3. Price registration  required  not required