**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