**Terms of reference for development and commercial production**

**Biologically active additives (dietary supplements)**

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 dietary supplements** (to be filled in for both development and commercial production)
	1. Form of release:

[ ]  Hard gelatin capsules № \_\_\_\_\_\_

[ ]  Cellulose capsules №\_\_\_\_\_\_

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

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

[ ]  Sachet package of \_\_\_\_\_\_ g

[ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. Composition:

 Active substance –

Auxiliary substances –

* 1. Dosage(s):
	2. Appointment of dietary supplements:
	3. Are there any manufacturing restrictions?

[ ]  hygroscopicity

[ ]  allergen

[ ]  coloring product

[ ]  probiotic

[ ]  no information available/other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. Shelf life of dietary supplements:
1. **Information about active substances** (to be filled in for both development and commercial production)
	1. Type of components of the composition (powder, liquid, etc.)
2. **Information about the packaging of dietary supplements** (to be filled in for both development and commercial production)
	1. **Primary packaging:**
		1. Type (blister, jar) –
		2. Packing (what is the number of capsules or tablets in a blister/jar) –
	2. **Secondary packaging:**
		1. type (cardboard pack):
		2. packing (number of blisters/cans/sachet bags per pack):
3. **Scope of work** (to be filled for both development and commercial production)

|  |  |  |  |
| --- | --- | --- | --- |
| **Work** | **Yes** | **No** | **Requirements** |
| * 1. Composition development
 | [ ]  | [ ]  |  |
| * 1. Development of the production process
 | [ ]  | [ ]  |  |
| * 1. Microbiological indicators
 | [ ]  | [ ]  |  |
| * 1. Development of analysis methods
 | [ ]  | [ ]  |  |
| * 1. Production of the 1st pilot series as part of technology development and for product registration
 | [ ]  | [ ]  |  |
| * 1. Preparation of documents for Registration with the regulatory authority (technical specifications, formulation, label text, etc.)
 | [ ]  | [ ]  |  |
| * 1. Registration of the product (receipt of the SGR)
 | [ ]  | [ ]  |  |

1. **List of goods and equipment (inventory items) for work (to be filled in for both development and commercial production)**

|  |  |  |
| --- | --- | --- |
| **Name of TMC** | **Customer** | **Contractor** |
| * 1. Active Pharmaceutical Substance
 | [ ]  | ☐ |
| * 1. Auxiliary substances
 | [ ]  | [ ]  |
| * 1. Reagents and chromatographic columns for analysis
 | [ ]  | ☐ |
| * 1. Primary packaging
 | [ ]  | [ ]  |
| * 1. Analytical or technological equipment (if necessary)
 | [ ]  | ☐ |

1. **Information about the commercial release of dietary supplements (to be filled in only for commercial production)**
	1. The timing of the start of commercial production of the product -
	2. Requirements for the seasonality of production (1st - 4th quarter of the year) based on the characteristics of active substances or production technology [ ]  yes [ ]  no
	3. If yes, which ones \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	4. Projected output 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 [ ]  not required

Jars

[ ]  Contract manufacturing [ ]  purchased by the Contractor [ ]  not required

Films

 [ ]  Contract manufacturing [ ]  purchased by the Contractor [ ]  not required

Foils

 [ ]  Contract manufacturing [ ]  purchased by the Contractor [ ]  not required

Self-adhesive labels

[ ]  Contract manufacturing [ ]  purchased by the Contractor [ ]  not required

Instructions

 [ ]  Contract manufacturing [ ]  purchased by the Contractor [ ]  not required

Corrugated box

[ ]  Contract manufacturing [ ]  purchased by the Contractor [ ]  not required

* 1. Acquisition of equipment (analytical or technological)

by and at the expense of [ ]  Customer [ ]  Contractor [ ]  not required