**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