

Tehničke specifikacije za predmet nabave:

Technical specifications for the procurement subject:

Ugovorno istraživanje – prilagodba tehnološkog procesa

Contract research – adaptation of the technological process

Predmet nabave je nabava usluga **Ugovorno istraživanje - prilagodba tehnološkog procesa** na proizvodnim linijama za potrebe projekta „Razvoj inovativnih formulacija kliničke prehrane“.

Procurement subject is supply of service **Contract research - adaptation of the technological process** on production lines for the implementation of the project "Development of innovative formulations of clinical nutrition".

Projekt „Razvoj inovativnih formulacija kliničke prehrane“ provodi istraživački tim Instituta Ruđer Bošković u suradnji s tvrtkom Belupo d.d. U sklopu projekta razvit će se nove formulacije kliničke prehrane namijenjene nutritivnoj potpori osoba koje se nalaze u riziku ili su oboljele od malnutricije, oboljelima od dijabetesa i onkološkim bolesnicima. Projekt se provodi kroz fazu industrijskog istraživanja i fazu eksperimentalnog razvoja.

Project „Development of innovative formulations of clinical nutrition“ is carried by the research team of the Ruđer Bošković Institute in cooperation with the company Belupo Inc. As part of the project, new formulations of clinical nutrition intended for the nutritional support of persons at risk or suffering from malnutrition, diabetes patients and oncology patients will be developed. The project is carried out through the phase of industrial research and the phase of experimental development.

Specifično, predmet nabave je nabava usluga **Ugovorno istraživanje - prilagodba tehnološkog procesa** na proizvodnim linijama, koja se provodi u sklopu faze eksperimentalnog razvoja projekta „Razvoj inovativnih formulacija kliničke prehrane“.

Specifically, procurement subject is supply of **service Contract research - adaptation of the technological process** on production lines, which is carried out as part of the experimental development phase of the project "Development of innovative formulations of clinical nutrition".

Provedba usluge **Ugovornog istraživanja – prilagodba tehnološkog procesa** na proizvodnim linijama rezultirat će definiranim tehnološkim procesom formulacija kliničke prehrane.

The implementation of the **Contract research - adaptation of the technological process** on the production lines will result in defined technological process of clinical nutrition formulations.

Predmetna provedba Ugovornog istraživanja obuhvaća provedbu tehnološke prilagodbe 4 formulacije na proizvodnim linijama. U nastavku su prikazane tehničke specifikacije cjelokupnog predmeta nabave.

The implementation of the subject Contract research includes the implementation of technological adaptation of 4 formulations on production lines. Technical specifications of whole procurement subject are shown below.

Tehničke specifikacije i sve relevantne tehničke pojedinosti predmeta nabave:

Technical specification and all relevant technical details regarding procurement subject:

- hrana s posebno prilagođenim sastavom hranjivih tvari za bolest, poremećaj ili medicinsko stanje (definirana je prema EU Uredbi 609/2013); *food with a specially adapted composition of nutrients for a disease, disorder or medical condition (defined according to the Regulation (EU) No. 609/2013);*
- nutritivno kompletne tekuće formulacije; *nutritionally complete liquid formulations;*
- tekući proizvodi, spremni za konzumaciju; *liquid products, ready for consumption;*
- proizvod mora biti UHT tretiran (tretiran na visokim temperaturama, iznad 135°C, kratko vrijeme), a proces punjenja na proizvodnoj liniji mora biti aseptičan; *the product must be UHT treated (treated at high temperatures, higher than 135°C, for short time) and filling process on production line must be aseptic;*
- kategorija trajnog proizvoda sa željenim rokom trajnosti od najmanje 12 mjeseci, uz uvjete čuvanja na sobnoj temperaturi i suhom mjestu; / *durable product category with a desired shelf life of at least 12 months, under conditions of storage at room temperature and in a dry place;*
- pakirani u višeslojnu ambalažu sa pretežitim udjelom kartona ili jednakovrijedno, za aseptično punjenje tekućih proizvoda sa željenim rokom trajnosti od najmanje 12 mjeseci uz čuvanje na sobnoj temperaturi. Svako pakiranje treba imati čep koji se aplicira na gornju plohu ambalaže, a zapremnine punjenja trebaju biti dostupne u verzijama od 200 ml do 250 ml, te u odgovarajuću zbirnu ambalažu koja štiti proizvode tijekom transporta i manipulacije; / *Packaged in multi-layer packaging with a predominant proportion of cardboard or equally, for aseptic filling of liquid products with a desired minimum shelf life of 12 months when stored at room temperature. Each package should have a cap that is applied to the top surface of the packaging, and the filling volumes should be available in versions of 200 ml to 250 ml, as well as suitable collective packaging that protects the products during transportation and handling;*
- obzirom da je riječ o hrani za posebne medicinske potrebe (enteralna hrana), potrebno je pridržavati se nadležnog EU zakonodavstva: Uredbe (EU) br. 609/2013, Uredbe (EU) 2016/128, Uredbe (EU) br. 1169/2011 i sve vezane uredbe koje se odnose na sukladnost i zdravstvenu ispravnost ove kategorije proizvoda i hrane općenito; / *considering that it is food for special medical purposes (enteral food), it is necessary to comply with the relevant EU legislation: Regulation (EU) no. 609/2013, Regulation (EU) 2016/128, Regulation (EU) no. 1169/2011 and all related regulations that refer to the conformity and healthiness of this category of products and food in general;*
- osnovne karakteristike formulacija koje su predmet Ugovornog istraživanja su sljedeće: / *the basic characteristics of the formulations which are the subject of Contract research are as follows:*
 - **Formulacija broj 1.** – formulacija namijenjena za dijetalnu prehranu bolesnika - onkoloških bolesnika. Visokokalorična, visokoproteinska, nutritivno kompletna

formulacija. Sadrži i EPA (eikozapentaenska kiselina), srednjelančane trigliceride (MTC), vlakna. Sadrži vitamine i minerale. Bez glutena.

Formulation number 1 - formulation intended for dietary nutrition of oncology patients. High-calorie, high-protein, nutritionally complete formulation. It also contains EPA (eicosapentaenoic acid), medium-chain triglycerides (MTC), fiber. Contains vitamins and minerals. Gluten free.

- **Formulacija broj 2.** – formulacija namijenjena za dijetalnu prehranu bolesnika kod malnutricije ili rizika njezine pojave. Izokalorična, visokoproteinska formulacija, sa sladilom. Sadrži vlakna. Sadrži vitamine i minerale. Bez glutena.

Formulation number 2 - formulation intended for dietary nutrition of patients with malnutrition or the risk of its occurrence. Isocaloric, high-protein formulation, with sweetener. Contains fiber. Contains vitamins and minerals. Gluten free.

- **Formulacija broj 3.** – formulacija namijenjena za dijetalnu prehranu kod bolesnika oboljelih od dijabetesa. Visokoenergetska, visokoproteinska formulacija, sa sladilom. Sadrži vlakna. Sadrži vitamine i minerale. Bez glutena.

Formulation number 3 - formulation intended for dietary nutrition in patients with diabetes. High-energy, high-protein formulation, with sweetener. Contains fiber. Contains vitamins and minerals. Gluten free.

- **Formulacija broj 4.** – formulacija namijenjena za dijetalnu prehranu kod malnutricije i rizika njezine pojave te kod gubitka mase, snage i funkcije mišića. Visokokalorična, visokoproteinska formulacija. Sadrži vlakna. Sadrži vitamine i minerale. Bez glutena.

Formulation number 4 - formulation intended for dietary nutrition in the case of malnutrition and the risk of its occurrence, as well as in the case of loss of muscle mass, strength and function. High-calorie, high-protein formulation. Contains fiber. Contains vitamins and minerals. Gluten free.

Predmet nabave – *Ugovorno istraživanje - prilagodba tehnološkog procesa* na proizvodnim linijama sastoji se od **4 aktivnosti**. Ponuditelj je pri formiranju cijene obavezan uzeti u obzir sav potreban rad, materijal, alat, opremu, troškove puta i smještaja, osiguranje adekvatnih sirovina, troškove zbrinjavanja ostataka i slično, posebne poreze, trošarine i carine, ako postoje, te troškove transporta, dostave i slično za **provedbu svih aktivnosti obuhvaćenih predmetom nabave**.

Procurement subject – *Contract research - adaptation of the technological process on the production lines* consists of **4 activities**. When forming the price, the Tenderer is obliged to take into account all necessary work, materials, tools, equipment, travel and accommodation costs, insurance of adequate raw materials, costs of waste disposal and similar, special taxes, excise duties and customs duties, if any, and costs of transport, delivery and similarly for the implementation of **all activities covered by the procurement**.

Provedba pojedine aktivnosti predmetne usluge ugovornog istraživanja nije vezana uz provedbu drugih projektom obuhvaćenih aktivnosti. Dodatno, provedba pojedine aktivnosti jedino je

ograničena krajnjim rokom isporuke usluge. **Sve 4 aktivnosti projekta moraju biti dovršene do 15.studenog 2023. godine.**

The implementation of individual activities of related service of contract research is not related to the implementation of other activities included in the project. Additionally, the implementation of an individual activity is only limited by the final deadline for service delivery. **All 4 project activities must be completed by November 15, 2023.**

Broj aktivnosti / No of activities	AKTIVNOST / ACTIVITY	KRAJNI ROK IZVRŠENJA / DEADLINE FOR EXECUTION
1.	<i>Provedba tehnološke prilagodbe formulacije broj 1 na proizvodnoj liniji / Implementation of technological adaptation of formulation number 1 on the production line</i>	<i>15.studeni 2023. / November 15 2023</i>
2.	<i>Provedba tehnološke prilagodbe formulacije broj 2 na proizvodnoj liniji / Implementation of technological adaptation of formulation number 2 on the production line</i>	<i>15.studeni 2023. / November 15 2023</i>
3.	<i>Provedba tehnološke prilagodbe formulacije broj 3 na proizvodnoj liniji / Implementation of technological adaptation of formulation number 3 on the production line</i>	<i>15.studeni 2023. / November 15 2023</i>
4.	<i>Provedba tehnološke prilagodbe formulacije broj 4 na proizvodnoj liniji / Implementation of technological adaptation of formulation number 4 on the production line</i>	<i>15.studeni 2023. / November 15 2023</i>

Procijenjeno vrijeme pružanja cjelokupne usluge Ugovornog istraživanja – prilagodba tehnološkog procesa: srpanj 2023. – 15. studeni 2023.

Estimated time of provision of complete service Contract research – adaptation of the technological process: July 2023 – November 15, 2023.

Aktivnost 1. Provedba tehnološke prilagodbe formulacije broj 1 na proizvodnoj liniji minimalno uključuje:

Activity 1. Implementation of technological adaptation of formulation number 1 on the production line includes minimum:

- Prilagodbu recepture¹ u laboratoriju za optimalnu proizvodnju na proizvodnoj liniji – industrijski scale up proces. / Adjustment of the recipe in the laboratory for optimal production on the production line - industrial scale up process¹.

¹ Receptura i parametri tehnološkog procesa sa pilot postrojenja će biti dostavljeni odabranom Ponuditelju po potpisivanju Ugovora o izvršenju predmeta nabave / The recipe and parameters of technological process from the pilot will be delivered to the selected Tenderer upon signing the Contract on the execution of the procurement subject.

- Osiguranje adekvatnih sirovina za provedbu tehnološke probe na industrijskoj proizvodnoj liniji², što *minimalno uključuje za tehnološku prilagodbu formulacije broj 1.*: proteini, ugljikohidrati i masti prikladni za formuliranje proizvoda za primjenu kod malnutricije onkoloških bolesnika. Masti moraju uključivati i izvor EPA (eikozapentaensku kiselinu) i MCT ulja (srednjelančani trigliceridi). Vlakna, vitamini, minerali, aditivi, arome pogodni za hranu za posebne medicinske potrebe. / *Provision of a supply of an adequate raw materials for conducting a technological trial on the industrial production line², which includes, at a minimum, the following for the technological adaptation of formulation number 1: proteins, carbohydrates, and fats suitable for formulating products for use in the nutritional support of oncology patients. The fats must include a source of EPA (eicosapentaenoic acid) and MCT oil (medium-chain triglycerides). Fibers, vitamins, minerals, additives, and flavors suitable for food for special medical purposes should also be included.*
- Provođenje tehnološke probe na industrijskoj proizvodnoj liniji uz aseptično punjenje u višeslojnu ambalažu zapremnine 200 do 250 ml, te u odgovarajuću zbirnu ambalažu koja štiti proizvode tijekom transporta i manipulacije. / *Conducting a technological trial on an industrial production line with aseptic filling into multi-layer packaging with a volume of 200 to 250 ml, and into appropriate collective packaging that protects the products during transport and manipulation.*
- Potrebna veličina jedne probe je jedna paleta (cca. 2000 kom) odnosno minimalna šarža proizvodnje kod koje se može optimalno odraditi proba na industrijskoj liniji. / *The required size of one trial is one pallet (aprox.2000 pcs) respectively the minimum production batch where the trial can be optimally performed on the industrial line.*
- Analiza kontrole kvalitete za tehnološku prilagodbu formulacije broj 1. uključuje provođenje procesnih analiza (potvrda sterilnosti proizvoda, fizikalno kemijske i organoleptičke sukladnosti) i dostava dokumentacije za otpuštanje probnih proizvoda. / *The quality control analysis for technological adaptation of formulation number 1 includes conducting process analyses (confirmation of product sterility, physico-chemical and organoleptic conformity) and delivery of documentation for the release of trial products.*
- Za tehnološku prilagodbu formulacije broj 1. planirane su analize sljedećih nutritivnih, kemijskih i mikrobioloških procesnih parametara: / *Analyses of the following nutritional, chemical and microbiological process parameters are planned for technological adaptation of formulation number 1:*

Nutritivne i kemijske analize / Nutritional and chemical analyses	Broj analiza / Number of analyses
Proteini / proteins (g)	1
Suha tvar/ Dry matter (°Bx ili/or %) ili/ or Vлага / moisture (g ili%)	1
Gustoća / density	1
Organolepika/Organoleptic	1
pH/pH	1

² Vrstu, količinu i specifične karakteristike sirovina komunicirat će se Ponuditelju nakon odabira Ponuditelja te potpisivanja Ugovora o izvršenju predmeta nabave / The type, quantity and specific characteristics of the raw materials will be communicated to the Tenderer after the Tenderer has been selected and the Contract on the execution of the procurement has been signed.

Mikrobiološka analiza / Microbiological analyses	Broj analiza / Number of analyses
Test sterilnosti / Sterility test (na / on 30°C)	1
Test sterilnosti / Sterility test (na / on 55°C)	1

- Dostavu uzoraka sa tehnološke probe na industrijskoj proizvodnoj liniji u Koprivnicu (sjedište Naručitelja). / Delivery of samples from the technological trial on industrial production line in Koprivnica (headquarters of the Contracting authority).
- Dostavu izvještaja sa tehnološke prilagodbe u laboratoriju i provedene tehnološke probe na industrijskoj proizvodnoj liniji (rezultate analiza, tehničko izvješće o provedenim probama na industrijskoj liniji, sa osnovnim pogonskim parametrima i dijagramom tehnološkog procesa) u Koprivnicu (sjedište Naručitelja). / Delivery of the report from the technological adjustment in the laboratory and conducted technological trial on production line (analysis results, technical report on the industrial line tests, with basic operating parameters and technological process diagram) to Koprivnica (Contracting authority headquarters).

Aktivnost 2. Provedba tehnološke prilagodbe formulacije 2 na proizvodnoj liniji minimalno uključuje:

Activity 2. Implementation of technological adaptation of formulation number 2 on the production line includes minimum:

- Prilagodbu recepture³ u laboratoriju za optimalnu proizvodnju na proizvodnoj liniji – industrijski scale up proces. / Adjustment of the recipe in the laboratory for optimal production on the production line – industrial scale up process³.
- Osiguranje adekvatnih sirovina za provedbu tehnološke probe na industrijskoj proizvodnoj liniji⁴ što minimalno uključuje za tehnološku prilagodbu formulacije broj 2.; proteini, ugljikohidrati i masti prikladni za formuliranje proizvoda za primjenu kod malnutricije. Vlakna, vitamini, minerali, sladila i ostali aditivi, arome pogodni za hranu za posebne medicinske potrebe. / Provision of a supply of an adequate raw materials for conducting a technological trial on the industrial production line⁴, which includes, at a minimum, the following for the technological adaptation of formulation number 2: proteins, carbohydrates and fats suitable for formulating products for use in malnutrition. Fibers, vitamins, minerals, sweeteners and other additives, flavors suitable for food for special medical purposes.
- Provođenje tehnološke probe na industrijskoj proizvodnoj liniji uz aseptično punjenje u višeslojnu ambalažu zapremnine 200 do 250 ml, te u odgovarajuću zbirnu ambalažu koja štiti proizvode tijekom transporta i manipulacije. / Conducting a technological trial on an industrial production line with aseptic filling into multi-layer packaging with a volume of 200 to 250 ml,

³ Receptura i parametri tehnološkog procesa sa pilot postrojenja će biti dostavljeni odabranom Ponuditelju po potpisivanju Ugovora o izvršenju predmeta nabave / The recipe and parameters of technological process from the pilot will be delivered to the selected Tenderer upon signing the Contract on the execution of the procurement subject.

⁴ Vrstu, količinu i specifične karakteristike sirovina komunicirat će se Ponuditelju nakon odabira Ponuditelja te potpisivanja Ugovora o izvršenju predmeta nabave. / The type, quantity and specific characteristics of the raw materials will be communicated to the Tenderer after the Tenderer has been selected and the Contract on the execution of the procurement has been signed

and into appropriate collective packaging that protects the products during transport and manipulation.

- Potrebna veličina jedne probe je jedna paleta (cca. 2000 kom) odnosno minimalna šarža proizvodnje kod koje se može optimalno odraditi proba na industrijskoj liniji. / The required size of one trial is one pallet (aprox.2000 pcs) respectively the minimum production batch where the trial can be optimally performed on the industrial line.
- Analiza kontrole kvalitete za tehnološku prilagodbu formulacije broj 2. uključuje provođenje procesnih analiza (potvrda sterilnosti proizvoda, fizikalno kemijske i organoleptičke sukladnosti) i dostava dokumentacije za otpuštanje probnih proizvoda. / The quality control analysis for technological adaptation of formulation number 2 includes conducting process analyses (confirmation of product sterility, physico-chemical and organoleptic conformity) and delivery of documentation for the release of trial products.
- Za tehnološku prilagodbu formulacije broj 2. planirane su analize sljedećih nutritivnih, kemijskih i mikrobioloških procesnih parametara: / Analyses of the following nutritional, chemical and microbiological process parameters are planned for technological adaptation of formulation number 2:

Nutritivne i kemijske analize / Nutritional and chemical analyses	Broj analiza / Number of analyses
Proteini / proteins (g)	1
Suha tvar/ Dry matter (°Bx ili/or %) ili/ or Vлага / moisture (g ili%)	1
Gustoća / density	1
Organolepika/Organoleptic	1
pH/pH	1

Mikrobiološka analiza / Microbiological analyses	Broj analiza / Number of analyses
Test sterilnosti / Sterility test (na / on 30°C)	1
Test sterilnosti / Sterility test (na / on 55°C)	1

- Dostavu uzoraka sa tehnološke probe na industrijskoj proizvodnoj liniji u Koprivnicu (sjedište Naručitelja). / Delivery of samples from the technological trial on industrial production line in Koprivnica (headquarters of the Contracting authority).
- Dostavu izvještaja sa tehnološke prilagodbe u laboratoriju i provedene tehnološke probe na industrijskoj proizvodnoj liniji (rezultate analiza, tehničko izvješće o provedenim probama na industrijskoj liniji, sa osnovnim pogonskim parametrima i dijagramom tehnološkog procesa) u Koprivnicu (sjedište Naručitelja). / Delivery of the report from the technological adjustment in the laboratory and conducted technological trial on production line (analysis results, technical report on the industrial line tests, with basic operating parameters and technological process diagram) to Koprivnica (Contracting authority headquarters).

Aktivnost 3. Provedba tehnološke prilagodbe formulacije 3 na proizvodnoj liniji minimalno uključuje:

Activity 3. Implementation of technological adaptation of formulation number 3 on the production line includes minimum:

- Prilagodbu recepture⁵ u laboratoriju za optimalnu proizvodnju na proizvodnoj liniji – industrijski scale up proces. / Adjustment of the recipe⁵ in the laboratory for optimal production on the production line - industrial scale up process.
- Osiguranje adekvatnih sirovina za provedbu tehnološke probe na industrijskoj proizvodnoj liniji⁶ što *minimalno uključuje za tehnološku prilagodbu formulacije broj 3.:* proteini, ugljikohidrati (složeni, sporoprobavljivi ugljikohidrati) i masti prikladni za formuliranje proizvoda za primjenu kod bolesnika oboljelih od dijabetesa. Vlakna, vitamini, minerali, sladila i ostali aditivi, arome pogodni za hranu za posebne medicinske potrebe. / Provision of a supply of an adequate raw materials for conducting a technological trial on the industrial production line⁶, which includes, at a minimum, the following for the technological adaptation of formulation number 3: proteins, carbohydrates (complex, slow-digesting carbohydrates) and fats suitable for formulating products for use in patients with diabetes. Fibers, vitamins, minerals, sweeteners and other additives, flavors suitable for food for special medical purposes.
- Provođenje tehnološke probe na industrijskoj proizvodnoj liniji uz aseptično punjenje u višeslojnu ambalažu zapremnine 200 do 250 ml, te u odgovarajuću zbirnu ambalažu koja štiti proizvode tijekom transporta i manipulacije. / Conducting a technological trial on an industrial production line with aseptic filling into multi-layer packaging with a volume of 200 to 250 ml, and into appropriate collective packaging that protects the products during transport and manipulation.
- Potrebna veličina jedne probe je jedna paleta (cca. 2000 kom) odnosno minimalna šarža proizvodnje kod koje se može optimalno odraditi proba na industrijskoj liniji. / The required size of one trial is one pallet (aprox.2000 pcs) respectively the minimum production batch where the trial can be optimally performed on the industrial line.
- Analiza kontrole kvalitete za tehnološku prilagodbu formulacije broj 3. uključuje provođenje procesnih analiza (potvrda sterilnosti proizvoda, fizikalno kemijske i organoleptičke sukladnosti) i dostava dokumentacije za otpuštanje probnih proizvoda. / The quality control analysis for technological adaptation of formulation number 3 includes conducting process analyses (confirmation of product sterility, physico-chemical and organoleptic conformity) and delivery of documentation for the release of trial products.
- Za tehnološku prilagodbu formulacije broj 3. planirane su analize sljedećih nutritivnih, kemijskih i mikrobioloških procesnih parametara: / Analyses of the following nutritional, chemical and microbiological process parameters are planned for technological adaptation of formulation number 3:

⁵ Receptura i parametri tehnološkog procesa sa pilot postrojenja će biti dostavljeni odabranom Ponuditelju po potpisivanju Ugovora o izvršenju predmeta nabave / The recipe and parameters of technological process from the pilot will be delivered to the selected Tenderer upon signing the Contract on the execution of the procurement subject.

⁶ Vrstu, količinu i specifične karakteristike sirovina komunicirat će se Ponuditelju nakon odabira Ponuditelja te potpisivanja Ugovora o izvršenju predmeta nabave. / The type, quantity and specific characteristics of the raw materials will be communicated to the Tenderer after the Tenderer has been selected and the Contract on the execution of the procurement has been signed

Nutritivne i kemijske analize / Nutritional and chemical analyses	Broj analiza / Number of analyses
Proteini / proteins (g)	1
Suha tvar/ Dry matter (°Bx ili/or %) ili/ or Vlaga / moisture (g ili%)	1
Gustoća / density	1
Organolepika/Organoleptic	1
pH/pH	1

Mikrobiološka analiza / Microbiological analyses	Broj analiza / Number of analyses
Test sterilnosti / Sterility test (na / on 30°C)	1
Test sterilnosti / Sterility test (na / on 55°C)	1

- Dostavu uzoraka sa tehnološke probe na industrijskoj proizvodnoj liniji u Koprivnicu (sjedište Naručitelja). / *Delivery of samples from the technological trial on industrial production line in Koprivnica (headquarters of the Contracting authority).*
- Dostavu izvještaja sa tehnološke prilagodbe u laboratoriju i provedene tehnološke probe na industrijskoj proizvodnoj liniji (rezultate analiza, tehničko izvješće o provedenim probama na industrijskoj liniji, sa osnovnim pogonskim parametrima i dijagramom tehnološkog procesa) u Koprivnicu (sjedište Naručitelja). / *Delivery of the report from the technological adjustment in the laboratory and conducted technological trial on production line (analysis results, technical report on the industrial line tests, with basic operating parameters and technological process diagram) to Koprivnica (Contracting authority headquarters).*

Aktivnost 4. Provedba tehnološke prilagodbe formulacije 4 na proizvodnoj liniji minimalno uključuje:

Activity 4. Implementation of technological adaptation of formulation number 4 on the production line includes minimum:

- Prilagodbu recepture⁷ u laboratoriju za optimalnu proizvodnju na proizvodnoj liniji – industrijski scale up proces. / *Adjustment of the recipe⁷ in the laboratory for optimal production on the production line - industrial scale up process.*
- Osiguranje adekvatnih sirovina za provedbu tehnološke probe na industrijskoj proizvodnoj liniji⁸ što *minimalno uključuje za tehnološku prilagodbu formulacije broj 4.:* proteini, ugljikohidrati i masti prikladni za formuliranje proizvoda za primjenu kod malnutricije i kod gubitka mase, snage i funkcije mišića. Vlakna, vitamini, minerali, aditivi, arome pogodni za hranu za posebne medicinske potrebe. / *Provision of a supply of an adequate raw materials for conducting a technological trial on the industrial production line⁸, which includes, at a*

⁷ Receptura i parametri tehnološkog procesa sa pilot postrojenja će biti dostavljeni odabranom Ponuditelju po potpisivanju Ugovora o izvršenju predmeta nabave / *The recipe and parameters of technological process from the pilot will be delivered to the selected Tenderer upon signing the Contract on the execution of the procurement subject.*

⁸ Vrstu, količinu i specifične karakteristike sirovina komunicirat će se Ponuditelju nakon odabira Ponuditelja te potpisivanja Ugovora o izvršenju predmeta nabave. / *The type, quantity and specific characteristics of the raw materials will be communicated to the Tenderer after the Tenderer has been selected and the Contract on the execution of the procurement has been signed*

minimum, the following for the technological adaptation of formulation trial number 4: proteins, carbohydrates and fats suitable for formulating products for use in malnutrition and loss of mass, strength and muscle function. Fibers, vitamins, minerals, additives, flavors suitable for food for special medical purposes.

- Provođenje tehnološke probe na industrijskoj proizvodnoj liniji uz aseptično punjenje u višeslojnu ambalažu zapremnine 200 do 250 ml, te u odgovarajuću zbirnu ambalažu koja štiti proizvode tijekom transporta i manipulacije. / [Conducting a technological trial on an industrial production line with aseptic filling into multi-layer packaging with a volume of 200 to 250 ml, and into appropriate collective packaging that protects the products during transport and manipulation.](#)
- Potrebna veličina jedne probe je jedna paleta (cca. 2000 kom) odnosno minimalna šarža proizvodnje kod koje se može optimalno odraditi proba na industrijskoj liniji. / [The required size of one trial is one pallet \(aprox.2000 pcs\) respectively the minimum production batch where the trial can be optimally performed on the industrial line.](#)
- Analiza kontrole kvalitete za tehnološku prilagodbu formulacije broj 4. uključuje provođenje procesnih analiza (potvrda sterilnosti proizvoda, fizikalno kemijske i organoleptičke sukladnosti) i dostava dokumentacije za otpuštanje probnih proizvoda. / [The quality control analysis for technological adaptation of formulation number 4 includes conducting process analyses \(confirmation of product sterility, physico-chemical and organoleptic conformity\) and delivery of documentation for the release of trial products.](#)
- Za tehnološku prilagodbu formulacije broj 4. planirane su analize sljedećih nutritivnih, kemijskih i mikrobioloških procesnih parametara: / [Analyses of the following nutritional, chemical and microbiological process parameters are planned for technological adaptation of formulation number 4:](#)

Nutritivne i kemijske analize / Nutritional and chemical analyses	Broj analiza / Number of analyses
Proteini / proteins (g)	1
Suha tvar/ Dry matter (°Bx ili/or %) ili/ or Vлага / moisture (g ili%)	1
Gustoća / density	1
Organolepika/ Organoleptic	1
pH/pH	1

Mikrobiološka analiza / Microbiological analyses	Broj analiza / Number of analyses
Test sterilnosti / Sterility test (na / on 30°C)	1
Test sterilnosti / Sterility test (na / on 55°C)	1

- Dostavu uzoraka sa tehnološke probe na industrijskoj proizvodnoj liniji u Koprivnicu (sjedište Naručitelja). / [Delivery of samples from the technological trial on industrial production line in Koprivnica \(headquarters of the Contracting authority\).](#)

- Dostavu izvještaja sa tehnološke prilagodbe u laboratoriju i provedene tehnološke probe na industrijskoj proizvodnoj liniji (rezultate analiza, tehničko izvješće o provedenim probama na industrijskoj liniji, sa osnovnim pogonskim parametrima i dijagramom tehnološkog procesa)) u Koprivnicu (sjedište Naručitelja). / Delivery of the report from the technological adjustment in the laboratory and conducted technological trial on production line (analysis results, technical report on the industrial line tests, with basic operating parameters and technological process diagram)) to Koprivnica (Contracting authority headquarters).

Zahtjevi definirani Prilogom 2. Tehničkim specifikacijama predstavljaju minimalne karakteristike odnosno standarde koje ponuđeni predmet nabave mora zadovoljavati.

The requirements defined in Annex 2. Technical specifications represent the minimum characteristics or standards that the offered procurement subject must meet.

Ponuditelj mora isporučiti predmet nabave na način kako je propisano Pozivom na dostavu ponuda te Prilogom 2. Tehničkim specifikacijama i ostalim priložima.

The Tenderer must deliver the procurement subject in the manner prescribed by the Call for proposals and Annex 2 Technical specifications and other annexes.