Warsaw, 13 June 2025
place and date

REQUEST FOR QUOTATION No. JODO/26/PR97811/2025
being conducted as a market assessment study

In connection with the implementation of the project titled "*Development and introduction to the medical market of the first non-antibiotic product in the treatment of infectious eye diseases – an innovative pharmaceutical form containing an antiseptic substance*" financed from the state budget from the Medical Research Agency, Zakłady Farmaceutyczne POLPHARMA S.A. requests for submission of bids for the **service consisting in the transfer of manufacturing technology, transfer of analytical procedures, manufacturing batches for the purposes of clinical and registration studies, as well as performance of stability studies of an innovative drug product (containing category OEB 3 antiseptic active substance) in the form of preservative-free eye drops.**

I. NAME AND ADDRESS OF THE CUSTOMER

Zakłady Farmaceutyczne POLPHARMA S.A.
ul. Pelplińska 19
83-200 Starogard Gdański

II. CONTRACT AWARD PROCEDURE

1. This contract is not subject to the provisions of the Public Procurement Law of 11 September 2019 (consolidated text: Journal of Laws of 2019, item 2019)
2. The procedure is being conducted as an intentional and cost-efficient market assessment study while respecting the following rules:
   1) to achieve the best possible outcomes using the allocated resources;
   2) to choose the best possible means and methods to meet the pre-defined objectives;
   3) to ensure transparency, fair competition and equal treatment of contractors.

III. DESCRIPTION OF THE SUBJECT OF CONTRACT

III.1. The subject of the Request is the **service consisting in the transfer of manufacturing technology, transfer of analytical procedures, manufacturing batches for the purposes of clinical and registration studies, as well as performance of stability studies of an innovative drug product (containing category OEB 3 antiseptic active substance) in the form of preservative-free eye drops.**

III.2. A detailed description of the subject of contract, which is attached as **Appendix 4** to the Request for Quotation, will be provided to the Contractor upon signing of the Confidential Disclosure Agreement **Appendix 3**. The Contractor should send the completed Confidential Disclosure Agreement in editable version via email to: andrzej.hoczyk@polpharma.com. After the receipt of the Confidential Disclosure Agreement, signatures by authorized person(s), in accordance with the rules of representation of the respective Contractor, will be collected via the DocuSign platform. **Appendix 4** will be made provided by the Customer to the Bidder within 2 business days of receipt of the Confidential Disclosure Agreement signed by the Bidder.

III.3. The Agreement must be completed and signed by a person authorized to represent the Bidder or having the appropriate power of attorney.

The Agreement should be accompanied by a power of attorney and/or a current excerpt from the relevant register confirming the authorization for representation.

III.4. All results of the services and intellectual property rights therein, industrial property rights, will be vested in the Customer. In the event that it is not possible to transfer all intellectual property rights for objective reasons, it is permissible to obtain/use a license granted for a minimum period until 2031, in a situation where the granting of a wider range of rights is not possible on objective grounds.

III.5. Any documentation produced in the performance of the service must be provided to the Customer at the expense of the Bidder.

III.6. CPV CODE: 73120000-9 – Research and development services

III.7. Scope of the Request:

III.7.1. Provision of starting materials (excipients) necessary for the manufacture of the product and the placebo conforming to the quality compliant with the European Pharmacopoeia (Ph. Eur.), API is provided by the Customer;

III.7.2. Performance of QC tests (including microbiological tests) for starting materials (API + excipient materials), verification of analytical procedures, issuance of CoA for excipient materials, API;

III.7.3. Provision of packaging materials (purchase of PE plastic for minims - 1 mL direct packaging) for packaging of the drug product, placebo; conforming to the quality compliant with the European Pharmacopoeia (Ph. Eur., for direct packaging materials) and/or conforming to the material specification, QC testing, verification of analytical procedures, issuance of CoA for packaging materials;

III.7.4. Purchase of aluminum foil for packaging of the product in sachet-type outer packaging, compliant with the material specification, QC testing, verification of analytical procedures, issuance of CoA for packaging materials;

III.7.5. Purchase of unit cartons for each validation/registration batch;

III.7.6. Reproduction of the product manufacturing technology on a laboratory scale to familiarize with the composition and the process - up to 3 batches technologically verified with a positive outcome;

III.7.7. Manufacture of up to 3 process/pilot batches of 50÷150 L (most preferred batch size), issuance of CoA;

III.7.8. Manufacture of up to 3 batches of 50÷150 L (most preferred batch size) for clinical trials, issuance of CoA;

III.7.9. Manufacture of the placebo up to 3 batches, issuance of CoA;

III.7.10. Transfer of analytical procedures of the drug product according to the Customer's Specification;

III.7.11. Verification of microbiological methods for the product, the placebo according to PH.EUR./ specification + sterility testing procedure;

III.7.12. Media fill and production line tests or justification for not testing;

III.7.13. Manufacture of 3 validation/registration batches of 50÷150L (most preferred batch size), issuance of CoA;

III.7.14. Preparation of a validation process protocol and summarizing the validation process in a report;

III.7.15. Conducting analyses related to validation of the manufacturing process;

III.7.16. Preparation of the drug product dossier in CTD format including the technology transfer, manufacturing process and validation of analytical procedures, and enabling submission of the registration dossier, support to CMO during the registration process as regards the development of sections 3.2.P.3 and 3.2.P.7;

III.7.17. Conduct of stability studies for registration batches (long-term test at 5°C ±3°C, in-use test);

III.7.18. Development of the Q3D risk analysis for the process and the manufactured product;

III.7.19. Development of the risk analysis (confirmed by tests) for nitrosamines;

III.8. The result from the work carried out will be to obtain a validated (ready for commercialization) process for manufacturing the finished drug product in the form of preservative-free eye drops containing an antiseptic active substance with proven 24-month stability.

III.9. Partial bids will not be accepted by the Customer. The service should be performed entirely by a single bidder due to the specifics of the subject of contract.

IV. PLACE AND DATE OF EXECUTION OF THE SUBJECT OF CONTRACT

IV.1. Time limit for execution of the subject of contract:

IV.1.1. Planned date of signing the Contract: August/September 2025.

1. **Planned start of service: October 2025.**
2. The term of the Contract performance must end no later than **30 months from the start of the study, no later than in 03.2028.**
3. **The date of transfer of the active substance (API) from the Customer to the Supplier shall be considered the time of commencement of the study.**
4. The results of the tests and the required documents (in electronic and paper form) generated in connection with the service provision must be delivered to the Customer's headquarters at the Contractor's expense.
5. The deadline constitutes a bid evaluation criterion and will be counted as the time from the start of the study until all final reports from the Audit are submitted to the Customer.

V. REQUIREMENTS FOR CONTRACTORS

V.1. The tender procedure is open to any Contractors who meet all of the following requirements:

V.1.1. The economic and financial situation of the Contractor is such that the Contractor is able to perform the subject of contract within the deadline and in line with the Contract, is not bankrupt, and no liquidation or recovery proceedings against the Contractor are pending.

Method of verification:
The Customer will accept that the Contractor has met the requirement if the Contractor submits a declaration of compliance with the requirements for participation in the tender procedure (Appendix 2 to the Request for Quotation).

V.1.2. The Contractor is authorized to carry out a specific business or activity:
- Good Manufacturing Practice (GMP) Certificate Bidder meets this requirement if it presents a GMP Certificate for the manufacture of the finished form of eye drops at its manufacturing site valid in the EU;

- Authorization to manufacture the product for research purposes and to release batches for research, issued in accordance with the requirements of Good Manufacturing Practice (GMP).

Method of verification:

The Customer will accept that the Bidder has met the requirement if the Bidder submits a declaration of compliance with the requirements for participation in the tender procedure ***(Appendix 2 to the Request for Quotation) and attaches to the bid the GMP Certificate for the manufacturing site, valid in the EU, covering the manufacturing of investigational products, including both the manufacturing process and the certification and testing of the product. It is also required to include an authorization to manufacture the investigational products and medicinal products in the scope of manufacturing sterile forms: manufacturing (sterilizing filtration), batch certification, primary and secondary packaging, Quality Control tests: microbiological tests for sterile forms, physicochemical tests.***

V.1.2. The Contractor has at least 5 years of experience in contract manufacturing of eye drop products.

- The Contractor has at least 5 years of experience in contract manufacturing of eye drop products

Method of verification:

*The Customer will accept that the Contractor has met this requirement if the Contractor submits a declaration of compliance with the requirements for participation in the tender procedure (**Appendix 2 to the Request for Quotation**). The Customer reserves the right to call on the Bidder to provide documents confirming compliance with this requirement.*

V.1.3. The Contractor has the necessary qualifications to properly execute the contract

As of the commencement of the service provision, the Contractor has specialists with at least 3 years of experience in contract manufacturing:

- at least 3 specialists qualified in technology transfer and process validation,
- at least 3 specialists in analytical and stability testing,
- at least 1 quality assurance specialist,
- at least 1 specialist in the preparation of GMP documentation.

Assessment of compliance with the requirement:

*The Customer will accept that the Contractor has met this requirement if the Contractor submits a declaration of compliance with the requirements for participation in the tender procedure (**Appendix 2 to the Request for Quotation**). The Customer reserves the right to call on the Bidder to provide documents confirming compliance with this requirement.*

V.1.4. As of the commencement of the service provision, the Contractor has technical and technological facilities to carry out technology transfer and process validation, analytical equipment to carry out transfer of analytical procedures, their validation and preparation of documents necessary for submission of the registration dossier.

Assessment of compliance with the requirement:

*The Customer will accept that the Bidder has met this requirement if the Bidder submits a declaration of compliance with the requirements for participation in the tender procedure (**Appendix 2 to the Request for Quotation**). The Customer reserves the right to call on the Bidder to provide documents confirming compliance with this requirement.*

V.2. The bids of Contractors who demonstrate compliance with the requirements will be admitted for examination and evaluation. Compliance with the above requirements will be evaluated based on a "meet/does not meet" basis. Bids submitted by Contractors who fail to meet any of the above requirements will be rejected.

V.3. Entities for which the following circumstances occur are also excluded from the tender procedure:

a) as described in Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract Support for the Aggression against Ukraine and to Protect National Security;

b) as described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine.

Method of verification of grounds/lack of grounds for exclusion:

*Verification will take place on the basis of the Bidder's declaration (**Appendix 1** to the Request).*

VI. PLACE AND DEADLINE FOR SUBMISSION OF BIDS

VI.1. The final deadline for submitting bids is **23/06/2025**
- in electronic format – as electronically signed documents or as a photocopy of signed document to the following address: andrzej.hoczyk@polpharma.com

VI.2. A bid will be considered to have been properly submitted if a complete bid is delivered to the above email address within the time limit stipulated in this section.

VI.3. No bids submitted past the submission deadline will be taken into consideration.

VII. CONTRACT AWARD CRITERIA

VII.1. The following criteria will be used by the Customer for the assessment of bids:
- total net price for the service - 60%,
- service execution time - 40%,

VII.2. The scoring of the bid will be calculated according to the following formula:

$$\boldsymbol{O_P = P_C + P_T}$$

where:

O_P	the bid score
P_C	the score for the criterion "Total net price"
P_T	the score for the criterion "Service execution time"

VII.3. The score (P_C) for the criterion "Total net price" will be calculated as follows:

$$P_C = \frac{C_N}{C_B} * 60\ points$$

where:

P_C	-	the score for the criterion "Total net price"
C_N	-	the lowest total net price based on non-rejected bids
C_B	-	total net price of the bid under evaluation

Bids with the price given in a currency other than PLN will be converted to PLN at the average exchange rate of the National Bank of Poland as at the final date for the submission of bids.

VII.4. The score (P_T) for the criterion "Service execution time" will be calculated as follows**:**

$$P_M = \frac{M_N}{M_B} * 40\ points$$

where:

P_M	-	the score for the criterion "Service execution time"
M_N	-	the shortest time of execution of the subject of contract based on non-rejected bids
M_B	-	the time declared in the bid for the execution of the subject of contract

The time for execution of the subject of contract should be expressed in months. Bids with the execution time of more than 30 months will be rejected.

VII.5. The maximum score that can be awarded to Bidder is 100 points. Calculations will be made to two decimal places.

VIII. PREPARATION OF BIDS

VIII.1. The Bidder should draw up one bid using the form attached as Appendix 1 hereto.
VIII.2. Partial bids will not be accepted by the Customer.
VIII.3. Bids may be modified or withdrawn prior to the end of the time limit for the submission of bids.
VIII.4. Bidders are required to carefully read the information contained in the Request for Quotation.
VIII.5. The costs of preparing and delivering bids will be borne by the respective Contractor.
VIII.6. For any matters related to this Request, please contact the Customer, email: andrzej.hoczyk@polpharma.com

IX. GENERAL PROVISIONS AND TERMS OF CONTRACT

IX.1. The Customer reserves the right to make material amendments to the Contract for the services offered as compared to the bid based on which the Contractor was awarded the contract, to the following extent and in the following situations:
IX.1.1. To reflect changes in law that affect the performance of the Contract (in particular changes in VAT rates);
IX.1.2. To improve technical parameters of the subject of the Contract resulting from updated solutions brought about by technological progress, without any impact on the gross flat rate;
IX.1.3. To extend the deadline for the performance of the Contract due to additional works which need to be carried out to ensure proper performance of the Contract and which the Customer, while exercising due diligence, could not have foreseen beforehand, subject to section IX.1.6 below;
IX.1.4. To extend the deadline for the performance of the Contract due to force majeure event(s), with any consequences of such an extension;
IX.1.5. To change the parameters of the subject of the Contract without altering the nature of the Contract – technology-related changes, in particular: the need to perform the Contract using other solutions – in terms of technology or materials – than those specified in the Request for Quotation in the event that the use of the original solutions could lead to non-performance or improper performance of the Contract, subject to section IX.1.7. below;
IX.1.6. To make changes with respect to additional deliveries or services to be provided by Contractor, which are not covered by the Contract, as long as they are necessary and when all of the following requirements are met:
– Contractor cannot be replaced due to economic or technical reasons, in particular relating to the interchangeability or interoperability of equipment, services or systems contracted under the original Contract,
– Contractor replacement could cause significant inconvenience or a material increase in costs for the Customer,
– Each subsequent change does not exceed 50% net of the original Contract net amount;
IX.1.7. To make changes without altering the nature of the Contract, when all of the following requirements are met:
– The Contract needs to be changed due to circumstances which could not have been foreseen by the Customer while exercising due diligence,
– The change does not exceed 50% of the original Contract net amount;

IX.1.8. To replace the Contractor with a new contractor:
– As a result of merger, division, transformation, bankruptcy, restructuring or purchase of Contractor or its enterprise as long as the new contractor meets the conditions for participating in the tender procedure, there are no grounds for its exclusion and the change does not result in other material amendments to the Contract,
– As a result of the Customer taking over Contractor's obligations towards its subcontractors;
IX.2. The Customer also allows for making non-material amendments to the concluded Contract in relation to the bid on the basis of which the Contractor was selected.
IX.3. Amendments to the Contract will be made in the form of annexes signed by both Parties and will require approval from the Customer.
IX.4. The Buyer requires other important parameters of the bid to be met:

- Payment term: a minimum of 30 days;
- Validity of the bid 90 days;

IX.5. Material Contractual Conditions:

IX.5.1. Inconsistencies or defects - In the event of any material inconsistencies or defects in the performance of the Services through the sole fault of the Supplier, the Supplier shall re-perform the Services at its own expense. Objections to the results should be reported to the Supplier by the Customer within fourteen (14) business days. The Customer will justify in detail any material inconsistencies and defects. Such work should be performed without delay, and the date for acceptance of services or materials specified in the corresponding Project Contract will be postponed accordingly. If the Supplier is unable to redeliver the Materials or re-perform the Services without such inconsistencies or defects, the Supplier will refund amounts paid for such services in the event of discovery of any inconsistencies or defects.
IX.5.2. Audit - The Customer reserves the right to audit the Supplier prior to or during the execution of the Contract.
IX.5.3. Contractual penalties - The Supplier will be required to pay contractual penalties for:

- postponement of the contract delivery deadline for each day of delay if the delay is not attributable to the Customer;
- improper performance of the Contract;
- incomplete performance of the Contract.

Detailed rules regarding contractual penalties, including but not limited to delay in contract delivery not attributable to the Customer, as well as improper or incomplete performance of the Contract, will be specified in the Master Contract concluded with the selected Supplier.

The Supplier consents to the deduction of contractual penalties directly from the payment of VAT invoice at the time of delivery.
IX.6. The Customer reserves the right to cancel the tender procedure without stating the reason.
IX.7. If the tender procedure is cancelled, suppliers will not be entitled to claim reimbursement of the costs of participating in the tender.
IX.8. When the Contractor was notified of the selection of its bid, withdrawal by the Customer from concluding the Contract may not be the basis for a claim for the costs incurred in participating in the tender.
IX.9. During the evaluation of the submitted bids, the Customer may request that the Contractors provide clarifications on the content of the documents submitted by them.
IX.10. If the bid does not contain all the required elements, the Customer may request the Contractor to supplement it.
IX.11. The Customer reserves the right to negotiate bids with the Contractor whose bid has the highest score, especially if the price offered by the Contractor exceeds the budget intended by the contracting

institution for the contract delivery. Negotiations may have several rounds, with the possibility to invite the bidder to submit an updated bid after each round of negotiations.

IX.13. The Customer provides for the possibility of changing the Contractor's remuneration depending on:

- changes in the acts regulating the rates of tax on goods and services and excise tax, the amount of the minimum wage and the amount of the minimum hourly rate, the rules for being subject and the rates of contributions to social security or health insurance, and the rules of collection and the amount of payments to employee equity plans; however, the change in remuneration will apply only to payments that have not yet been made on the date of amendment of the Contract,
- changes in the prices of materials or costs affecting the Contractor's remuneration, however, the manner of determining the change will be before contracting/signing of Contract with the Contractor.

The increase in remuneration may be due to increased costs of the performance of the Contract resulting from a possible unfavorable increase in the level of component costs related to the execution of the service, based on an objective index announced by the President of the Central Statistical Office or, in the situation of a bidder from outside Poland, the equivalent of such a body operating in the Bidder's country.

The valorization of remuneration requires the presentation of justification to the Customer including objective evidence, calculations confirming the increase in the aforementioned costs, and may not be carried out more than once a year. The valorization requires the consent of the Customer and will be implemented in the form of an annex to the Contract/Order. The parties will proceed to renegotiate the amount of remuneration specified in the Contract, while the target change in remuneration **may not exceed 3% with respect to the unit prices presented in the bid and subsequently included in the Contract.** A change in remuneration will require an annex, and failure to reach an agreement on this subject may be grounds for termination of the Contract by the Contractor.

IX.14. Regarding Subcontractors:

- The Customer allows subcontracting part or all of the subject of the Contract, including the entrustment of some or all of the work by the Contractor to subcontractors.

- The Contractor shall be fully responsible for the acts, omissions or failures of any subcontractor or their agents or employees as if they were the acts, omissions or failures of the Contractor.

- The Contractor shall pay all obligations to subcontractors in a timely manner. If all or part of the work is entrusted to a subcontractor, the Contractor shall make its own payment of the remuneration due to the subcontractor within the payment terms specified in the agreement with the subcontractor.

- The Contractor may enter into a subcontract agreement with the subcontractor for the performance of work performed under the Contract after approval of the subcontractor by the Customer.
- For this purpose it shall notify the subcontractor to the Customer in writing, including a specification of the scope of work entrusted to the notified subcontractor.

- The subcontractor shall transfer to the Contractor all copyrights and subsidiary rights to the design specifications in all known fields of exploitation, in particular those indicated in Article 50 of the Copyright Law.

X. ADDITIONAL INFORMATION

X.1. Any costs and expenses incurred in connection with the preparation and submission of bids are to be paid by the respective Bidders.

X.2. Until the end of the time limit for the submission of bids, the Customer reserves the right to amend or add new information to this Request for Quotation.

XI. LIST OF APPENDICES

The following appendices are attached to this Request:

Appendix number	Appendix title
Appendix 1	Bid form
Appendix 2	Declaration of compliance with the eligibility criteria for the participation in the Request for Quotation
Appendix 3	Confidential Disclosure Agreement Template
Appendix 4	Detailed description of the subject of the Request for Quotation

Appendix 1 to the Request for Quotation No. JODO/26/PR97811/2025

BID FORM

Bidder:

Full name (company) or first and last name	
Registered office/place of residence/address of the principal place of business	
Email address to which the Customer can send correspondence related to the tender procedure	
NIP [Taxpayer ID Number]:	
REGON [Statistical ID Number]	
Phone number	
Contact person for the Customer	

We offer to perform the contract as regards ***the service consisting in the transfer of manufacturing technology, transfer of analytical procedures, manufacturing batches for the purposes of clinical and registration studies, as well as performance of stability studies of an innovative drug product (containing category OEB 3 antiseptic active substance) in the form of preservative-free eye drops*** in accordance with the requirements of the Request for Quotation, at a **price:**

The service described in sections III.7.1 – III.7.19

Scope of service	**Net price**	**Gross price**	**Currency**	**Execution time (months)**
The service consisting in the transfer of manufacturing technology, transfer of analytical procedures, manufacturing batches for the purposes of clinical and registration studies, as well as performance of stability			PLN / EUR/ USD*	

studies of an innovative drug product (containing category OEB 3 antiseptic active substance) in the form of preservative-free eye drops.				
TOTAL **The net amount will be used for scoring in accordance with the provisions of section**			PLN / EUR/ USD*	**Total …….**
Invoice payment date **Minimum 30 (days)**	**…….. days**			

We also declare that:

a) The Bidder has read the tender procedure documentation and accepts the terms and conditions of the tender procedure,
b) The Bidder has received the information necessary to properly prepare the bid,
c) The subject of the bid is in full compliance with the description of the subject of contract and the other terms and conditions of the Request for Quotation,
d) The bid price includes compensation for all duties of the future Contractor necessary to deliver the contract,
e) The Bidder has no capital or personal ties with the Customer.
Capital or personal ties mean mutual ties between the Bidder and the Customer or persons authorized to contract obligations on behalf of the Customer, or persons performing on behalf of the Customer any actions involved in the preparation and performance of the Contractor award procedure, including in particular:
   - Participation in the company in the capacity of a partner in a civil law company or partnership,
   - Ownership of at least 10% of shares or stock, provided that a lower threshold is not mandated under legal regulations or specified by IZ PO,
   - Holding of a function of a member of a supervisory or management body, a commercial representative or an attorney,
   - Being married to or having lineal consanguinity or direct affinity, collateral consanguinity or affinity to the second degree to or being adopted by, under the guard or custody of the beneficiary or of such persons.
   - Remaining in cohabitation with the Bidder, its legal deputy or members of the management or supervisory bodies of the Bidder bidding for the contract,
   - Remaining with the Bidder in such a legal or factual relationship that there is reasonable doubt as to impartiality or independence in connection with the contract awarding procedure,
f) There are no circumstances with respect to the Bidder:
   - as described in Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract Support for the Aggression against Ukraine and to Protect National Security,

- as described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine,

g) The Bidder shall be deemed to be bound by the bid for a period of 90 days starting from the end date of the time limit for the submission of bids,

h) The Bidder consents to the processing of its personal data for the purposes necessary for the bid selection process, in accordance with the Act of 10 May 2018 on Personal Data Protection (Journal of Laws of 2018, item 1000) and in accordance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC,

i) Persons signing the Bid Form are authorized to submit a bid on behalf of the Bidder.

Also we represent, being aware of criminal responsibility, that the documents attached to the bid give a fair and true picture of the facts as at the day of submitting the bid (Article 233 of the Criminal Code).

……	……
(place and date)	(signature(s) of person(s) authorized to submit statements of will on behalf of the Bidder)

Appendix 2 to the Request for Quotation No.
JODO/26/PR97811/2025

DECLARATION ON MEETING CONDITIONS FOR PARTICIPATING IN THE REQUEST FOR QUOTATION

..... *(name of the Bidder)*

I/We represent that we meet the conditions for participation in the tender procedure as specified by the Customer in Part V of the Request for Quotation and relating to:

1) economic and financial situation,

2) technical or professional capacity,

The Bidder has the authority to perform the contract, i.e.

- Good Manufacturing Practice (GMP) Certificate Bidder meets this requirement if it presents a GMP Certificate for the manufacture of the finished form of eye drops at its manufacturing site valid in the EU;
- Authorization to manufacture the investigational products and medicinal products in the scope of manufacturing sterile forms: manufacturing (sterilizing filtration), batch certification, primary and secondary packaging, Quality Control tests: microbiological tests for sterile forms, physicochemical tests;
- product for research purposes and to release batches for research, issued in accordance with the requirements of Good Manufacturing Practice (GMP);
- Bidder has the technical potential understood as technical and technological facilities to carry out technology transfer and process validation, analytical equipment to carry out transfer of analytical procedures, their validation and preparation of documents necessary for submission of the registration dossier.

3) personnel capability,

- The Bidder, at the time of commencement of the service, has personnel with the necessary qualifications for the proper delivery of the contract:
  - specialists with at least 3 years of experience in contract manufacturing:
  - at least three specialists qualified in technology transfer and process validation,
  - at least three specialists in analytical and stability testing,
  - at least one quality assurance specialist,
  - at least one specialist in the preparation of GMP documentation,

4) experience.

- The Bidder has at least 5 years of experience in contract manufacturing of eye drop products,

Appendices to the Declaration:

a) ***Good Manufacturing Practice (GMP) Certificate Bidder meets this requirement if it presents a GMP Certificate for the manufacture of the finished form of eye drops at its manufacturing site valid in the EU;***
b) ***Authorization to manufacture the product for research purposes and to release batches for research, issued in accordance with the requirements of Good Manufacturing Practice (GMP)***

.....	.....
(place and date)	(signature(s) of person(s) authorized to submit statements of will on behalf of the Bidder)