

MINIMUM TECHNICAL REQUIREMENTS AND GENERAL CONDITIONS FOR THE INTERNATIONAL PROCUREMENT OF PHARMACEUTICAL PRODUCTS

1. DEPENDENCY REQUIRING THE PHARMACEUTICAL PRODUCT:

Central Supply of Strategic Goods (CEABE) of EsSalud, with legal address at Jr. Domingo Cueto No. 120, Jesús María – Lima – Peru.

2. PUBLIC PURPOSE OF THE PROCUREMENT OF THE PHARMACEUTICAL PRODUCT

EsSalud's international procurement procedures aim to provide timely supply, under the best quality and price conditions, of pharmaceutical products that are unavailable in the domestic market, or that lack therapeutic alternatives, or that lack sanitary registration, or that are due to declared urgent or emergency situations. Therefore, the purpose of this requirement is to strengthen care at all levels with a focus on primary care and emphasis on the first level.

STRATEGIC ACTIONS AND OBJECTIVES 2026-2030
Institutional Strategic Objective (OEI)
OEI OEI 1. To improve social health security through the efficient, equitable, and timely provision of health, economic, and social benefits for the benefit of insured members.

3. NAME OF THE REQUIREMENT:

International Contracting of Pharmaceutical Products **Delamanid 50 mg-TB**, for healthcare facilities within Essalud's Healthcare Networks.

Annex - A: Table of Items by Quantity.

- Name and technical specifications of the pharmaceutical product required by the Entity.

4. REQUIREMENTS:

4.1. Sanitary Registration, Sanitary Registration Certificate or valid Exceptional

Authorization, granted by DIGEMID ¹, management that will be carried out by CEABEESSALUD, prior to sending the information that will be sent by the non-domiciled supplier, in the language of origin where the pharmaceutical product is manufactured (include its translation into Spanish).

5. TECHNICAL REQUIREMENTS:

These must be certified with a simple copy, in the language of origin where the pharmaceutical product is manufactured, and a translation into Spanish must be attached.

¹ Authorization that will be managed by CEABE-ESSALUD



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5.1. Certificate of Good Manufacturing Practices (CBPM) or its equivalent

Valid Good Manufacturing Practices Certificate or equivalent document, issued by the competent authority of the country of origin, covering the area for the manufacture of the pharmaceutical product or type of product offered.

In the case of staged production, each of the laboratories and/or countries involved in the manufacture of the pharmaceutical product must present the Good Manufacturing Practices (GMP) Certification for each country.

In the event that the Certificate of Good Manufacturing Practices does not state an effective date, the date of issue must not be greater than two (02) years, counted from the date of submission of your offer.

5.2. The Certificate of Analysis of the finished pharmaceutical product (Analysis Protocol)

5.2.1. Technical report signed by the professional(s) responsible for quality control at the Manufacturing Laboratory.

5.2.2. The Certificate of Analysis must correspond to the batch or batches to be delivered.

5.2.3. The certificate of analysis must include at least the following information:

- Product name
- Pharmaceutical form
- Concentration of Active Pharmaceutical Ingredient(s)
- Batch number
- The analyses carried out on all its components
- The limits and results obtained in said analyses, in accordance with the requirements contemplated in the pharmacopoeia or methodology declared by the manufacturer.
- Expiration date
- Date of analysis
- The technical specifications and pharmacopoeia(ies) or the manufacturer's own technical specifications to which the manufacturer adheres.
- The signature(s) of the professional(s) responsible for quality control.

5.3. Own Analytical Methodology

If the analysis methodology used by the manufacturer is its own methodology or technical standard, it must attach them to comply with **section 7**, and if deemed necessary, it may present additional documentation, stating its version and validity.

5.4. CLV (certificate of free sale) or CPP (Pharmaceutical Product Certificate) or equivalent document

5.4.1. Issued by the competent authority of the country that manufactures the pharmaceutical product or the exporting country.



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5.4.2. The document must expressly state validity or will be considered valid if it is no older than two (02) years from its date of issue.

5.4.3. According to Supreme Decree No. 018-2019-SA of Peru, the following countries are considered to be under high health surveillance: France, the Netherlands, the United Kingdom, the United States, Canada, Japan, Switzerland, Germany, Spain, Italy, Belgium, Sweden, Norway, Australia, Denmark, Portugal, South Korea, Ireland, Hungary, and Austria. For this group of countries under high health surveillance, other countries with which Peru has signed agreements or mutual recognition agreements in force at the time of submitting the offer, such as the Pacific Alliance or the Andean Community (CAN), are exempt from this requirement.

5.5. Labeling and insert of the product offered

5.5.1. The bidder must submit labeling in Spanish for the intermediate and immediate packaging and insert of the finished product being offered, including warning information on the pharmaceutical product's use and storage.

5.5.2. The labeling of the immediate and intermediate packaging must be printed or adhered to said packaging in an **indelible, legible, and visible manner, without superimposing** any information corresponding to the pharmaceutical product.

5.5.3. The content of the labels on the immediate and intermediate containers must contain the information established in Articles 44, 45 and 48 of Supreme Decree No. 016-2011/SA.

5.5.4. Labels must contain the information that will be authorized in the Exceptional Authorization Document for Importation and Use for Public Health Situations.

5.6. Product Packaging

Product packaging must meet the following requirements:

5.6.1. New, sturdy boxes that guarantee integrity, order, preservation, transport, and proper storage. Boxes that are easy to count and stack, specifying the number of stackable boxes.

5.6.2. Properly labeled boxes indicating the name of the medication, concentration, pharmaceutical form, presentation, quantity, batch, expiration date, supplier's name, and storage and preservation specifications.

5.6.3. This information may be indicated on labels, in accordance with the Affidavit specifying the special storage and packaging conditions (Annex - B).

If the information is recorded in a language other than Spanish, you must submit a simple copy of the translation into Spanish, as appropriate.



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6. MINIMUM PRODUCT VALIDITY

The minimum validity of the pharmaceutical product must be equal to or greater than **eighteen (18) months**, at the time of its entry into Peru.

7. QUALITY CONTROL

7.1. The pharmaceutical product will be subject to quality control, with ESSALUD assuming the costs of the quality control service for each delivery, in accordance with current legislation and regulations and as established by the National Center for Quality Control (CNCC) of the National Institute of Health (INS) of the Ministry of Health (MINSa), as the authority of the authorized laboratories belonging to the National Network of Official Quality Control Laboratories.

7.2. For products from countries with high health surveillance, this condition will be excepted. According to Supreme Decree No. 016 - 2011 - SA and amendments (2011-2019), the following are categorized as high health surveillance countries (PAVS): France, the Netherlands, the United Kingdom, the United States, Canada, Japan, Switzerland, Germany, Spain, Australia, Denmark, Italy, Norway, Belgium and Sweden.

7.3. When the product is acquired through Cooperating Organizations (PAHO/WHO, UNICEF, UNFA, others) for the first time, only the first delivery to the country will be subject to control, with ESSALUD assuming the costs of the quality control service for each delivery, according to current legislation and regulations and as established by the National Center for Quality Control (CNCC) of the National Institute of Health (INS) of the Ministry of Health (MINSa), as the authority of the authorized Laboratories belonging to the National Network of Official Quality Control Laboratories.

7.4. The quantities of samples for quality control will be in accordance with **R.D N° 001-2020CNCC/INS**, which approves the General List of Critical Tests and quantities of samples for quality control.

7.5. The specifications of the required tests must correspond to the Certificate of Analysis or technical specifications, as authorized by the ANM.

7.6. Sampling:

7.6.1. ESSALUD must request the corresponding quality control from the Network laboratory when it has at least the total quantities agreed upon for the scheduled delivery for quality control. From this total, the batch (if more than one batch is submitted) from which the quality control laboratory will take samples for analysis will be randomly selected. The sampling results and the events related to the sample collection must be recorded in the Sampling Certificate; this must be signed by representatives of the quality control laboratory and the supplier; and it will be considered a mandatory requirement for delivery of the medication to the destination.



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7.6.2. The non-resident supplier must submit the following:

- Analysis protocol or protocol for the sampled batch(ies). Updated analytical technique or methodology for the finished medicine, as authorized by the ANM. In the case of proprietary methodology, the version and year of the methodology must be specified.
- The standard in sufficient quantity to reproduce three (03) times the identification and content tests of the active ingredient, as well as the secondary standard when applicable, quantity that will be used in case of confirmation of a non-compliant result.
- Standards, which must be valid for no less than six (06) months from sampling, indicating the lot number, expiration date, storage temperature, potency (indicating whether it is the active pharmaceutical ingredient in the form of base or salt) and other conditions specific to the medicine.
- Certificate of analysis of the standard. For secondary standards, their traceability to a primary standard must be indicated, indicating the lot number of the primary standard and the methodology used, where applicable.
- A document indicating the packing list, the box number containing the standard, and the technical documentation you are submitting.

7.6.3. Additional aspects to be considered in Quality Control:

- The units in the sampled lot represent the sampled sample (the total number of units in the sampled lots). A "COMPLIANT" quality control result is interpreted as the conformity of all units in the lots comprising the sampled sample. A "NONCOMPLIANT" quality control result means that the sampled sample does not meet the conformity requirement for quality control requested in this document, and none of the lots comprising the sampled sample may be distributed.
- In the event that a delivery is compliant for more than one batch and a "NONCOMPLIANT" quality control test report is obtained for the sampled batch, CEABEESALUD will immediately request a laboratory in the Network to perform quality control of the remaining batches, the costs of which will be borne by the supplier not domiciled in the country, and will also assume the replacement of non-compliant batches, within a maximum period of 60 days. In this case, only the batches that obtain the "COMPLIANT" quality control results will be included in the delivery.
- The sample size for quality control according to RD N°001-2020-CNCC/INS Sample Size Requirement Table of the National Center for Quality Control (CNCC) of the National Institute of Health (INS) of the Ministry of Health (MINSAs).



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8. DELIVERY TIMES

8.1. The service will be provided in a **SINGLE DELIVERY**:

8.1.1. SINGLE DELIVERY: Up to a maximum of thirty (30) calendar days, counted from the day after the purchase order is notified.

9. RECEIPT AND COMPLIANCE

9.1. Pharmaceutical products must meet the required and awarded specifications and comply with the storage and transportation conditions, as declared by the manufacturer of the contracted product.

9.2. The non-resident supplier must submit, prior to arrival in the country (electronically), the commercial and customs documentation in accordance with the requirements set forth in the regulations of the National Superintendence of Customs and Tax Administration - SUNAT, which will consist at least of:

9.2.1. Invoice (Commercial Invoice, detailing product, quantity, batches, presentation method, brand if applicable, manufacturer, origin of shipment, agreed incoterms, unit and total prices, shipping method and payment method).

9.2.2. Notice of Arrival

9.2.3. Packing List (Shipping list, with details of the batch or batches to be delivered and their expiration dates)

9.2.4. Certificate of Good Manufacturing Practices (CBPM) or its equivalent accepted in the technical evaluation of the requirement

9.2.5. Certificate of Analysis of the finished pharmaceutical product (Analysis Protocol) of the batch or batches to be delivered.

9.3. Reception and approval will be given by the Warehouse Manager (or whoever acts in his place).

9.4. If the pharmaceutical product is subject to quality control, the deadline for issuing the conformity will begin the day after the quality control result is obtained.

9.5. When applicable, compliance with technical specifications will be monitored by the Strategic Assets Estimation and Control Management, which will be represented by assigned personnel from the Pharmaceutical Products Needs Assessment and Control SubManagement or the Medical Devices and Equipment Needs Assessment and Control SubManagement, depending on the area that issued the request.

9.6. If there are any observations, a report detailing the observation must be issued, and the supplier will be given a mandatory deadline to make the necessary corrections.

9.7. In the event of unjustified delay by the contractor in the execution of the contract services, a late payment penalty will automatically be applied for each day of delay.



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10. PENALTIES FOR DELAYS²

Up to 10% of the contracted amount will be applied.

In the event of unjustified delay by the contractor in the execution of the services subject to the contract, the entity will automatically apply and calculate it according to the following formula:

$$\text{Daily penalty} = \frac{0.10 \times \text{benefit amount}}{F \times \text{term in days (of the benefit)}}$$

Where F has the value of 0.40 (PEN new soles)

Both the amount and the term refer, as appropriate, to the contract or item that should have been executed or, if these involve periodic execution obligations, to the partial performance that was the subject of the delay.

11. METHOD OF PAYMENT:

Payment will be made after receipt of the goods and approval of the service has been granted, unless, due to the nature of the service, payment is a condition for delivery of the goods.

The Entity may only make advance payments at the request of the non-resident supplier and upon presentation of a guarantee.

For the return of the guarantee, quality control and acceptance approvals must be provided.

12. WARRANTIES

To ensure the proper execution and fulfillment of the obligations assumed by the contracted non-resident supplier, advance payment guarantees must be considered. These guarantees must be backed by letters of credit or other international guarantee instruments. To this end, the following must be considered:

12.1. The entity will coordinate the issuance of the letter of credit, which must specify the agreed Incoterm. This letter will be valid throughout the purchasing process.

12.2. In cases of payment by letter of credit, the processing cost will be borne by agreement between the parties.

12.3. For advance payments, the non-domiciled supplier must provide a guarantee corresponding to one hundred percent (100%) of the amounts granted as an advance.

² General Management Directive No. 02-CEABE-ESSALUD-2019-V.01, approved by General Management Resolution No. 121-GC-ESSALUD-2019 (01/23/2019)



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13. NON-COMPLIANCE BY THE NON-RESIDENTIAL SUPPLIER

In the event of non-compliance by the non-resident supplier with the terms and conditions established for the delivery of the goods, they will be required to comply with their obligations by means of a simple letter notified via email, under penalty of cancellation and/or termination of the purchase order(s) for the required delivery.

If non-compliance persists, CEABE-ESSALUD will proceed to cancel and/or terminate the purchase order(s) for the required delivery, partially terminating the contractual relationship with the non-resident supplier regarding said delivery, provided that it is separable and independent.

14. PLACE OF DELIVERY

Deliveries of the contracted product will be made according to the quote, in accordance with the international terms agreed upon with Essalud (Incoterms). This must be indicated in the respective purchase order(s), under the following conditions:

14.1. The supplier assumes full responsibility for the quality of the product until delivery.

14.2. For delivery to the ESSALUD Central Warehouse, please contact the address at **Avenida El Sol No. 400, Constitutional Province of Callao, Peru.**

14.3. For delivery to the air/sea terminal; delivery will be in the primary zone of the customs territory in Peru.

14.4. In the case of sea transport, a period of no less than 10 days free of demurrage for containers must be considered.

ANNEXES

Annex – A Table of Requirements by Item

Annex – B Affidavit specifying the special storage and packaging conditions

Annex – C Affidavit specifying the presentation, size, material of the primary packaging, secondary packaging and image of the product.



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Annex – A

Item Requirement Table

No.	CODE SAP	DESCRIPTION	UNIT OF PRESENTATION	AMOUNT
1	10250334	DELAMANID 50 MG	TB	28,872



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Annex - B

Affidavit specifying the special storage and packaging conditions

Sirs

Selection Committee/Body in Charge of Hiring

Type of selection procedure No. [Enter procedure nomenclature] Present.

-

Dear Sir/Madam:

The undersigned, Mr. / Mrs., identified with Identity Document No..... Legal Representative of....., with RUC No..... I DECLARE UNDER OATH the information detailed below regarding the special storage and packaging conditions of:

ITEM NO.: NAME:

.....

1.....

2.....

3.....

4.....

[INSERT CITY AND DATE]

.....
Signature, Name and Surname of the bidder or Legal representative, as appropriate



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Annex – C

Affidavit specifying the presentation, size, material of the primary packaging, secondary packaging and image of the product.

Sirs

Selection Committee/Body in Charge of Hiring

Type of selection procedure No. [Enter procedure nomenclature] Present.

-

Dear Sir/Madam:

The undersigned, Mr. / Mrs., identified with Identity Document No..... Legal Representative of....., with RUC No..... I DECLARE UNDER OATH the information detailed below regarding the presentation, size, material of the primary packaging, secondary packaging and product image.

ITEM NO.: NAME:

.....

Presentation:	
Size (cm3):	
Primary packaging material:	
Secondary packaging material:	
Product image:	

[INSERT CITY AND DATE]