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In reply please
refer to: P5-447-3/DC/MG/1
Your reference:

Mr Rocío Mota Tapia
Laboratorios de Especialidades
Immunologicas S.A. de CV
Av. Gran Canal sin numero, locales 3 y 4 Col
Cascas Aleman Ampliacion
Alcaldia Gustavo A. Madero
Mexico City 07580
Mexique

16 February 2026

Dear Mr Mota Tapia,

**WHO Prequalification Unit (PQT) – Inspection Services Team (INS)
Closing of Inspection:
Laboratorios de Especialidades Immunologicas S.A. de CV (LEI)**

I refer to the inspection that was performed by the WHO World Health Organization (WHO) Prequalification Unit (PQT) Inspection Services Team (INS) and specifically Dr Dimitrios Catsoulacos and Ms Maria Santos Beade the details of which are outlined below:

Name: Laboratorios de Especialidades Immunologicas S.A. de CV (LEI)
Address: Av. Gran Canal sin numero, locales 3 y 4 Col, Cascas Aleman Ampliacion, Alcaldia
Gustavo A. Madero, Mexico City, 07580 Mexico
Date: from 22 to 23 September 2025

Thank you for your correspondence dated 29 November 2025 and 23 January 2026 and the corrective actions to the deficiencies listed in the inspection report. The actions taken, or proposed to be taken, to correct the deficiencies have been reviewed by PQT-INS.

As no significant deficiencies representing non-compliance were identified during the inspection, PQT-INS has confirmed that the Laboratory can be considered to be compliant with the standards of WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) published by the World Health Organization (WHO), for the scope of activities listed below:

Areas of expertise inspected and considered compliant with the standards of WHO GPPQCL		
Type of Analysis	Finished Products	Active Pharmaceutical Ingredients
Physical/ Chemical analysis	pH, Loss on Drying, Water Content, Disintegration Tests, Dissolution, Uniformity of Dosage Units	pH, Loss on Drying, Water Content, Disintegration Tests, Dissolution.
Identification	Chromatography (HPLC), Spectrophotometry (UV-Vis, FTIR) Basic tests (TLC)	Chromatography (HPLC), Spectrophotometry (UV-Vis, FTIR) Basic tests (TLC)
Assay, impurities and related substances	Chromatography (HPLC, TLC), Spectrophotometry (UV-Vis, FTIR), Volumetric titration.	Chromatography (HPLC, TLC), Spectrophotometry (UV-Vis, FTIR), Volumetric titration.

Based on the said conclusion, the prequalification of the laboratory can be finalized. Kindly be advised that the next step in the process is an agreement on the published information following which the prequalification of the laboratory by WHO will be declared through a separate letter/communication.

Yours sincerely,



Mr Mustapha Chafai
Team Lead, Inspection Services
Prequalification Unit
Regulation and Prequalification Department
Health Systems, Access and Data Division