

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Labesfal - Laboratórios Almiro S.A. submitted in 2018 an application for Magnesium Sulphate Labesfal 5000 mg/10 ml solution for injection ¹, (Sulfato de Magnésio Labesfal Solução Injectável 5000 mg/10 ml Solução injectável) (RH072) to be assessed with the aim of including Magnesium Sulphate Labesfal in the list of prequalified medicinal products for the treatment of reproductive health conditions in women on 19 June 2018.

Magnesium Sulphate Labesfal was assessed according to the ‘Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies’ by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

Based on the data submitted the team of assessors advised that Magnesium Sulphate Labesfal is included in the list of prequalified medicinal products. Magnesium Sulphate Labesfal was listed on 19 June 2018.

Magnesium Sulphate Labesfal ‘s conformance to the requirements of the current SRA guideline was re-evaluated by the team of WHO assessors.

2. Steps taken in the re-evaluation of the product

August 2024	WHO letter of request for requalification was sent to the applicant.
December 2025	The application letter was received.
December 2025	The assessment team reviewed the submitted data and further information was requested
December 2025	The applicant’s response letter was received.
January 2026	The submitted data were reviewed and found to comply with the relevant WHO requirements.
27 January 2026	Requirements of requalification were met. Sulfato de Magnésio Labesfal Solução Injectável 5000 mg/10 ml Solução injectável remained on the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>

¹ Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority’s responsibility. Throughout this WHOPAR the proprietary name is given as an example only.