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UNSATISFACTORY RESULTS

Suspended batch of magnesium sulphate from Samtec

Laboratory identified unsatisfactory results in the appearance assays, in addition to foreign body in the solution and leakage in the ampoule.

By: Ascom / Anvisa

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The Agency ruled on Monday (7/7) the ban (<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=1&pagina=45&data=17/07/2017>) on the specific medicine Magnesium Sulphate 100 mg / ml solution for injection, 10 ml ampoule, MFA 08/2018, manufactured by the company Samtec Biotecnologia Ltda.

The Agency received a Report of Fiscal Analysis from the Central Laboratory of Public Health of Paraná (Lacen / PR), which presented unsatisfactory results in the aspect tests for the product in question. In addition, the test detected the presence of foreign body in solution and leakage in the ampoule.

The **aspect assay** evaluates the medicine and the packaging to see if the visual characteristics and the appearance of the product conform to the quality standard.

Specific medicinal products are prophylactic, curative or palliative pharmaceutical products which do not fall under the categories of new, generic, similar, biological, herbal or notified medicinal product and whose active substance (s), regardless of nature or origin, do not Is eligible for a bioequivalence test with respect to a comparator product.

Learn more about different types of medications (<http://portal.anvisa.gov.br/conceitos-e-definicoes7>) .

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