

Steps taken following Prequalification of Magnesium sulfate-Kalceks 500 mg/ml solution for injection, BP*:

Changes	WHOPAR parts affected	Accepted on
Change in the shelf-life of the FPP involving extension	4	02 November 2017
Change in the shelf-life of the FPP involving extension	4	10 January 2019
Change in address of FPP batch release site	3	31 July 2019
Change in the shelf-life of the FPP involving	4	06 January 2021
Change in the address of the FPP supplier	3, 4, 5	08 April 2022
Addition of FPP manufacturing site	3	03 May 2022

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the Proprietary Name is given as an example only.

