

Scharlab S.L.

Crtra.Polinya a Sentmenat, Km 8,2 08181 Sentmenat

\(+34937456400

CERTIFICATE OF ANALYSIS

Product Magnesium sulfate heptahydrate, Pharmpur®, Ph Eur, BP, USP		Batch 20774001	
MA0084		Quality release date 28/04/2020	
		Expiry date 04/2025	
Analysis	Batch value	Specifications	
Assay (Complexometric, referred to dried sample)	100,49 %	99,0 - 100,5	
Assay (Complexometric, on ignited substance)	99,36 %	99,0 - 100,5	
Identification	passes test	passes test	
Appearance of solution	clear and colourless	clear and colourless	
pH (5 %, H2O)	6,52	5,0 - 9,2	
Acidity or alkalinity	passes test	passes test	
Chlorides (CI)	< 0,0140 %	≤ 0,014	
Arsenic (As)	< 2 ppm	≤ 2	
Iron (Fe)	< 20 ppm	≤ 20	
Selenium (Se) ppm	< 30 ppm	≤ 30	
Loss on drying	51,17 %	48,0 - 52,0	

Elemental impurities are analysed according to guideline CHMP/ICH/353369/2013.

Residual solvents are analysed according to guideline CPMP/ICH/283/95.

This product is intended to be suitable for the manufacture of pharmaceuticals, medical devices, cosmetics and food products, but is entirely under the user's responsibility.