



Certificado de Analisis

Referencia:	Factura No. 17550142 / 5502989 // 18.06.2017 Ref.: PC 00026066-1
Producto:	METAMIZOL MAGNESICO
Cantidad:	2.400 KG
Batch-Nr.:	B091
Certificado(s) segun anexo	
ANDENEX-CHEMIE Engelhard + Partner GmbH	



SANOFI

Certificate of Analysis

Andenex-Chemie
Engelhard & Partner GmbH
Albert-Einstein-Ring 11
22761 Hamburg
Germany

Hoechst AG
Hoechst Marion Roussel
Deutschland GmbH
Aventis Pharma Deutschland GmbH
Sanofi-Aventis Deutschland GmbH
Industriepark Hoechst
65926 Frankfurt am Main
phone: +49 (0)180 / 2 222010

Customer-No.: 125948
Delivery-No.: 38792106

Metamizol Magnesium 25 Kg Material: 160009 Batch: B091
GMID: 183737
Date of manufacturing: 26.Feb.2017 Expiry date.: 25.Feb.2020

Test item	Result	Specification
Appearance	corresponds	crystalline powder, white to nearly white
IR spectrum	corresponds to reference standard	spectrum (sample) = spectrum (standard)
Magnesium	corresponds	corresponds to identification reaction
Appearance of solution (clarity), (water)	clear	clear, not more opalescent than reference suspen- sion I (Ph.Eur.)

This certificate of analysis was issued electronically



SANOFI

Certificate of Analysis

Customer-No.: 125948
Delivery-No.: 38792106

Metamizol Magnesium 25 Kg

Material: 160009

Batch: B091

GMID: 183737

Date of manufacturing: 26.Feb.2017

Expiry date.: 25.Feb.2020

Test item	Result	Specification
Appearance of solution (colour), (water)	greenish yellow GY7	not more intensely coloured than reference solution GY5 (Ph.Eur.)
pH	7,2	7,0 - 7,5
Acidity or alkalinity corresponds		corresponds to limit test
Absorbance	0,03	<= 0,13
Measured at wavelength	405 nanometer	
Further by-products, each (LC)	< 0,1 per cent	<= 0,2 per cent
Greatest unknown by-product (LC)	< 0,03 per cent	<= 0,05 per cent
Further by-products, sum [excluding 4-Methylaminoantipyrine], (LC)	< 0,1 per cent	<= 0,2 per cent
4-Methylaminoantipyrine (LC)	< 0,1 per cent	<= 0,5 per cent
Residual solvents (GC)	corresponds (tested on a regular basis)	Ethanol <= 5000 ppm

This certificate of analysis was issued electronically



SANOFI

Certificate of Analysis

Customer-No.: 125948
Delivery-No.: 38792106

Metamizol Magnesium 25 Kg Material: 160009 Batch: B091
GMID: 183737
Date of manufacturing: 26.Feb.2017 Expiry date.: 25.Feb.2020

Test item Result	Specification
Sulphates < 0,1 per cent	<= 0,1 per cent
Heavy metals < 20 µg/g	<= 20 µg/g
Content of water 14,7 per cent	13,5 - 15,5 per cent
Magnesium 3,22 per cent	3,15 - 3,30 per cent
Metamizole magnesium (Titr.) calculated with reference to anhydrous substance 100,1 per cent	98,5 - 101,0 per cent
Sieve analysis <= 90 µm 37 per cent	<= 60 per cent
Sieve analysis <= 1000 µm 100 per cent	>= 99 per cent
Regulatory restrictions apply Not for Poland.	

This certificate of analysis was issued electronically



SANOFI

Certificate of Analysis

Customer-No.:	125948
Delivery-No.:	38792106

Metamizol Magnesium 25 Kg	Material: 160009	Batch: B091
	GMID: 183737	
	Date of manufacturing: 26.Feb.2017	Expiry date.: 25.Feb.2020

COMPLIES to the requirements.

Data on stability and shelf-life only apply under appropriate conditions of storage.

Produced by Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany in accordance with the principles of Good Manufacturing Practices as detailed in ICH Q7 Guideline

I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

batch technically released and electronically signed by

Kathrin Ladwein

14.Mar.2017 12:57

Release authorized by Product Responsible Manager respectively Qualified Person
Dr. C. Bongards

This certificate of analysis was issued electronically