

**Certificado de Analisis**

Referencia: **Factura No. 12550245 / 5501995 // 27.10.2012**  
**Ref.: PC00008373-1**

Producto: **METAMIZOL MAGNESICO**

Cantidad: 1.000 KG

Batch-Nr.: A048  
A049

**Certificado(s) segun anexo**



# 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

65926 Frankfurt am Main  
phone: +49 (0)180 / 2 222010

Customer-No.: 125948  
Delivery-No.: 37485210

Metamizol Magnesium 25 Kg

Material: 160009

Batch: A049

GMID: 183737

Date of manufacturing: 15.Mar.2012 Expiry date: 13.Mar.2017

Test item	Method	Specification
Result		
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.)



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**Customer-No.:** 125948  
**Delivery-No.:** 37374693

Metamizol Magnesium 25 Kg      **Material:** 160009      **Batch:** A048  
**GMID:** 183737  
**Date of manufacturing:** 09.Feb.2012      **Expiry date:** 06.Feb.2017

Test item	Method	Specification
Result		
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.)



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## Certificate of Analysis

Customer-No.: 125948  
Delivery-No.: 37374693

Metamizol Magnesium 25 Kg

Material: 160009

Batch: A048

GMID: 183737

Date of manufacturing: 09.Feb.2012

Expiry date: 06.Feb.2017

Test item Result	Method	Specification
Appearance of solution (colour), (water)		
colourless		not more intensely coloured than reference solution GY5 (Ph.Eur.)
pH 7,3		7,0 - 7,5
Acidity or alkalinity corresponds		corresponds to limit test
Absorbance 0,01		$\leq 0,13$
Measured at wavelength 405 nanometer		
Further by-products, each (LC) < 0,1 per cent		$\leq 0,2$ per cent
Greatest unknown by-product (LC) < 0,03 per cent		$\leq 0,05$ per cent
Further by-products, sum [excluding 4-Methylaminoantipyrine], (LC)		
< 0,1 per cent		$\leq 0,2$ per cent
4-Methylaminoantipyrine (LC) < 0,1 per cent		$\leq 0,5$ per cent



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Metamizol Magnesium 25 Kg

Material: 160009

Batch: A048

GMID: 183737

Date of manufacturing: 09.Feb.2012 Expiry date: 06.Feb.2017

Test item Result	Method	Specification
Residual solvents (GC) corresponds (tested on a regular basis)		Ethanol <= 5000 ppm
Sulphates < 0,1 per cent		<= 0,1 per cent
Heavy metals < 20 µg/g		<= 20 µg/g
Content of water 14,5 per cent		13,5 - 15,5 per cent
Magnesium 3,21 per cent		3,15 - 3,30 per cent
Metamizole magnesium (Titr.) calculated with reference to anhydrous substance		
100,4 per cent		98,5 - 101,0 per cent
Sieve analysis <= 90 µm 39 per cent		<= 60 per cent
Sieve analysis <= 1000 µm 100 per cent		>= 99 per cent



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Customer-No.:	125948
Delivery-No.:	37374693

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Metamizol Magnesium 25 Kg	Material: 160009	Batch: A048
	GMID: 183737	
	Date of manufacturing: 09.Feb.2012	Expiry date: 06.Feb.2017

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**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.

released and electronically signed by

Robert Braunsdorf

05.Mar.2012 13:23

Product Responsible Manager respectively Qualified Person

Dr. R. Braunsdorf