CoA API pour Vladik C.
(Metamizol)

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Certificate of Analysis

Andenex-Chemie
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Industriepark Hoechst
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Customer-No.: 125948
Delivery-No.: 38806829

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 suspension I (Ph.Eur.)

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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

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Metamizol Magnesium 25 Kg

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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.	

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	GMID: 183737	
	Date of manufacturing: 26.Feb.2017	**Expiry date.:** 25.Feb.2020

C O M P L I E S 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