

**CERTIFICATE OF ANALYSIS**

Material No: **291836**  
**Morphine sulphate**  
Ph.Eur.

Lot No : **0645H018**  
CAS No: 64-31-3  
Formula: C<sub>34</sub>H<sub>40</sub>N<sub>2</sub>O<sub>10</sub>S · 5 H<sub>2</sub>O  
Mol weight: 758.8

Manufacturing date: Nov/2006  
Retest date: Nov/2008  
Actual specification: 07/25/2006

<b>Test</b>	<b>Specification</b>	<b>Result</b>
Description	white or almost white, crystalline powder	conforms
Assay (Non-aqu. titr.)	98.0 to 102.0 % (calculated on the anhydrous basis)	100.0 %
IR-Spectrum	in accordance with the reference spectrum	conforms
Identity	sulphate positive	conforms
Water (KF)	10.4 to 13.4 %	11.93 %
Sulphated ash	not more than 0.1 %	0.01 %
Clarity of solution	not more than 3 FTU; clear (2 % m/V in water)	1.7 FTU
Colour of solution	6 to 7 on scale Y or BY (2 % m/V in water)	7
Specific rotation	-110 to -107 ° (2 % m/V in water) (calculated on the anhydrous basis)	-108.8 °
Acidity or alkalinity	not more than 0.2 ml 0.02 M NaOH or 0.02 M HCl / 0.2 g	0.15 ml
Iron	not more than 5 ppm	<5.0 ppm
Related substances (HPLC)	not more than 0.4 % 2,2'-bimorphine	<0.050 %
Related substances (HPLC)	not more than 0.2 % oripavine	<0.050 %
Related substances (HPLC)	not more than 0.2 % codeine	<0.050 %
Related substances (HPLC)	not more than 0.2 % (10R)-10-hydroxymorphine	0.08 %
Related substances (HPLC)	not more than 0.10 % greatest unknown impurity (no unknown impurity greater than 0.10 %)	<0.050 %
Related substances (HPLC)	not more than 1.0 % sum of impurities	0.08 %
Residual solvents/ OVI	conformity to CPMP ICH 283/95 and USP test <467>	conforms
Residual solvent	not more than 0.5 % ethanol	0.08 %

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Release Comment: Meets specification

Released on: 02/14/2007  
Siegfried Ltd  
Released by: A. Studer  
Quality Assurance

This certificate of analysis is signed electronically.  
It has been created automatically by the validated Siegfried Laboratory Information Management System (LIMS).

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