


## Typical COA form: bulk product

Lipomed's bulk standards are certified for purity and identity.

## Certificate of Analysis includes both Specifications and Quality Control results.



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**Specifications and Certificate of Analysis**

Lipomed Document: QC-CA-35HC      Supersedes: 004-19.Nov.2007  
Version 005-15.Sep.2008

Chemical name:	<b>Morphine.HCl</b> 4,5- $\alpha$ -Epoxy-17-methylmorphinan-3,5- $\alpha$ -diol.hydrochloride	
CAS Registry Nr:	6055-06-7	
Chemical formula:	C <sub>17</sub> H <sub>19</sub> NO <sub>5</sub> Hydrochloride – 2.92 Hydrate	Molwt: 285.35 374.41
Lot No: 35.180.2 Art. Nr. M-35-HC		Release date: 16.07.2009 Retest date: July 2014

TEST	SPECIFICATIONS	RESULTS
1. Appearance	white to off-white crystalline powder	conforms
2. Identity	IR: in nanopure water UV: $\lambda_{max}$ = 285.0 $\pm$ 1.0 nm $\epsilon_{max}$ = 1200 $\pm$ 300 Melting point: > 290 °C	IR corresponds UV: in nanopure water $\lambda_{max}$ = 284.8 nm $\epsilon_{max}$ = 1151
3. Purity <small>The purity is calculated from the distribution of 6 HPLC analyses with a 95% level of confidence.</small>	HPLC > 98.5 %	99.850 $\pm$ 0.050 %
4. Optical rotation	$[\alpha]_D^{25}$ = - 226 $\pm$ 3° (corrected for content, c = 2.0 in water)	$[\alpha]_D^{25}$ = - 227.9° (corrected for content, c = 2.0 in water)
5. Free base content <small>(Corrected from purity and water)</small>	> 67.3 %	74.6 %
6. Water content <small>Karl Fischer &lt; 20 %</small>		14.0 %
7. Calculated hydrochloride content		9.74 %

**FOR ANALYTICAL PURPOSES ONLY: NOT FOR HUMAN USE!**  
The material should be stored at +2 to +8 °C in a dry and cool area in a closed container. Lipomed certifies that the identity and chemical purity of this reference standard is based on exhaustive analytical tests. Gravimetric preparation of this bulk standard is ensured by using balances calibrated with IAC-MRA traceable weights.

QC - Officer: Deputy: Dr. L. Prévot

Date sign: Ariesheim,  
July 16, 2009

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Lot and product numbers

Purity determined by HPLC and/or GC

Storage recommendations

Batch validity expressed as retest date

Free base content corrected from purity and water content

Gravimetric preparations are ensured by using balances calibrated with IAC-MRA traceable weights