

## Certificate of Analysis

Product: **T61 1x50ml 720**  
Batch: **A219A01**



Country: **Romania**  
Sales Order Number: **1103988583 / 10**  
Delivery Number: **1204984912 / 900001**

Material Number:  
**038615**  
Type of Container: **Vial**  
Package Size: **50 ML**  
Manufacturing Date: **19-Aug-2015**  
Expiry Date: **Jul-2018**  
Storage Conditions:  
**Below 25°C**

### CERTIFICATION BY THE MANUFACTURER

I herewith certify that the presented information is authentic and accurate. All measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended. This batch has been manufactured /fabricated (incl. APIs and intermediates if applicable) including packaging and quality control, 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.

Name:  
Function:  
Date:  
Signature:

**This document has been  
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and is valid without signature**

Anke Andres, Qualified Person

# Certificate of Analysis

Product: **T61 1x50ml 720**

Batch: **A219A01**

## Results of Analysis

Test	Method	Specification	Result
Characters - Color	Visual Examination	Colorless or Yellowish	Complies
Characters - Physical State	Visual Examination	Liquid	Complies
Characters - Clarity	Visual Examination	Clear	Complies
Identification Mebezonium Iodide	TLC	Rf of the Corresponding Spots Comply	Complies
Identification Mebezonium Iodide	Chemical Reaction	Complies	Complies
Identification Embutramide	HPLC	Rt of the Corresponding Peaks Comply	Complies
Identification Embutramide	UV-Spectrum with HPLC-PDA	PDA Spect.of the Correspond.Peaks Comply	Complies
Identification Tetracaine Hydrochloride	HPLC	Rt of the Corresponding Peaks Comply	Complies
Identification Tetracaine Hydrochloride	UV-Spectrum with HPLC-PDA	PDA Spect.of the Correspond.Peaks Comply	Complies
Relative Density (20 °C)	Ph. Eur. 2.2.5.	1.020 - 1.030	1.027
pH	Ph. Eur. 2.2.3	5.5 - 7.0	6.5
Assay Mebezonium Iodide	TLC	47.5 - 52.5 mg/mL	49.7 mg/mL
Assay Embutramide	HPLC	190 - 210 mg/mL	203 mg/mL
Assay Tetracaine Hydrochloride	HPLC	4.75 - 5.25 mg/mL	5.01 mg/mL

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