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LUSOCHIMICA

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QUALITY CONTROL MANAGER
FR 04106118

# CERTIFICATE OF ANALYSIS

Certificate N.: 279/19 — Issue n° 19 of 10/01/2019

Product: **DILTIAZEM HYDROCHLORIDE** — Batch: **DIL 219** — Batch size: 612.100kg

Conforms to: Ph. Eur. 9th ed. - Lusochimica specifications Issue N° 23 of January 10, 2019;
Code: 25 — effective from: 10/01/2019
Manufacturing date: January 2019 — Retest date: January 2024

DESCRIPTION AND SOLUBILITY
White or almost white crystalline powder.
Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol .

| TESTS | RESULTS | SPECIFICATIONS |
|---|---|---|
| Description | corresponds | corresponding |
| Identification | | |
| - IR | corresponds | corresponding |
| - Chloride reaction | positive | positive |
| Melting point | 211°-212° with decomposition | about 213°C with decomposition |
| Appearance of solution | | |
| - Clarity | clear | clear |
| - Colour | colourless | colourless |
| pH | 5.2 | 4.3 to 5.3 |
| Specific optical rotation (dried substance) | +116° | + 115° to + 120° |
| Related substances: | | |
| - Impurity F | 0.1% | not more than 0.3% |
| - Impurity E | less than 0.05% (DL) | not more than 0.10% |
| - Each unknown impurity | less than 0.05% (DL) | not more than 0.10% |
| - Total of related substances | 0.1% | not more than 0.3% |
| Loss on drying | 0.2% | not more than 0.5% |
| Sulphated ash | less than 0.1% | not more than 0.1% |
| Assay (on dried substances): | | |
| - potentiometric | 100.2% | 98.5% to 101.0% |
| ADDITIONAL TESTS: | | |
| Residual solvents (HS-GLC) | | |
| - Butanol | 346 ppm | not more than 1000 ppm |
| - Acetone | 26 ppm | not more than 300 ppm |
| - Toluene | less than 0.5 ppm (DL) | not more than 50 ppm |
| - N,N-dimethylformamide | less than 90 ppm (DL) | not more than 800 ppm |

Residual solvent content complies to current USP <467> and ICH Q3C.

MANUFACTURING SITE: Lusochimica S.p.A. Lomagna (LC) ITALY

NOTES: store in tight, light-resistant container.

APPROVED BY Q.C. MANAGER — Date 12/04/2019

I declare that the product is manufactured in accordance with the guidelines on Good Manufacturing Practice for Active substances.

RELEASED BY Q.P. — Release date: 18/04/19

Fecha Entrada: 02-07-2019
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