

Certificate of analysis



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|-----------------|-------------|--------------------------|---------|
| Article | 5575 | Sotalolhydrochlorid, API | |
| Synonym | | Sotaloli hydrochloridum | |
| Synonym | | | |
| Batch | 21001470 | | |
| Specification | Ph.Eur.10.0 | | |
| Production date | 11.2019 | Retest date | 10.2024 |

| Test | Specification | Result |
|-------------------------------------|----------------------------|-----------|
| Characters | According to specification | Complies |
| Appearance | According to specification | Complies |
| Solubility | According to specification | Complies |
| Identification | According to specification | Complies |
| IR spectrophotometry | According to specification | Complies |
| Chloride | According to specification | Complies |
| Tests | According to specification | Complies |
| Appearance of solution | According to specification | Complies |
| pH-Value | 4,0 ... 5,0 | 4,8 |
| Optical rotation | -0,10 ... 0,10 | -0,01 ° |
| Related substances | According to specification | Complies |
| Impurity B | Max. 0,1 % | < 0,1 % |
| Any other impurity | Max. 0,1 % | < 0,1 % |
| Total of all impurities | Max. 0,5 % | < 0,1 % |
| Palladium | Max. 0,5 ppm | < 0,5 ppm |
| Loss on drying | Max. 0,5 % | 0,2 % |
| Sulphated ash | Max. 0,1 % | 0,0 % |
| Assay | 99,0 ... 101,0 % | 100,9 % |
| Correction factor weighing (f, NRF) | | 0,993 |
| Complies specification | | Yes |

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| | | | |
|----------------------|--|-------------|----------------------------|
| Release date | 23.04.2021 | Released by | Frau Dr. Haßel, QP, LQK |
| Manufacturer | M/s. Neuland Laboratories Ltd.; Unit-I | | |
| Manufacturer batch | SHI1119112 | | |
| Manufacturer street | Temple Road, Gummadidala Mandal | | |
| Manufacturer city | 502313 Sangareddy Distict, Telangana | | |
| Manufacturer country | Indien | | |

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 21001470 complies specification.

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