

Certification of Substances Department

Certificate of suitability No. CEP 2010-138 - Rev 01

1 *Name of the substance:*

2 **METOPROLOL TARTRATE**

3 *Details of holder:*

4 **MICROSIN S.R.L.**

5 Str. Pericle Papahagi no. 51-63

6 Romania-032364 Bucharest

7 SPOR ORG ID: 100020983

8 SPOR LOC ID: 100029693

9 After examination of the information provided on the production method and control strategy for the
10 substance, we certify that its quality is suitably controlled by the current version of the European
11 Pharmacopoeia monograph for **METOPROLOL TARTRATE** No. 1028 and any supplementary tests
12 deemed necessary which are mentioned below. The approved site(s) of production and any
13 supplementary test procedure(s) are included on the following pages as annexes, which constitute
14 an integral part of this certificate.

15 – Test for the following impurity by liquid chromatography (Annex 2)
16 *N*-nitrosometoprolol not more than 0.5 ppm

17 – Test for residual solvents by gas chromatography (Annex 3)
18 Isopropanol not more than 500 ppm
19 Toluene not more than 200 ppm

20 No elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of the
21 substance.

22 The re-test period of the substance is 5 years if stored in double polyethylene bags, placed in a
23 carton drum.

24 No material of human or animal origin is used in the production of the substance.

25 The holder of the certificate should fulfil the following conditions in order to maintain the validity of
26 this certificate.

27 The dossier submitted must be updated in accordance with EDQM guidance on the requirements
28 for revision of certificates of suitability.

29 Production of the substance shall take place in accordance with the dossier submitted and Good
30 Manufacturing Practice.

31 Necessary information from the submitted dossier shall be shared with authorised users in order
32 to enable them to evaluate the suitability of this substance for its intended use. This includes
33 informing them of any relevant change in the associated dossier.

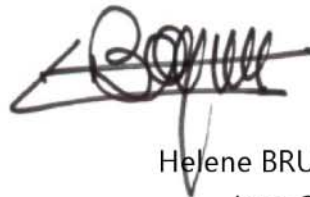
34 Failure to comply with any of these provisions will render this certificate void.

35 This certificate is granted within the framework of Resolution AP-CSP (07) 1 adopted by the Council
36 of Europe Public Health Committee (Partial Agreement) (CD-P-SP) in February 2007. With regard
37 to its use in the member states of the European Union/European Economic Area, it is granted in
38 accordance with the provisions of Directive 2001/83/EC and Regulation (EU) 2019/6 as amended,
39 and the related guidelines.

40 This certificate is valid from 21 June 2024.

On behalf of the
Director of EDQM

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A handwritten signature in black ink, appearing to read 'H. Bruguera', with a long horizontal stroke extending to the left.

Helene BRUGUERA
June 21, 2024