

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2006-171 - Rev 03

1 *Name of the substance:*
2 **CHLORHEXIDINE DIGLUCONATE SOLUTION**

3 *Name of holder:*
4 **R.N. LABORATORIES**
5 404 VIP Plaza, Off Link Road
6 Andheri W
7 India-400 053 Mumbai

8 *Site(s) of production:*
9 **SEE ANNEX 1**

10 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
11 **R1-CEP 2006-171 - REV 02**

12 After examination of the information provided on the manufacturing method and subsequent
13 processes (including purification) for this substance on the site(s) of production listed in annex, we
14 certify that the quality of the substance is suitably controlled by the current version of the
15 monograph **CHLORHEXIDINE DIGLUCONATE SOLUTION** no. 658 of the European
16 Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s)
17 mentioned below, based on the analytical procedure(s) given in annex.

18 – Test for residual solvents by gas chromatography (Annex 2)
19 *n*-Butanol not more than 2000 ppm
20 Methanol not more than 1000 ppm

21 In the last steps of the synthesis water is used as solvent.

22 The re-test period of the substance is 24 months if stored in a polyethylene container.

23 The holder of the certificate has declared the absence of use of material of human or animal
24 origin in the manufacture of the substance.

25 The submitted dossier must be updated after any significant change that may alter the quality,
26 safety or efficacy of the substance.

27 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice
28 and in accordance with the dossier submitted.

- 29 Failure to comply with these provisions will render this certificate void.
- 30 This certificate is renewed from **26 June 2013** according to the provisions of Resolution AP-CSP
31 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,
32 and the related guidelines.
- 33 This certificate has two annexes, the first of 1 page and the second of 4 pages.
- 34 This certificate has:
- 35 lines.



On behalf of the
Director of EDQM

Strasbourg, 19 August 2022

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

R.N. LABORATORIES, as holder of the certificate of suitability

R1-CEP 2006-171 - Rev 03 for Chlorhexidine digluconate solution

hereby authorises
(name of the pharmaceutical company)

to use the above-mentioned certificate of suitability in support of their application(s) for the following
Marketing Authorisation(s): *(name of product(s) and marketing number(s), if known)*

The holder also certifies that no significant changes to the operations as described in the CEP dossier
have been made since the granting of this version of the certificate.

Date and Signature *(of the CEP holder)*: