

Certification of Substances Division

**Certificate of suitability
No. R0-CEP 2014-131-Rev 00**

1 *Name of the substance:*

2 **ETODOLAC**

3 *Name of holder:*

4 **KREATIVE ORGANICS PRIVATE LIMITED**

5 D-123, Phase-III, I.D.A. Jeedimetla

6 India-500 055 Hyderabad, Telangana

7 *Site(s) of production:*

8 **SEE ANNEX 1**

9 After examination of the information provided on the manufacturing method and subsequent
10 processes (including purification) for this substance on the site(s) of production listed in annex, we
11 certify that the quality of the substance is suitably controlled by the current version of the
12 monograph **ETODOLAC** no. 1422 of the European Pharmacopoeia, current edition including
13 supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical
14 procedure(s) given in annex.

15 – Test for residual solvents by gas chromatography (Annex 2)
16 Methanol not more than 1000 ppm –

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

18 The re-test period of the substance is 60 months if stored in double polyethylene bags, placed
19 in a polyethylene container.

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

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

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

26 Failure to comply with these provisions will render this certificate void.

27 This certificate is granted within the framework of the procedure established by the European
28 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from
29 **16 September 2015**. Moreover, it is granted according to the provisions of Directive 2001/83/EC
30 and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

31 This certificate has two annexes, the first and the second of 1 page each.

32 This certificate has:

33 lines.

On behalf of the
Director of EDQM



Strasbourg, 16 September 2015

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

KREATIVE ORGANICS PRIVATE LIMITED, as holder of the certificate of suitability

RO-CEP 2014-131-Rev 00 for Etodolac

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)*: