

Certification of Substances Division

Certificate of suitability
No. R0-CEP 2005-038-Rev 00

1 *Name of the substance:*
2 **CARBOPLATIN**

3 *Name of holder:*
4 **OFICHEM BV**
5 Heembadweg 5
6 The Netherlands-9561 CZ Ter Apel

7 *Site(s) of production:*
8 **OFICHEM BV**
9 Heembadweg 5
10 The Netherlands-9561 CZ Ter Apel

11 After examination of the information provided on the manufacturing method and
12 subsequent processes (including purification) for this substance on the site(s) of
13 production mentioned above, we certify that the quality of the substance is suitably
14 controlled by the current version of the monograph **CARBOPLATIN** no. 1081 of the
15 European Pharmacopoeia, current edition including supplements.

16 Any other impurity than those mentioned in the monograph and detected by the test
17 for related substances of the monograph is individually limited to not more
18 than 0.10%.

19 The test for soluble barium described in the monograph is not necessary since this
20 compound is not used in the synthesis.

21 – Test for residual solvents by gas chromatography as determined using the test for
22 residual solvents of the European Pharmacopoeia (2.4.24, System A, sample
23 preparation 1)
24 Dimethylformamide not more than 880 ppm
25 Isopropanol not more than 5000 ppm

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


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

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

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

33 This certificate is granted within the framework of the procedure established by the
34 European Pharmacopoeia Commission [Resolution AP-CSP (93) 5 as amended] for a
35 period of five years starting from **19 December 2008**. Moreover, it is granted according
36 to the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any
37 subsequent amendment, and the related guidelines.

38 This certificate has:
39 lines.


On behalf of the
Director of EDQM



Strasbourg, 19 December 2008

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

Ofichem BV, as holder of the certificate of suitability

R0-CEP 2005-038-Rev 00 for CARBOPLATIN

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)*: