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APPLICATION NUMBER:

50-805

CHEMISTRY REVIEW(S)



NDA 50-805

**Oracea (Doxycycline), capsules 40mg
CollaGenex Pharmaceuticals, Inc.**

Division of Dermatology and Dental Products

Zhengfang Ge, Ph.D.

**Branch III, Division of Pre-Marketing Assessment II
Office of New Drug Quality Assessment**



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Chemistry Review Data Sheet

1. NDA # 50-805
2. REVIEW # 1
3. REVIEW DATE: May 25, 2006
4. REVIEWER: Zhengfang Ge

5. PREVIOUS DOCUMENTS:

Previous Documents

Document Date

None

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Document Date

Original submission

August 1, 2005

7. NAME & ADDRESS OF APPLICANT:

Name: COLLAGENEX PHARMACEUTICALS, INC

Address: 41 University Drive, Suite 200, Newtown, PA
18940

Representative:

Telephone: 215-579-7388



CHEMISTRY REVIEW



Chemistry Review Data Sheet

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Oracea
- b) Non-Proprietary Name (USAN): Doxycycline
- c) CAS No: 17086-28-1
- d) Code Name/# (ONDQA only): COL101, MA64
- e) Chem. Type/Submission Priority (ONDQA only):
 - Chem. Type: 5
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: This application was filed under the provisions of section 505(b)(1) of Federal Food, Drug and Cosmetic act and 21 CFR 314.50.

10. PHARMACOL. CATEGORY: inflammatory lesions in patients with rosacea

11. DOSAGE FORM: Capsules

12. STRENGTH/POTENCY: 40 mg

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: Rx OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

SPOTS product – Form Completed

Not a SPOTS product

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