

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206276Orig1s000

CHEMISTRY REVIEW(S)



Executive Summary Section

Overall Manufacturing Inspection Recommendation Next task »

NDA 206276-Orig1-New/NDA(1)

Task Summary Task Data **Task Updates** More ▾

Update Status Log Time

Enter an Update...

✓ **Linda Ng** marked this as Done and made 3 updates.

Yesterday at 9:31 am - Comment

- Updated Facility Inspection - Overall Application Recommendation to Approve.
- Updated Facility Inspection - Overall Application Re-evaluation Date to 3/16/16.
- Changed the status to Complete.

▾ Parent: Profile Evaluation for ALCON RESEARCH, LTD. - (b) (4) | COMPLETE | (5)

Office of Process and Facilities Recommendation (b) (4)

(b) (4)

NDA 206276-Orig1-New/NDA(1)

Task Summary Task Data **Task Updates** More ▾

Update Status Log Time

Enter an Update...

✓ **Linda Ng** marked this as Done and made 5 other updates.

Jan 20 at 9:19 am - Comment

- Changed the status to Complete.
- Updated Office of Process and Facilities - Facility Recommendation Comments to Found AC based on inspection of 9/8/2014.
- Updated Office of Process and Facilities - Facility Inspection Re-evaluation Date to 9/8/16.
- Updated Office of Process and Facilities - Facility Recommendation Reasons - Acceptable to Based on Inspection Review.
- Updated Office of Process and Facilities - Facility Inspection Recommendation to Approve Facility.



CHEMISTRY REVIEW



Executive Summary Section

Parent: Profile Evaluation for N.V. ALCON-COUVREUR S.A. - (b) (4)

Office of Process and Facilities Recommendation (b) (4)

NDA 206276-Orig1-New/NDA(1)

Task Summary Task Data **Task Updates** More ▾



Update Status | Log Time

Enter an Update...

Linda Ng volunteered to work on this.
Dec 15, 2014 at 8:57 am - Comment

DARRTS Migration changed the status to Complete and made 4 other updates.

Nov 6, 2014 at 8:59 pm - Comment

- Updated Office of Process and Facilities - Facility Recommendation Comments to (b) (4)
- Updated Office of Process and Facilities - Facility Inspection Re-evaluation Date to 3/26/16.
- Updated Office of Process and Facilities - Facility Recommendation Reasons - Acceptable to District Recommendation.
- Updated Office of Process and Facilities - Facility Inspection Recommendation to Approve Facility.

Parent: Profile Evaluation for (b) (4) - CSN NON-STERILE API BY CHEMICAL SYNTHESIS | COMPLETE | (6)

Office of Process and Facilities Recommendation CSN NON-STERILE API BY CHEMICAL SYNTHESIS

Next task >

NDA 206276-Orig1-New/NDA(1)

Task Summary Task Data **Task Updates** More ▾



Update Status | Log Time

Enter an Update...

Linda Ng marked this as Done and made 5 other updates.

(b) (4) Comment

Changed the status to Complete.

Updated Office of Process and Facilities - Facility Inspection Re-evaluation Date to (b) (4)

Updated Office of Process and Facilities - Facility Inspection Recommendation to Approve Facility.

Updated Office of Process and Facilities - Facility Recommendation Comments to Decision based on summary from investigator for inspection dated (b) (4)

Updated Office of Process and Facilities - Facility Recommendation Reasons - Acceptable to Based on File Review.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY GRACE LUBAO
02/23/2015

NDA 206-276

**Pazeo
(olopatadine hydrochloride
ophthalmic solution), 0.7%**

Alcon Research, Inc.

**Libaniel Rodriguez, Ph.D.
Division of Transplants & Ophthalmology Drug Products
HFD-590**

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