



DBSQ/OCBQ ANALYTICAL METHOD REVIEW MEMO

To The file: STN 125798

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Applicant Neurotech Pharmaceuticals Inc. (Neurotech)

Subject Review of Mycoplasma, Endotoxin, and Sterility Analytical Methods for NT-501

Recommendation: Approval

Executive Summary:

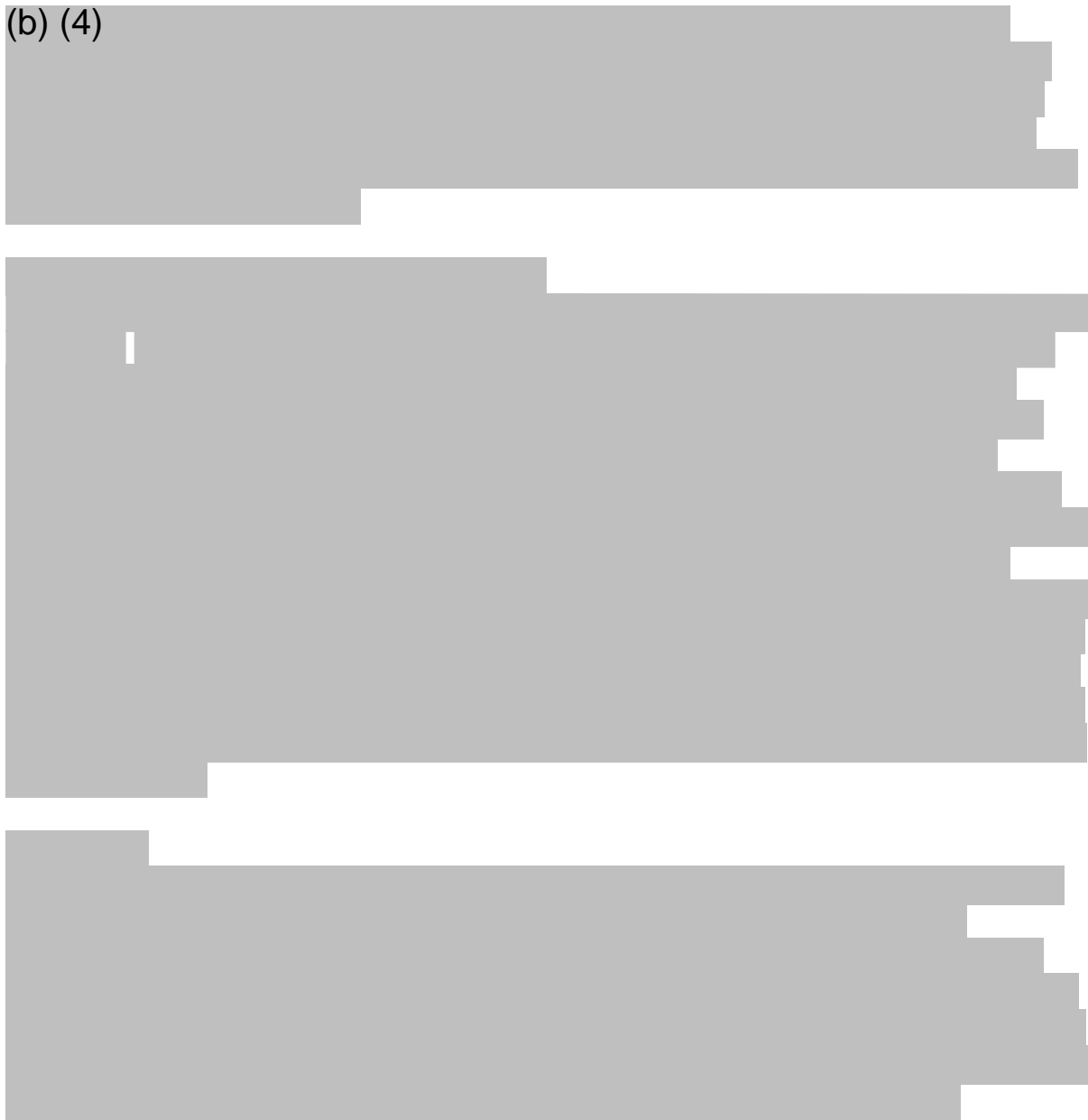
The mycoplasma, endotoxin, and sterility analytical methods used for testing and release of NT-501 and the associated analytic method qualifications or validations, were reviewed. The assays were adequately described and shown to be suitable for their intended purpose.

Conclusion: The analytical methods and their qualifications or validations reviewed for NT-501 (b) (4) drug product were found to be adequate for their intended use.

Documents Reviewed

Information in sections of the original submission that describe control of (b) (4) Drug Product (DP) (3.2.S.4 and 3.2.P.5, respectively), including descriptions of (b) (4) DP specifications, analytical procedures of (b) (4) DP and qualifications or validation of these analytical procedures were reviewed. In addition, responses to CBER's Information Requests (IRs) received on May 24, 2024 (Amendment #5), June 27, 2024 (Amendment # 12), July 16, 2024 (Amendment # 18), August 6, 2024 (Amendment # 20) and October 30, 2024 (Amendment # 59), were also reviewed as mentioned below.

(b) (4)




2. Endotoxin Method (b) (4) DP)

Introduction

Bacterial endotoxin testing (BET) for (b) (4) NT-501 (DP) is performed at Neurotech, Cumberland, RI (b) (4) . Specification of (b) (4) /NT-501 DP must be met for release.

Method

(b) (4)



(b) (4)

Conclusion

The method suitability tests were performed and compliant with (b) (4) for DP and the test results indicate there is no product interference from (b) (4) NT-501 samples, thus indicating the (b) (4) and (b) (4) method are appropriate under the actual conditions of use.

3. **Sterility Method** (b) (4) DP

Introduction

Sterility testing for (b) (4) NT-501 (DP) is performed at Neurotech, Cumberland, RI. Acceptance criterion of 'No Growth Detected' must be met for the release of (b) (4) DP.

Method

(b) (4)


The method is described below, together with the tests that were performed to demonstrate suitability of the test method according to its indicated use.

The submission lacked sufficient information to complete review of sterility tests, therefore, IRs were sent requesting missing information and responses were received on May 24, 2024 (Amendment #5), June 27, 2024 (Amendment # 12), July 16, 2024 (Amendment # 18), August 6, 2024 (Amendment # 20), and October 30, 2024 (Amendment # 59), which was found acceptable and explained below. Additionally, two teleconferences were held between the CBER and Neurotech on July 23, 2024, and November 14, 2024, to discuss expectations of (b) (4) requirements and (b) (4) testing results.

(b) (4)

1 page determined to be not releasable: (b)(4)

(b) (4)



Conclusion

The method suitability tests were performed and compliant with (b) (4) and the test results indicate there is no product inhibition of microorganism growth from (b) (4) NT-501 samples, thus indicating the (b) (4) test method is appropriate under the actual conditions of use.