

Glatiramer Expert Panel
of the Biologics Monographs 1 – Peptides and Insulins Expert Committee
Monday – Tuesday, October 16 - 17, 2017
USP – U.S., Rockville

Agenda

Goals and Anticipated Outcomes

- To review the draft monograph and current status
- To make a decision on the Molecular Weight method to be added to the monographs
- To make a decision on the Bioidentity Method to be added to the monograph(s)
- To make a decision on the RS's needed in support of the tests selected in the monographs

Attendees

Attendee list provided on the day of the meeting

Monday, October 16, 2017

[CLOSED to all Observers and Government Liaisons]

- | | | |
|-----------|--|--|
| 8:30 a.m. | 1. Procedural Matters and Standards of Conduct
a. Call Meeting to Order
b. Establish Quorum
c. Identification of Observers and Confidential Information
d. Conflict of Interest, Confidentiality, Code of Ethics
e. Review of the Agenda | Dr. Gratzl
Ms. Gould-Kostka
Dr. Gratzl
Ms. Gould-Kostka
Dr. Gratzl |
|-----------|--|--|

[END of CLOSED section]

- | | | |
|-----------|---|--|
| 8:45 a.m. | 2. Open Procedural Matters
a. Welcome
b. Meeting Center Announcements
c. Introductions of New Staff and Observers
d. Approval of Agenda and Minutes of the Previous Meeting
e. Open Action Items from Previous Meetings | Dr. Gratzl
Ms. Fletcher
All
Dr. Gratzl
Dr. Curti |
|-----------|---|--|

9:00 a.m. **3. Glatiramer Acetate Updates**

Goal: To review the progress made and current draft monographs

- | | | |
|--|---|-------------------|
| | a. Updates and overview of the draft monographs | Drs. Gratzl/Curti |
| | b. Discussion | All |

10:30 a.m. **Break**

[CLOSED to all Observers]

10:45 a.m. **4. ELISA-based Identity Tests**

Goal: To review and discuss pros and cons of potential identity tests and select suitable method(s)

- | | | |
|--|---|---|
| | a. Potential ELISA-based tests and needs for the monograph(s) | Subject Matter
Experts from Both
Sponsors |
| | b. Discussion | All |

[END of CLOSED section]

12:00 p.m. **Group Photo and Lunch**

[CLOSED to all Observers]

1:00 p.m. **5. Bioidentity**

Goal: To review and discuss pros and cons of potential bioidentity tests and select suitable method(s)

- | | |
|---|---|
| a. Potential Bioidentity Tests and needs for the monograph(s) | Subject Matter
Experts from Both
Sponsors |
| i. Experimental Allergic Encephalomyelitis in Mice | |
| ii. In Vitro Potency Test | |
| b. Discussion | All |

[END of CLOSED section]

2:30 p.m. **Break**

2:40 p.m. **6. Molecular Weight Determinations**

Goal: To review proposed Methods for Molecular weight Determination and to select the method to be added in the monographs and anticipate required RS(s)

- | | |
|--|------------|
| a. Review of the Method Comparison Study Data | Dr. Keire |
| b. Discuss and approve the method for Molecular Weight determination, System Suitability(SS) Criteria, and SS RS | All |
| c. Discuss the feasibility of the Molecular Weight Method as Assay | Dr. Mulloy |
| d. Discussion | All |

4:45 p.m. **7. Wrap-up of Day 1**

- | | |
|-----------------------------|------------|
| a. Summary and Action Items | Dr. Gratzl |
|-----------------------------|------------|

5:00 p.m. Meeting adjourns, Bus transportation to Cambria Hotel & Suites

6:15 p.m. Depart from hotel lobby to restaurant

6:30 p.m. Expert Panel dinner at TBD

Tuesday, October 17, 2017

8:30 a.m. **8. Impurities**

Goal: To review the method for determination of impurities in the GA Drug Product

- | | |
|--|---------------|
| a. Review of the Reversed Phase Chromatography method for determination of impurities/degradation products In Glatiramer Acetate for Injection | Dr. Weinstein |
| b. Discuss | All |

9:15 a.m. **9. Glatiramer Acetate Reference Standards**

Goal: To plan the development and qualification of required Reference Standards (RS)

- | | |
|-----------------------------------|-----------|
| a. USP Glatiramer Acetate RS | Mr. Metta |
| b. RS for MW determination method | Mr. Metta |

- c. Amino Acid Analysis RS
 - d. Bioidentity RS & Reagents
 - e. Others?
- Mr. Metta
Mr. Metta
All

10:15 a.m. **Break**

10:30 a.m. **10. Definition**

Goal: To review the Definitions proposed for the Drug Substance and Product

- a. Glatiramer Acetate Drug Substance Definition
 - b. Glatiramer Acetate Drug Product Definition
 - c. Discussion
- Dr. Curti
Dr. Curti
All

11:30 a.m. **11. Timeline and Next Steps**

Goal: To review monograph and RSs timelines and discuss next steps

- a. Monograph and RSs Timelines
 - b. Discussion
- Dr. Curti/Mr. Metta
All

11:45 a.m. **12. Meeting Wrap-up and Action Items**

- a. Action Items and Point
 - b. Next Expert Panel Meeting
- Ms. Palmer
Dr. Gratzl

12:00 p.m. **Adjourn and Lunch**