



Pharmacopeia Working Group

9th MEETING

March 9, 2005

Washington DC

Members

ARGENTINE PHARMACOPEIA (FA)

Hela Beltramini, Technical Coordinator of the Argentine Pharmacopeia

BRAZILIAN PHARMACOPEIA (FB)

Celso Bittencourt, General Director of the Permanent Commission of the Brazilian Pharmacopeia
Lauro Moretto, Member of FB and Executive Vice President of
SINDUSFARMA/FEBRAFARMA

PHARMACOPEIA OF THE UNITED MEXICAN STATES (FEUM)

María del Carmen Becerril Martínez, Executive Director

PHARMACOPEIA OF THE UNITED STATES (USP)

Gabriel Giancaspro, Associated Director (DSD)
Horacio Pappa, Scientist and Specialist in America Latina.(DSD)
Damián Cairatti, Associate Scientist Sr. (DSD)
María Gil Montero, International Affairs Specialist (DSD)

Special Guest (SOQUIFICH)

Andrés Vega González, Director of Regulatory Affairs, Pasteur Lab, Chile

1) **Harmonization of General Chapters**

Residue on Ignition –The group discussed differences in ignition temperature. Even apparently large differences, e.g., 600° C versus 800° C, are not critical. USP and PE (WHO IS PE) maintained this difference of the ignition temperature for many years, although the method was considered equally interchangeable. Finally, PWG members agreed to sign off the harmonization of this chapter, and also committed themselves to eliminate the differences for the next publication of each one of their Pharmacopeias.

Particles in injections - Discrepancies related to the definition of small and large volume of injections were discussed. The representative of FA clarified that in Argentina, the term large volume is applied to containers of 100 mL or larger. The other PWG pharmacopeias differ from FA's position. FA's representative added that a change in the classification of volume for injections would critically affect the control of products in the Argentine market. She added that this issue will motivate revisions for the corresponding Expert Committees of FA. If the issue is resolved then FA would be in a position to sign off the harmonization. The FEUM representative indicated an intention of not including the calibration method within the text of this chapter. This position, however, couldn't be considered as an obstacle for harmonization. Finally, the Working Group agreed that the four pharmacopeias would utilize the same analytical procedure and that

the topic should be better discussed at the next PWG meeting

Bacterial Endotoxins FB clarified that there is no a working group for this subject. Bittencourt added that Brazil would adopt the harmonized PDG text. FEUM declared not to have differences with the proposed method. FA agreed to reevaluate the proposal for this topic.

2) **New General Chapters to Harmonize**

Dosage Unit uniformity (FEUM as the Leader) - Recently PDG adopted the procedure utilized by the Japanese Pharmacopeia. This procedure presents differences in the treatment of statistical data. FA and FEUM commented that they both would apply the USP classic procedure. It was agreed, that in accordance with the terms of the PWG protocol, the Pharmacopeia leader should prepare a document with a comparative table reflecting the differences and similarities of the texts of each Pharmacopeia and send such a document to the other members of the Working Group.

Dissolution (Argentine Pharmacopeia as the Leader) – The group agreed to work in the harmonization of the general procedures using Apparatus 1; 2; 3 and 4. In accordance with the PWG protocol, the leader should prepare also a document reflecting the differences/similarities of the texts of each Pharmacopeia and distribute such a text to the other members

Disintegration (USP) - USP will be the Leader and provide a comparative table to the other members in order to initiate the harmonization process.

Capillary Electrophoresis - FA offered to be the leader for the harmonization process of this chapter. USP indicated that its chapter on Capillary Electrophoresis will be rewritten; therefore, it was advisable to wait until the review is finalized, and then work for harmonization.

Thirty (30) days was the term agreed for the preparation and delivery of comparative tables for each the preceding topics.

3) **Monographs**

Amiodarone - The process of harmonization of this monograph has been delayed because USP Expert Committee couldn't reach agreement on the impurity test to be utilized. Although the Expert Committee seemed inclined to use EP method, USP will send the text to the Argentine Pharmacopeia for its consideration the observations referred to the method presented by the same.

Cat Claw - USP staff commented that PWG has previously agreed to work in the harmonization of this monograph, and that in January 2004, the USP monograph was published in the Pharmacopeial Forum. USP will send the PF f monograph to the other three members.

Other monographs were listed as topics of interest Green Tea; Soybean; Extract of Grape Seed, Turmeric and Gel of Aloe Vera.

Aspirin - FB agreed to send its monograph to AP to start the initial harmonization process.

4) **PANDRH**

Horacio Pappa summarized the topics of the last PANDRH meeting in the Dominican Republic. USP representatives presented a report of PWG activities at the PANDRAH IV Conference, and as a result PWG mission was approved by the Steering Committee. Also the proposed protocol



for the harmonization process was approved while recognizing the importance of including medicinal plants (botanicals) within the harmonization aforementioned process.

FIFARMA expressed its interest in participating in the PWG meetings. In this regard, FIFARMA nominated Dr. Ana Martha Barravecchia de Dehó as representative and Dr. Bautista Marinero as alternate. Copies of these PWG minutes will then be sent to them.

Other Latin American countries that don't have pharmacopeias (Chile and others) also expressed interest to become PWG members to participate in its meetings.

5) Next meeting of PWG

Two options were considered for the next PWG meeting: Brazil proposed a meeting to be held on May 17-19, 2005 at the headquarters of SINDUSFARMA, in Sao Paulo, Brazil. FEUM proposed that the next meeting be held in Cancun next November 2005, coinciding with the Mexican Pharmaceutical Association's Congress. It was agreed that PWG members will be in contact in order to determine the date for the next meeting.

