

**PHARMACOPOEIAL DISCUSSION GROUP**

**SIGN-OFF DOCUMENT**

**STATEMENT OF HARMONISATION POLICY**

Revision October 2023

**European Pharmacopoeia**

Signature



Name

C. Vielle

Date

03 Oct. 2023

**Indian Pharmacopoeia Commission**

Signature





Name DR. GAURAV PRATAP  
SINGH

Date 03-10-2023

**Japanese Pharmacopoeia**

Signature

Name

Hikoichiro Maegawa

Date

03 Oct. 2023

**United States Pharmacopoeia**

Signature



Name

JAAP VENEMA

Date

03 OCT 2023

# PHARMACOPOEIAL DISCUSSION GROUP

## STATEMENT OF HARMONISATION POLICY

(Revision October 2023)

### 1. General Information

In 1989, the Pharmacopoeial Discussion Group (PDG) was formed by the European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe, the United States Pharmacopoeial Convention, Incorporated, and the Japanese Pharmacopoeia of the Ministry of Health, Labour and Welfare (MHLW). Since then, the PDG has generally met twice a year – either face-to-face or by videoconference – to work on pharmacopoeial harmonisation topics. Since May 2001, the World Health Organization (WHO) has participated in PDG activities as an observer. In October 2023 the Indian Pharmacopoeia Commission (IPC) joined PDG as a member.

### 2. Purpose

A pharmacopoeial monograph for a medicinal product, an active ingredient, an excipient or any other product used in the manufacture or compounding of a medicinal product generally provides a name, a definition, a description, and sometimes packaging, labelling, and storage statements. Thereafter, the monograph provides the tests, procedures and acceptance criteria that constitute the specification. For frequently cited procedures, a monograph may refer to a general chapter for editorial convenience. PDG works to harmonise excipient monographs and general chapters. This will reduce manufacturers' burden of performing analytical procedures in different ways, using different acceptance criteria. At all times, PDG works to maintain an optimal level of science consistent with protection of the public health.

### 3. Definition of Harmonisation

PDG has defined harmonisation of a pharmacopoeial monograph or general chapter as follows:

*A pharmacopoeial general chapter or other pharmacopoeial document is harmonised when a substance or preparation tested by the harmonised procedure yields the same results and the same accept/reject decision is reached.*

Harmonisation is achieved when the text has become official in all pharmacopoeias.

### 4. Indication of Harmonisation

4.1 When using a fully harmonised pharmacopoeial monograph or general chapter, an analyst will reach the same results, irrespective of which PDG pharmacopoeia is referenced. This approach provides a basis for interchangeability (same accept/reject decision) and each pharmacopoeia will flag, in an appropriate manner, its fully harmonised monographs and general chapters.

42 4.2 When full harmonisation of a pharmacopoeial monograph or general  
43 chapter is not possible, PDG works to harmonise using an approach termed  
44 “harmonisation by attribute.” According to this approach, some elements of a  
45 monograph or general chapter may be harmonised but others may not. When  
46 a monograph or general chapter is harmonised by attribute, a combination of  
47 approaches is needed. For non-harmonised elements, reliance on  
48 the individual PDG pharmacopoeia is necessary.<sup>1</sup>

## 49 5. Process

50 Harmonisation of pharmacopoeial documents in PDG occurs based upon  
51 decisions of the expert bodies of each pharmacopoeia. PDG works  
52 transparently in many ways, including, principally, the public notice and  
53 comment procedures of each pharmacopoeia. The details are described in  
54 the Working Procedures of the PDG.

## 55 6. Implementation

56 The implementation of a harmonised document varies in the PDG regions,  
57 depending upon their legal requirements, need for translation, and publication  
58 schedules. Each pharmacopoeia generally allows a defined period of time after  
59 publication to implement official harmonised texts to allow manufacturers and  
60 other users to achieve conformity.

## 61 7. Revision of Harmonised Monographs and General Chapters

62 The pharmacopoeias participating in PDG have agreed not to revise unilaterally  
63 any harmonised document after publication. Should revisions be necessary for  
64 any appropriate reasons, the initiating pharmacopoeia notifies the other  
65 pharmacopoeias and revision proceeds according to the Working Procedures  
66 of the PDG.

## 67 8. Maintenance of ICH Q4B annexes

68 While not part of the International Council of Harmonisation of Technical  
69 Requirements for Pharmaceuticals for Human Use (ICH), the PDG is closely  
70 collaborating with ICH and tasked with the maintenance of the 14 annexes of  
71 ICH Q4B that give details on regulatory interchangeability of 16 PDG  
72 harmonised pharmacopoeial texts. The PDG prepares revised Q4B Annexes  
73 and submits them to ICH for possible regulatory consultation, adoption and  
74 publication. Other pharmacopoeias are informed by the PDG via the contact list  
75 of the International Meeting of World Pharmacopoeias (IMWP). More  
76 information can be found in Annex 5 of the ICH Standard Operating Procedure  
77 of the ICH Working Groups (available [here](#)).

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<sup>1</sup> All PDG pharmacopoeias contain a statement in the General Notices regarding alternative methods. Use of alternative methods is subject to approval by the competent authority.