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# Policy Guidance for Pharmaceutical Reference Standard

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**Version 1.2**

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# **Policy Guidance for Pharmaceutical Reference Standard**

Version 1.2

# Saudi Food & Drug Authority

## Drug Sector

For Comments

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Please visit [SFDA's website](#) at for the latest update



## Saudi Food and Drug Authority

### Vision and Mission

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#### Vision

To be a leading international science-based regulator to protect and promote public health

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#### Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

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## Document Control

Version	Author	Date	Comments
1.0	Registration Department	01 September 2008	Draft
1.1	Product Evaluation and Standards Setting Department	01 September 2010	Final
1.2	Executive Directorate of Regulatory Affairs	03 November 2021	Update (This version doesn't include any scientific update)



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## Foreword

This policy will provide assistance to industry as well as all testing laboratories on how to comply with respect to using reference standard material during testing.

Alternative approaches may be acceptable provided they are supported by scientific justification. It should be noted that the Saudi Food and Drug Authority (SFDA) has the right to request information or material within the context of this policy in order to assess adequately the safety, efficacy and quality of pharmaceutical products available in the Kingdom of Saudi Arabia.



## 1. Background

Standards and reference substances play a vital role in evaluating the quality of active pharmaceutical ingredients and finished products. They are highly characterized specimens of drug substances, excipients, impurities and degradation products that are used to conduct tests such as:

- Identity
- Purity
- Potency

They are used in many chromatographic and spectrophotometric procedures.

## 2. Pharmacopoeial Reference Standards

### 2.1. United States Pharmacopoeia Reference Standards

USP Reference Standards are based on official monographs in USP and NF whose standards and procedures are forceable by the U.S. Food and Drug Administration (FDA). They are recognized in the U.S. and other countries. The pharmaceutical industry and FDA laboratories participate in the development of these standards through collaborative testing.

Some of these reference standards have been identified as:

- Ph. Eur: CRS (Chemical Reference Standards)
- BP: BPCRS (British Pharmacopoeia)
- Intern. Pharm. : WHO international CRS
- USP: USP reference Standards

### 2.2. European Pharmacopoeia Reference Standard

The EDQM (European Department of Quality Medicine and health care) supplies chemical standard reference substances and biological reference preparations, as well as reference spectra for tests and assays. These tests and assays are to be carried out in accordance with the official methods of the European Pharmacopoeia.



Reference Standards are specially selected and verified batches certified by the European Pharmacopoeia Commission (EPC). They can be subjected to international collaborative studies.

### **2.3. International Pharmacopoeia Reference Standard**

The World Health Organization (WHO), a specialized agency of United Nations with a primary responsibility of international public health matters, is issuing an International Pharmacopoeia. With the help of international cooperation, they also establish international reference standards for biologicals and pharmaceuticals.

### **2.4. British Pharmacopoeia Reference Standard**

The British Pharmacopoeia (BP) Reference Standard substances and preparations are selected and verified by BP laboratories as being suitable for use as prescribed in the relevant monograph of the BP.

## **3. Types of Reference Standards**

For the purpose of this policy, the reference standards are of the following types:

### **Primary Reference Standard**

This reference standard is obtained from official sources and referred to as pharmacopoeial reference standard.

### **Secondary/working Reference Standard**

This reference standard is developed by manufacturers by analyzing and validating a lot of the drug substance against a primary reference standard.

### **House or Manufacturer Reference Standard**

This reference standard is referred to as the reference standard that was manufactured, purified and fully characterized and structurally elucidated (e.g. IR, UV, MNR, Ms, etc.). This is common in the case of New Chemical Entity (NCE), where there is no compendial monograph.



## 4. Policy Objective

The objective of the policy is to provide information that is required when using the reference standard material during test analysis. This policy will provide sponsors with the SFDA expectations for the use of reference standard material for the analysis of the drug substance (API) and the dosage form.

## 5. Policy Statement

The SFDA expects that:

- i. The source of the reference standard used in the testing of the drug substance and dosage forms should be properly specified.
- ii. The official pharmacopoeial reference standard should be used.
- iii. In case the official pharmacopoeial reference standard is not available, a house reference standard is acceptable, providing complete information on the manufacturing and purification process is submitted.
- iv. A secondary reference standard can also be used by providing a copy of the certificate of analysis and validating it against a suitable official pharmacopoeial reference standard.

## 6. Scope and Application

The scope of this policy includes all New Drugs, Generic Drugs, Veterinary Drugs applications and their supplement and variation.

The SFDA expects that the principles established in this policy should be applied in all test analyses of drug products manufactured and marketed in the Kingdom of Saudi Arabia.

## 7. Acronyms

- SFDA Saudi Food and Drug Authority
- APIs Active Pharmaceutical Ingredients
- WHO World Health Organization
- BP British Pharmacopoeia
- Ph. Eur. European Pharmacopoeia
- Ph. Int. International Pharmacopoeia
- USP United States Pharmacopoeia
- US FDA Food and Drug Administration of the United States



- EDQM European Department of Quality Medicine
- EPC European Pharmacopoeial Commission
- NF National Formulary



## 8. REFERENCES

- United States Pharmacopoeia
- British Pharmacopoeia
- European Pharmacopoeia
- International Pharmacopoeia