MEMORANDUM OF UNDERSTANDING BETWEEN

The Indian Pharmacopoeia Commission,

Ministry of Health and Family Welfare,

Government of the Republic of India

And

The Bhutan Food and Drug Authority, Ministry of Health,

Royal Government of Bhutan

On

Cooperation concerning sharing reference standard, pharmacopoeia, vigilance and testing of medical products.

The Indian Pharmacopoeia Commission (hereafter referred to as "IPC"), Ministry of Health and Family Welfare, of the Government of the Republic of India located at Sector 23, Raj Nagar, Ghaziabad-201 002, UP, India and the Bhutan Food and Drug Authority (hereinafter referred to as "BFDA"), Ministry of Health, of the Royal Government of Bhutan located at Drophen Lam, Kawang Jangsa, Thimphu; "BFDA" and "IPC" jointly referred to as the "Parties" and individually as a "Party" for the purpose of this Memorandum of Understanding (MoU),

Desiring to recognize the importance of developing close cooperation and exchanging information in the field of the supporting reference standard including pharmacopoeia, testing and vigilance of medical products in accordance with their respective national laws, rules, policies and regulations.

Have reached the following understandings:

Article 1: Purpose/Objective

1. The purpose/objective of this MoU is to strengthen, facilitate, promote and develop cooperation and collaboration on safety and quality of medical products in the region through reliance and recognition of Indian Pharmacopoeia (IP), reference standards sharing, product testing and vigilance.

Article 2: Areas of Cooperation and collaboration

2. BFDA to accept Indian Pharmacopoeia as a book of standards in addition to the existing adopted standards in the country for medicines in Bhutan so as to ensure quality of medicines being manufactured and/or imported in Bhutan;

3. BFDA to accept the Certificate of Analysis issued by Indian manufacturers and certified testing laboratory in India as per IP for market authorization; except for Post marketing Control activities;

4. IPC to facilitate BFDA in obtaining IP Reference Standards and Impurity Standards from IPC at a reasonably low cost to be used during the quality control analysis;

5. IPC to facilitate access to updated Indian Pharmacopoeia editions to BFDA at discounted prices.

6. BFDA and IPC to jointly promote an understanding of pharmacopoeia in regulatory framework, requirements and processes;

7. IPC and BFDA to collaboratively strengthen the safety aspects of medicines through capacity building, resource sharing and exchange programs.

8. IPC to facilitate the exchange of information and documentation relating to the development of monographs of IP;

9. BFDA and IPC collaboratively to enhance the ability of regulatory authorities in the provision of their services relating to or in connection with public health, to meet the needs of their respective Population; and

10. IPC and BFDA to explore opportunities for technical cooperation in areas of mutual benefit in the development of monographs and future technologies.

Article 3: Obligation of the Parties

11. The present MoU is not an international treaty and does not establish any right and/or legal or any obligations to the Parties under the international or national laws, rules and regulations.

Article 4: Expenses

12. Each Party will bear its own expenses connected with activities under this MoU.

Article 5: Intellectual Property Rights

13. Each Party is the copyright owner of its respective pharmacopoeia and shall retain all Intellectual Property Rights (IPR) in the items published. This MoU does not transfer any of the Intellectual Property Rights possessed by the respective Parties. All Intellectual Property Rights developed or created by a Party pursuant to the project shall be owned by that Party.

Article 6: Validity

14. This MoU shall remain valid until terminated by either of a Party.

Article 7: Termination

15. This MoU may be terminated by either Party, at any time, by giving three (3) months advance written notice to each other. The Parties with mutually written consent shall determine whether ongoing activities or projects under the MoU should continue or not after the termination of this MoU. Termination will not affect the validity of any contracts or agreements made under the MoU prior to its termination.

Article 8: Amendment

16. This MoU may be amended with the mutual written consent of the Parties.

Article 9: Dispute Settlement

17. Any dispute regarding the interpretation or application of this MoU will be resolved through mutual consultations between the Parties and based on mutual understanding and respect.

Article 10: Commencement

18. This MoU shall come into effect on the date of its signing by the Parties.

IN WITNESS WHEREOF the undersigned, being duly authorized by their respective Government, have signed this MoU

Done at Thimphu on Twenty First day of March of the year Two Thousand Twenty Four in two originals in the English language.

Signed for and on behalf of The Indian Pharmacopoeia Commission (IPC), Ministry of Health and Family Welfare, Government of the Republic of India	**Signed for and on behalf of The Bhutan Food and Drug Authority (BFDA), Ministry of Health, Royal Government of Bhutan**
Signature:	Signature: .....
Name: Mr. Sudhakar Dalela	Name: Mr. Pemba Wangchuk
Designation: Ambassador of India to Bhutan	Designation: Secretary, Ministry of Health, Royal Government of Bhutan