



**Bureau of Laboratory Quality Standards
Ministry of Public Health**

This is to certify that

The laboratory of

Pharma Nueva Co., Ltd.

**48 Soi Chokechairuammitr, Vibhavadi - Rangsit Road,
Chomphon, Chatuchak, Bangkok 10900, Thailand**

has been accepted as an

accredited laboratory complying with the ISO/IEC 17025 : 2017
and the requirements of the Bureau of Laboratory Quality Standards

The laboratory has been accredited for specific tests

listed in the scope within the field of

Drug Testing

A blue ink signature, appearing to read 'Surasak Muenphon', written in a cursive style.

(Mr. Surasak Muenphon)

Director of Bureau of Laboratory Quality Standards

Date of Accreditation : 17 February 2025

Valid Until : 23 February 2027

Accreditation Number 1090/49

The laboratory of Pharma Nueva Co., Ltd has been accepted as an accredited laboratory in the field of drug testing for following scopes.

No.	Type of Sample	Test	Method
1	Solid form* - Tablets	Elemental impurities: 1. Vanadium 2. Cobalt 3. Nickel 4. Arsenic 5. Cadmium 6. Mercury 7. Lead	USP - NF 2024 <232>, <233>
2	Liquid form and Solid form** - Solution, Powder	Elemental impurities: 8. Vanadium 9. Cobalt 10. Nickel 11. Arsenic 12. Cadmium 13. Mercury 14. Lead 15. Lithium 16. Antimony 17. Copper	USP - NF 2024 <232>, <233>
3	Metformin 500 MG (Tablet)	18. N-Nitrosodimethylamine (NDMA)	In-house method, SD-TD-AD-11, Code no. NI-002, based on USP-NF 2024

List of active pharmaceutical ingredients:

Solid form*

- Atorvastatin

- Sitagliptin

Liquid form and Solid form**

- Parecoxib

- Ketorolac Tromethamine

Bureau of Laboratory Quality Standards

Page 1 of 1

Accreditation No. 1090/49

Revision No. 00

Date of Accreditation: 17 February 2025

Date Revised 17 February 2025

Valid Until : 23 February 2027

Reviewed by Head of Laboratory Accreditation Section.....*Saovanee Aromsook*.....(Ms.Saovanee Aromsook)

The laboratory of Pharma Nueva Co., Ltd has been accepted as an accredited laboratory in the field of drug testing for following scopes.

No.	Type of Sample	Test	Method
1	Raw material - Irbesartan	1. Limit of Azide	USP -NF 2024
2	Vancomycin 125 mg (capsule)	Elemental impurities: 2. Vanadium 3. Cobalt 4. Nickel 5. Arsenic 6. Cadmium 7. Mercury 8. Lead	USP -NF 2024
3	Raw material - Losartan potassium - Olmesartan medoxomil - Irbesartan	Nitrosamine impurities: 9. N-nitrosodimethylamine (NDMA) 10. N-nitrosodiethylamine (NDEA) 11. N-nitroso ethyl isopropylamine (EIPNA) 12. N-nitroso diisopropylamine (DIPNA) 13. N-nitrosodibutylamine (NDBA)	In-house method SD-TD-AD-11-0, Code no.NI-001 based on USP -NF 2024