REPUBLIC OF KENYA

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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Pharmacy and Poisons Board Building
Lenana Road
P.O Box 27663-00506
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GMP CERTIFICATE No: PPB/INS/GMP/CERT/060/23

CERTIFICATE OF GOOD MANUFACTURING PRACTICES (GMP) COMPLIANCE OF A MANUFACTURER

PART 1

This Certificate is issued in accordance with Section 35B of the Pharmacy and Poisons Act (Cap 244) of the Laws of Kenya. The Pharmacy and Poisons Board, The National Medicines Regulatory Authority of Kenya, confirms the following:

The manufacturer: **Sobhan Oncology Pharmaceutical Co**

Site address: **3rd Avenue, 2 Sanat Blvd, Industrial City, Rasht – Iran**

Has been inspected in connection with Marketing Authorization(s) listing manufacturers located outside Kenya.

From the knowledge gained during the inspection of this manufacturer, the latest of which was conducted on **4th – 5th October, 2023,** GMP Report No. **PPB/INS/GMP/RPT/060/23,** the site complies with the prescribed Good Manufacturing Practices as per the relevant WHO Technical Report Series and other internationally acceptable guidelines.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the Kenya Pharmacy and Poisons Board should be consulted.

PART 2

1. Manufacturing operations authorised/subject to inspection

1.1 Sterile Products

1.1.1 Aseptically prepared

CATEGORY	PRODUCT TYPE	ACTVITIES
Cytotoxic	Small Volume Parenteral Liquids and Lyophilized Powders in Vials	All manufacturing activities including all operations of purchase of materials and products, production, quality control testing and/or batch release, storage and distribution of pharmaceutical products, and the related controls.

1.2 Non-sterile products

DOSAGE FORM	CATEGORY	PRODUCT TYPE	ACTIVITIES
Oral solids	Cytotoxic	Tablets, Capsules	All manufacturing activities including all operations of purchase of materials and products, production, quality control testing and/or batch release, storage and distribution of pharmaceutical products, and the related controls.

The compliance status shall be deemed valid unless it is invalidated under any of the following conditions;

1. The activities and/or categories certified herewith are changed.
2. The site is no longer considered to be in compliance with WHO cGMP.
3. The manufacturing site is changed.

The authenticity of this certificate may be verified with the Kenya Pharmacy and Poisons Board.

REGISTRAR
PHARMACY AND POISONS BOARD
MINISTRY OF HEALTH
P. O. Box 27663 - 00506, NAIROBI
Date: 1st December 2023

DR. F. M. SIYOI
REGISTRAR/CHIEF EXECUTIVE OFFICER
PHARMACY AND POISONS BOARD