



CERTIFICATE OF GOOD MANUFACTURING PRACTICE

Issue Date: March 30, 2017

Issued following an inspection in accordance with Article 57 of the Pharmaceutical Affairs Law and relevant Regulations of the Republic of China (Taiwan).

The competent authority of the Republic of China confirms the following:

The manufacturer: PET Pharm Biotech Co., Ltd.

Site address: 1~2F., No.141 & 143, Hougang 1st Rd., Xinzhuang Dist., New Taipei City 24257., Taiwan

Manufacturer's licence number: (AP) 0435072

is the manufacturer of medicinal products for human use that has been inspected with the following pharmaceutical dosage forms:

- Sterile products (radiopharmaceuticals): injection (aseptic preparation)
- Non-Sterile products (radiopharmaceuticals):
Solid dosage form: capsule

From the knowledge gained during inspection performed on April 20-22, 2016, it is considered that the manufacturer complies with the Pharmaceutical Inspection Convention/Co-operation Scheme Guide to Good Manufacturing Practice (PIC/S GMP) for medicinal products.

This certificate is valid until September 6, 2018.

This certificate may be revoked at anytime as warranted.

Signed by

Shou-Mei Wu, Ph.D.

Director-General

Food and Drug Administration

(<http://www.fda.gov.tw/TC/index.aspx>)

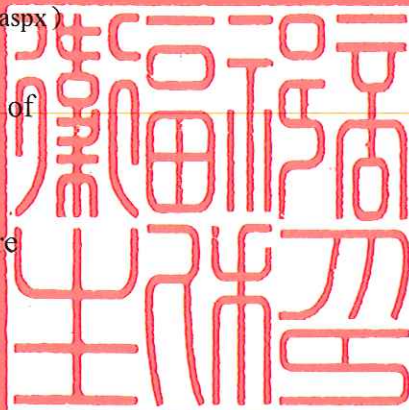
Under the delegated authority of

Shih-Chung Chen, D.D.S.

Minister

Ministry of Health and Welfare

Republic of China (Taiwan)



中華民國衛生福利部
MINISTRY OF HEALTH AND WELFARE,
REPUBLIC OF CHINA (TAIWAN)

Date: MAR 27 2017

No: 067902

證明書

Certificate

茲證明下述藥品經衛生福利部核准許可登記，准予產銷。

該藥品之製造廠亦經評定已實施經濟部與衛生福利部聯合公布推行之藥品優良製造規範，並接受定期與不定期之稽查。

Ministry of Health and Welfare, Republic of China (Taiwan) hereby certifies that the product as described below is subject to its jurisdiction and is legally approved for distribution within the Republic of China (Taiwan).

It is also certified that the manufacturing establishment has been in compliance with the requirements for Good Manufacturing Practices as jointly promulgated by the Ministry of Economic and Energy Affairs and Ministry of Health and Welfare, R.O.C. and is subject to inspections at appropriate intervals.

製造廠名稱：

Manufacturer: 士宣生技股份有限公司 PET Pharm Biotech Co., Ltd

製造廠地址：

Manufacturing Plant Location: 新北市新莊區後港一路 141 號 1、2 樓及 143 號 1、2 樓 1~2F., No.141&143, Hougang 1st Rd., Xinzhuang Dist., New Taipei City 24257., Taiwan

藥品名稱：

劑型：

Product Name: 士宣氟去氧葡萄糖注射劑 PPhB Fludeoxyglucose 【F-18】 Injection

Dosage Form: 注射液劑(無菌製備) Injection(aseptic preparations)

許可證字號：

MOHW-PM-R00033

核准日期：

Registration Number: 衛部藥製字第 R00033 號

Date of Issue: 01.16.2015

處方：

Formula:

2-Deoxy-2-[18F]fluoro-D-glucose 370MBq at calibration time (10mCi at calibration time)

適應症：

Indication(s): (中英並排)

肺癌、大腸癌、淋巴瘤、黑色素瘤、冠心病、癲癇之偵測

Detection of lung cancer、Colorectal cancer、Lymphoma、Melanoma、Coronary artery disease、epileptic seizures

Shou-Mei Wu

Signed by

Director General
Food and Drug Administration
for Shih-Chung Chen, D.D.S.
Minister
Ministry of Health and Welfare
, R.O.C.