衛 生 福 利 部
MINISTRY OF HEALTH AND WELFARE

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

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)

3611

中 華 民 國 衛 生 福 利 部

MINISTRY OF HEALTH AND WELFARE,

REPUBLIC OF CHINA (TAIWAN)

Date: MAR 2 7 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及能源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

Signed by Shou-Mei Wu

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