

*NTP Radioisotopes SOC Ltd –  
Pioneer [<sup>18</sup>F] FDG Producer in Africa*



**Gluscan® [<sup>18</sup>F] FDG  
Radiopharmaceutical**

NTP Radioisotopes SOC Ltd is one of the world's leading producers of radiochemicals, radiopharmaceuticals and other radiation technology-based products. The NTP Cyclotron facility comprises a 16 MeV GE PETtrace cyclotron and integrated radiopharmaceutical production, QC, dispensing and dispatch systems. The facility is located at Pelindaba, on the South African Nuclear Energy Corporation (Necsa) site, some 35 km west of Pretoria, South Africa.

NTP produces radiopharmaceutical grade Gluscan® FDG (registered with the Medicines Control Council of South Africa) for use in positron emission tomography (PET) and positron emission tomography-computed tomography (PET-CT) medical imaging centres within a three to four hour total transport radius of the facility. A PET-CT scan combines a CT scan and a PET scan into one image to give more detailed information about the cancer.

In order for PET imaging centres that are distant from Pelindaba to benefit from approved Gluscan® FDG formulation, NTP entered into an agreement with iThemba LABS whereby NTP purchased and located an 11 MeV cyclotron at the iThemba LABS site. This cyclotron is operated by iThemba LABS and supplies Gluscan® to users of PET-CT scanners in the Cape Town vicinity.

## Gluscan® FDG production and application cycle

FDG is used for diagnostic imaging, most commonly for the reliable and accurate diagnosis and staging of cancers, as well as for monitoring and assessing the impact of therapeutic interventions.

NTP produces certain short-lived isotopes for cardiac and other PET-CT imaging procedures and participates in pharmaceutical development and collaborative research projects.



*Short-lived isotopes  
for diagnostic imaging are a  
NTP priority*



## Benefits for FDG users

Gluscan® FDG has a 12-hour shelf life and fully conforms to the requirements of the European Pharmacopoeia.

The agreement with iThemba LABS provides users with a high degree of certainty of supply of the same quality product to which they have become accustomed. Managed by a first-class team trained in Europe, and with a considerable depth of isotope and radiopharmaceutical production experience, NTP manufactures FDG of unmatched quality, having invested in QC equipment, training and procedures that meet the most stringent regulatory requirements and reliability of supply. All production operations at NTP are performed under the continuous surveillance of a qualified Radiation Protection Officer (RPO) and a production pharmacist, in addition to the skilled production crew.

Due to its short half-life of 110 minutes, logistics plays a key role in the distribution of the product that has necessitated the establishment of fast, reliable and effective transport routes by highly skilled logistics personnel. Each FDG order is closely and carefully co-ordinated to ensure that the risks of delivery delays or failures are minimised. A fleet of specialised transport containers, designed and manufactured exclusively for NTP, are all fully licensed and have undergone stringent tests in order to comply with all relevant regulatory requirements.

Our competent personnel are qualified to advise users on radiation protection protocols and procedures as well as shielding designs that will meet regulatory requirements.

Gluscan® FDG complies with the following statutory and other requirements including, but not limited to:

- ISO 9001:2008
- Current Good Manufacturing Practice (cGMP)



*FDG manufacturing  
of unmatched quality*



## Product Specification of Gluscan®

*Specification (Complies with Ph Eur)	Requirement/Specification
Appearance	Clear, colourless or slightly yellow solution free of particulate matter
Radionuclidic Identity and Purity	Half-life = 110 minutes Gamma energy = 511 keV
Activity Concentration	540–660 MBq/ml at Calibration Time
Chemical Purity	2-Fluoro-2-deoxy-D-glucose < 1000 ppm
	Aminopolyether < 2.2 mg/10 ml
	Acetonitrile < 0.04%
	2-Chloro-2-deoxy-D-glucose (CDG) < 50 ppm
pH	pH 4.5 to 8.5
Sterility	Sterile
Bacterial Endotoxins	175/MRD EU/ml
Shelf life	12 hours

\*Please refer to package insert for further details

Dosage	Specification
Adult Dose	200–500 MBq*

\*Subject to variations in bodyweight of patient, type of camera used, etc.

## Physical Decay Chart of FDG

Minutes	Fraction Remaining
0	1.00
15	0.909
30	0.826
60	0.683
110 (1 half-lives)	0.500
220 (2 half-lives)	0.250
440 (4 half-lives)	0.060



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