Radiopharmaceutical Production

Quality Control

Quality Control Testing

Quality Control (QC)

- FDG must conform to various quality attributes of purity, efficacy and safety prior to being considered suitable for patient use. Customarily, monographs contained within the National Pharmacopoeia are the official reference source of quality specifications for a pharmaceutical product. PET radiopharmaceuticals, including FDG, being the emerging products, are likely not incorporated into many National Pharmacopoeias. In such a situation, FDG quality specifications detailed in the International Pharmacopoeia (IP), the European Pharmacopoeia (Ph. Eur.) or the United States Pharmacopoeia (USP) may serve as valuable reference sources for establishing the FDG quality specifications.

Contents

Review of Procedures

The quality control of PET radiopharmaceuticals is one of the most important parts of production. These tests ensure that the quality assurance program is working and that you are producing a safe and effective product.

This tutorial describes some example procedures that may be used in the testing of PET radiopharmaceuticals. These procedures may not be acceptable in some situations. Other processes and procedures that are not described in this tutorial may also be acceptable

A discussion of the various procedures and requirements may be found in the following sources.

Reviews of QC procedures

Hung 2004

Yu 2006

Shankar 2008

Examples of Procedures

To learn more about each of the quality control tests required for FDG, follow the links below to a discussion and example demonstration of the tests

- Radionuclidic identity
- Radiochemical identity
- Visual Inspection
- Radionuclidic purity
- Radiochemical purity
- Radioassay
- Chemical Purity
  - Residual solvents
  - Phase transfer catalyst
  - Chloro-deoxyglucose
  - [^{18}F]FDM
- Pyrogen
- Sterility
- Filter integrity
- Product stability

Literature

- The following links will lead you to the web sites of the major documents on the quality control tests required by differenct organizations.

- International Pharmacopoeia (IP),
  http://www.who.int/medicines/publications/pharmacopoeia/overview/en/index.html

- European Pharmacopoeia (Ph. Eur.)
- http://www.edqm.eu/en/Work-ProgrammeStatus-607.html

- United States Pharmacopoeia (USP)
- http://www.usp.org/

- A discussion of these tests can be found in the following papers.

Reviews of QC procedures

Hung 2004

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