Certificate of Analysis

Material	**FASTlab FDG Phosphate Cassette Pack**
Batch number	Assembled Cassette: 14819784 Cassette Pack: 14837237
Expiry date	01 April 2021
Manufacturer	GE Healthcare AS, Oslo, Norway

Conclusion
The batch is approved for use in production of [^{18}F]FDG intended for human administration.

- Every batch of components used in this batch has been tested and released for use in the manufacturing of the cassette according GE Healthcare's internal specifications.
- All test results are within specification.
- This batch should be used in conjunction with the sequence GE_FDG_GEMS115FL.

Test results

Tests	Acceptance Criteria	Results
Description		
Visual inspection	All vials and components present and in correct locations	Pass
	Vacuum wrap and outer packaging undamaged	Pass
Microbiological Tests		
Total Viable Aerobic Count	NMT 150 CFU/ cassette*	NMT 150 CFU/ cassette

* Corresponds to NMT 10 CFU/ml.

Mannose Triflate Solution Vial

Tests	Acceptance Criteria	Results
Description		
Visual inspection	Clear, colourless solution	Pass
Identification		
ID	Conforms with reference	Pass
Assay		
Mannose triflate	17.5 – 21.5 mg/ml	19.4 – 19.9 mg/ml
Related Substances (Mannose Triflate)		
Impurities by HPLC		
- 1,3,4,6-tetra-O-acetyl-β-D-mannopyranose	NMT 0.2% area	Not detected
- Greatest single related substance	NMT 0.10% area	Not detected
- Sum of related substances	NMT 0.5% area	Not detected
Impurities by ^{19}F NMR		
- Trifluormethane sulfonic acid	NMT 0.24% m/m	Not detected
- Greatest single other ^{19}F-containing impurities	NMT 0.14% mol	NMT 0.02% m/m
- Sum of other ^{19}F-containing impurities	NMT 0.34% mol	NMT 0.02% m/m
Microbiological tests		
Bacterial endotoxins	NMT 45 EU/vial	NMT 1 EU/vial
Other Tests		
Water content	NMT 2800 µg/g	NMT 1684 µg/g

Eluent Vial

Tests	Acceptance Criteria	Results
Description		
Visual inspection	Clear, colourless solution	Pass
Identification		
ID	Conforms with reference	Pass
Assay		
Water	18.0 – 23.0% v/v	20.0 – 20.1 % v/v
Kryptofix	46.0 – 60.0 mg/ml	51.2 – 53.3 mg/ml
Potassium carbonate	7.5 – 11.5 mg/ml	9.3 – 9.4 mg/ml
Microbiological tests		
Bacterial endotoxins	NMT 10 EU/vial	NMT 0.4 EU/vial

Acetonitrile Vial

Tests	Acceptance Criteria	Results
Description		
Visual inspection	Clear, colourless solution	Pass
Identification		
ID	Conforms with reference	Pass
Other Tests		
Water content	NMT 2000 µg/g	NMT 207 µg/g

Sodium Hydroxide Vial

Tests	Acceptance Criteria	Results
Description		
Visual inspection	Clear, colourless solution	Pass
Identification		
ID	Presence of sodium confirmed	Pass
Assay		
Sodium hydroxide	1.940 – 2.085 M	1.989 – 1.991 M

Phosphoric Acid Vial

Tests	Acceptance Criteria	Results
Description		
Visual inspection	Clear, colourless solution	Pass
Identification		
ID	Presence of phosphate confirmed	Pass
Assay		
Phosphoric acid	220.2 – 238.7 mg/ml	226.4 – 227.3 mg/ml

Water Bottle

Tests	Acceptance Criteria	Results
Description		
Visual inspection	Conforms with reference sample	Pass
Microbiological tests		
Sterility	Passes USP & Ph Eur	Pass
Bacterial Endotoxins	NMT 0.25 EU/ml	NMT 0.01 EU/ml
Other Tests		
Chemical Analysis	Passes USP test for Water for Injection & Ph Eur test for Water for Injection	Pass

Raw material specifications:

Raw material	Test	Acceptance Criteria
Mannose triflate	Review of Certificate of analysis (CoA)	Passes
	Appearance	White to faintly yellow, odourless crystalline powder
	Identification by IR	Conforms to reference spectrum
Acetonitrile	Review of Certificate of analysis (CoA)	Passes
	Appearance	Colourless liquid
	Identification by IR	Conforms to reference spectrum
Kryptofix	Review of Certificate of analysis (CoA)	Passes
	Appearance	White to off-white crystalline powder
	Identification by IR	Conforms to reference spectrum of Kryptofix ®222
	Purity by UV-VIS	Less than 0.05 AU at 310 nm
	Total Viable Aerobic Count	NMT 10 CFU/100 mg
Potassium carbonate	Review of Certificate of analysis (CoA)	Passes
	Appearance	White to off-white granular powder
	Identification by IR	Conforms to reference spectrum
	Total Viable Aerobic Count	NMT 100 CFU/g
Sodium Hydroxide	Review of Certificate of analysis (CoA)	Passes
	ID by Na	Passes
	ID by pH	Passes
Phosphoric acid	Review of Certificate of analysis (CoA)	Passes
	Appearance	Clear colourless syrupy liquid
	Identification (Ph.Eur)	Presence of phosphate and strong acid confirmed

The reagents are made compliant to GMP requirements for API's, the assembly of the cassette is done in compliance to the local site Quality Management System.

Bioburden statement:

The reagent vials are manufactured under cGMP conditions to maintain low bioburden. Contribution of the bioburden from the total cassette in the [18F] FDG manufactured using the cassette is low enough to assure a sterile product after terminal sterilisation or sterile filtration.

Document Approvals

Approved Date: 12 Dec 2019

Approval Task - with eSignature manifestation Verdict: Approve	Astri Luraas, Oslo (astriluraas@ge.com) On behalf of department 12-Dec-2019 11:10:52 GMT+0000

Authorisation Task - with eSignature manifestation Verdict: Authorise	Anne-Cathrine Schelver Hyni, Oslo (Anne-Cathrine.Hyni@ge.com) As Qualified Person 12-Dec-2019 17:00:49 GMT+0000