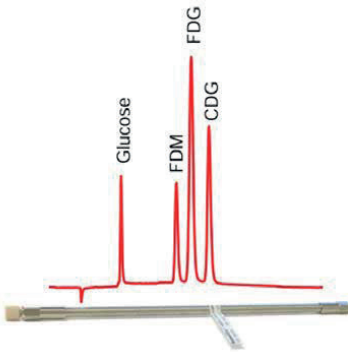
Technical Note

SweetSep™ AEX18 columns



Certificate of Compliance SweetSep™ AEX18 column for FDG and Impurities Analysis

Ph. Eur. 11 method equivalence Monograph

1325 Fludeoxyglucose (^{18}F)

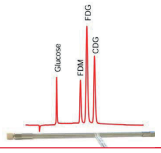
Summary

The 2.1 x 185 mm SweetSep AEX18 column (pn 260.0051), operated as described in Antec Application Note 217_045_07 [1], is equivalent to the conditions prescribed in Ph. Eur. monograph 01325 (Fludeoxyglucose (18F) injection) for the determination of 2-fluoro-2-deoxy-D-glucose and impurity A (CDG).

Every adjusted parameter – stationary phase chemistry, column length/particle size (L/dp ratio), internal diameter, flow rate, injection volume, temperature, and mobile phase composition/pH – falls within the ranges explicitly permitted by Ph. Eur. general chapter 2.2.46 for isocratic liquid chromatography (itself applied under the umbrella of general chapter 2.2.29, Liquid chromatography).

All numerical claims in this table were independently rederived from the EP equations in the monograph and general chapter 2.2.46 [2,3] and cross checked against the application note's own values.

This document serves as a guide for end users to verify compliance of the SweetSep AEX18 column for the impurity analysis of CDG in (18F) FDG following the Ph. Eur.



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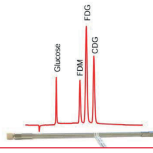
EP method Equivalence Table — SweetSep™ AEX18 vs. Ph. Eur. Monograph 01325, Fludeoxyglucose (^{18}F) Injection*

Basis: Ph. Eur. 11.0 monograph 01325 (Fludeoxyglucose (18F) injection); Ph. Eur. general chapters 2.2.29 (Liquid chromatography) and 2.2.46 (Chromatographic separation techniques, isocratic LC adjustment rules); USP Chromatographic Columns database (packing L46); Antec Scientific Application Note 217_045_07 ('[18F]FDG – Fluorodeoxyglucose according EP method').

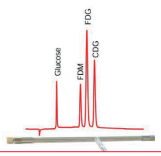
#	Parameter	Prescribed Condition (EP Monograph 01325)	EP-Allowed Adjustment (Gen. chapter 2.2.29 / 2.2.46)	Allowed Range / Calculated Limit	Actual Condition (App Note 217_045_07)	Compliance Check	Result	Evidence / Reference
1	Stationary phase — chemical identity	Strongly basic anion-exchange resin for chromatography R (10 µm): quaternary amine groups on a polystyrene/divinylbenzene latex lattice (Ph. Eur. ch. 4.1.1 Reagents).	2.2.46 (isocratic LC): 'No change of identity of the substituent… other physico-chemical characteristics (support, surface modification, extent of modification) must be similar.'	Same functional group (quaternary amine) and same support chemistry (PS/DVB – latex) required.	SweetSep AEX18: polystyrene/divinylbenzene particles agglomerated with quaternary-amine-functionalised latex nano-beads, 5 µm, USP L46 listed.	Identical functional chemistry (quaternary amine on PS/DVB latex); USP L46 generic description matches ('PS/DVB substrate agglomerated with quaternary amine functionalized latex beads').	Equivalent	Monograph 01325 p.1 (Definition/Tests); USP Chromatographic Columns – L46 description; App Note p.3 (Column section)
2	Compendial packing classification (USP)	EDQM practical-information sheet for mono. 1325 notes 'Column: CarboPac PA10 is suitable' (a USP L46 packing).	Not an adjustable parameter — cross-check of compendial packing class only.	n/a	SweetSep AEX18 is listed in the official USP Chromatographic Columns database under packing L46, category 'Other columns (manufacturer submitted)'.	AEX18 confirmed present in the USP L46 listing alongside CarboPac PA10/PA1, ICSep AN1, Metrosep A Supp 1/3, OmniPac PAX100.	Equivalent	EDQM Knowledgebase mono/1325 (Practical Information); USP Chromatographic Columns database (L46 search)
3	Column length (L)	l = 0.25 m (250 mm)	2.2.46: length may change provided L/dp ratio stays within −25% to +50% of prescribed ratio (see L/dp row below).	Evaluated jointly with particle size via L/dp ratio.	185 mm	See L/dp ratio row.	Equivalent	Monograph 01325 p.2 (Column); App Note p.2 Table 1, p.3–4
4	Particle size (dp)	10 µm	2.2.46: particle size may change provided L/dp ratio stays within −25% to +50% of prescribed ratio.	Evaluated jointly with column length via L/dp ratio.	5 µm	See L/dp ratio row.	Equivalent	Monograph 01325 p.2 (Column); App Note p.3 (Column section)
5	L/dp ratio (length ÷ particle size)	25000	2.2.46: −25% to +50% of the prescribed L/dp ratio.	18750 – 37500	37000	+48% vs. monograph; within allowed −25%/+50% window	Equivalent	App Note p.3–4 (text & eq.); EP 2.2.46 'Column dimensions (particle size, length)', Ph. Eur. 11.0 p.93
6	Column internal diameter (dc)	Ø = 4.0 mm	2.2.46: 'Internal diameter: No restrictions' — may be adjusted even without a change in particle size/length.	No restriction	2.1 mm (microbore)	Adjustment explicitly unrestricted by EP — reduces solvent consumption / increases mass sensitivity.	Equivalent	Monograph 01325 p.2 (Column); App Note p.2 Table 1, p.3 Table 2 ('Internal diameter: No restrictions'); EP 2.2.46, Ph. Eur. 11.0 p.93

*) Claude.ai was used for the initial research and verification of all info in the abovementioned resources (application note, EP documentation). The shown method equivalence table shown above was compiled after review of the ai output. Reference: Anthropic, Claude.ai, 2026, Claude for Windows version 1.15962.1, Large Language model Sonnet 4.6, https://claude.ai/

Certificate of Compliance SweeSep™ AEX18 column for FDG and Impurities Analysis



#	Parameter	Prescribed Condition (EP Monograph 01325)	EP-Allowed Adjustment (Gen. chapter 2.2.29 / 2.2.46)	Allowed Range / Calculated Limit	Actual Condition (App Note 217_045_07)	Compliance Check	Result	Evidence / Reference
Mobile phase								
7	Mobile phase composition (NaOH concentration)	4 g/L NaOH in CO2-free water ≡ 100 mM (monograph eluent)	2.2.46 (isocratic LC): mobile phase component(s) adjustable ±10% absolute.	90 – 110 mM	90 mM NaOH (LPG-mixed from 100 mM stock (A) + DI water (B), 90:10)	90 mM = exactly −10% vs. monograph — at the boundary of the allowed window	Equivalent (at limit)	Monograph 01325 p.1 (Tests, Mobile phase); App Note p.2 Table 1, p.4 (Mobile phase text), p.3 Table 2
8	Mobile phase pH	Not stated numerically (defined via NaOH concentration); corresponds to ≈ pH 13.	2.2.46: pH of the aqueous mobile-phase component adjustable ±0.2 pH units.	≈ 12.8 – 13.2	≈ pH 13 (90 mM NaOH, carbonate-free)	Calculated pH shift from 100 → 90 mM NaOH (≈ −0.05 pH units) is far inside the ±0.2 unit allowance.	Equivalent	App Note p.4 (Mobile phase preparation); EP 2.2.46, Ph. Eur. 11.0 p.93
9	Protection from atmospheric CO2 / carbonate build-up	'Protected from the atmosphere during chromatography' (carbon dioxide-free water R).	Not an EP-quantified adjustment — qualitative requirement.	n/a	N2-blanketed ET 210 eluent tray; carbonate-free 50% w/w NaOH; N2-sparged 18.2 MΩ·cm water; PPCO (not glass) bottles to avoid silicate/borate leaching.	Requirement met and reinforced with additional engineering controls beyond the literal monograph text.	Equivalent	Monograph 01325 p.2 (Mobile phase); App Note p.2 (ET 210 description), p.4 (Mobile phase preparation)
Flow rate, detection settings, separation temperature and injection volume								
10	Flow rate (F)	1.00 mL/min	2.2.46: $F2 = F1 \times [(dc2^2 \times dp1)/(dc1^2 \times dp2)]$ for dimension changes, plus a further ±50% allowed after that adjustment.	0.276 – 0.827 mL/min (around corrected F2 = 0.55 mL/min)	0.28 mL/min	0.28 mL/min falls within the ±50% window around the dimension-corrected 0.55 mL/min (chosen for optimal resolution & lower eluent use)	Equivalent	Monograph 01325 p.2 (Mobile phase, flow rate 1 mL/min); App Note p.3–4 (eq. 1 & flow-rate text); EP 2.2.46, Ph. Eur. 11.0 p.93
11	Separation / column temperature	25 °C	2.2.46: ±10 °C where an operating temperature is specified.	15 – 35 °C	35 °C (used for separation and detection)	35 °C sits exactly at the +10 °C upper boundary — selected for best resolution/S-N and lower backpressure	Equivalent	Monograph 01325 p.2 (Column, temperature 25 °C); App Note p.2 Table 1, p.4 (Temperature text); EP 2.2.46, Ph. Eur. 11.0 p.93
12	Injection volume	20 µL (based on 4 mm ID column)	2.2.46: $Vinj2 = Vinj1 \times [(L2 \times dc2^2)/(L1 \times dc1^2)]$ for dimension changes; a further decrease is always permitted if detection (S/N) and repeatability remain satisfactory.	4.1 µL (dimension-corrected value); further decrease permitted if S/N & RSD remain satisfactory	2 µL (full loop)	2 µL is a deliberate further decrease below the 4.1 µL corrected value; justified by S/N(FDG) = 1013 (req. >10) and area RSD ≤ 0.2% (n=10).	Equivalent	Monograph 01325 p.2 (Tests, injection 20 µL); App Note p.4 (eq. 2 & text), p.5 Table 3 & 6; EP 2.2.46, Ph. Eur. 11.0 p.94
13	PAD potential waveform	No specific potential waveform is prescribed in the monograph.	Not restricted — user may select/optimise waveform since none is mandated.	n/a	Classical 4-step waveform optimised for carbohydrates (E1–E4: +0.1, −2.0, +0.6, −0.1 V).	Permitted because the monograph is silent on waveform; selection improves reproducibility (RSD ≤ 0.2%) and minimises electrode wear.	Equivalent	Monograph 01325 p.2 ('no specific potential waveform… is described', by implication via detector text); App Note p.2 Table 1, p.4 (Detection)



Certificate of Compliance SweeSep™ AEX18 column for FDG and Impurities Analysis

#	Parameter	Prescribed Condition (EP Monograph 01325)	EP-Allowed Adjustment (Gen. chapter 2.2.29 / 2.2.46)	Allowed Range / Calculated Limit	Actual Condition (App Note 217_045_07)	Compliance Check	Result	Evidence / Reference
Retention & run time								
14	Retention time of FDG	12 min (informational only — EP 2.2.46: no acceptance criteria apply to retention times)	2.2.46: retention times in monographs are for information only; no acceptance criterion attached.	n/a (informational)	3.67 min	Faster elution is an expected/acceptable consequence of smaller particle size & shorter, narrower column; no EP criterion is breached because RT itself carries no pass/fail limit.	Equivalent	Monograph 01325 p.2 (Tests); App Note p.5 Table 4; EP 2.2.46 'Adjustment of chromatographic conditions' note, Ph. Eur. 11.0 p.93
16	Relative retention time — FDM vs. FDG	≈ 0.9	2.2.46: relative retentions in monographs are informational; no acceptance criteria apply.	n/a (informational; expected ≈ 0.9)	0.9 (3.30 min / 3.67 min)	Identical to the compendial relative retention value — confirms equivalent selectivity/elution order.	Equivalent	Monograph 01325 p.2 (Tests, Relative retention); App Note p.5 Table 4
17	Relative retention time — Impurity A (CDG) vs. FDG	≈ 1.1	2.2.46: relative retentions in monographs are informational; no acceptance criteria apply.	n/a (informational; expected ≈ 1.1)	1.1 (4.12 min / 3.67 min)	Identical to the compendial relative retention value — confirms equivalent selectivity/elution order.	Equivalent	Monograph 01325 p.2 (Tests, Relative retention); App Note p.5 Table 4
System suitability								
18	Resolution, FDM–FDG (reference solution c)	Minimum 1.5	System-suitability acceptance criterion — not an adjustable parameter; must be met regardless of adjustments made.	≥ 1.5 (pass/fail criterion)	2.4 (analytical column alone); 2.5 (with optional precolumn)	Measured resolution exceeds the EP minimum by a wide margin in both configurations.	Equivalent	Monograph 01325 p.2 (System suitability); App Note p.5 Table 3, p.7 Table 8
19	Signal-to-noise ratio, FDG (reference solution c)	Minimum 10	System-suitability acceptance criterion — not an adjustable parameter.	≥ 10 (pass/fail criterion)	1013 (analytical column alone); 956 (with optional precolumn)	Measured S/N exceeds the EP minimum by two orders of magnitude.	Equivalent	Monograph 01325 p.2 (System suitability); App Note p.5 Table 3, p.7 Table 8
Acceptance limits & method capability								
20	FDG limit in finished product	Maximum 0.5 mg per maximum recommended dose, V (mL) — e.g. 25 µg/mL at V = 20 mL.	Product specification, not a chromatographic adjustment — included to confirm method fitness-for-purpose.	Method must reliably quantify around 25 µg/mL.	LOQ(FDG) = 115 ng/mL (> 200× below the limit); linearity R = 0.99998 over 1–50 µg/mL.	Method sensitivity and linearity comfortably support quantitation at/around the EP limit.	Equivalent	Monograph 01325 p.1 (Definition, Content); App Note p.5–6 (Linearity Table 5; Limit of FDG & impurity A; Table 7)
21	Impurity A (CDG) limit in finished product	Maximum 0.5 mg per maximum recommended dose, V (mL) — e.g. 25 µg/mL at V = 20 mL.	Product specification, not a chromatographic adjustment — included to confirm method fitness-for-purpose.	Method must reliably quantify around 25 µg/mL.	LOQ(CDG) = 159 ng/mL (> 150× below the limit); linearity R = 0.99997 over 1–50 µg/mL.	Method sensitivity and linearity comfortably support quantitation at/around the EP limit.	Equivalent	Monograph 01325 p.2 (Tests, Limits); App Note p.5–6 (Linearity Table 5; Limit of FDG & impurity A; Table 7)
Matrix robustness								
22	Performance in authentic injection matrix	Test solution = the (undiluted) ^{18}F-FDG preparation to be examined (saline, residual ethanol, citrate/phosphate buffer typical of production).	Not an EP-quantified adjustment — robustness check supporting suitability for real samples.	Resolution and S/N must remain ≥ EP minima in the authentic matrix.	Standards spiked into a saline–citrate–ethanol matrix (6.6 mg/mL NaCl, 0.4 mg/mL sodium citrate dibasic sesquihydrate, 2.6 mg/mL trisodium citrate dihydrate, 1 mg/mL ethanol).	Resolution FDM–FDG = 2.4 and FDG–CDG = 2.5 in matrix — identical to DI-water results; matrix has no adverse effect on separation.	Equivalent	Monograph 01325 p.1 (Definition, sterile solution composition note); App Note p.6 (Sample analysis, Fig. 4)

Resources

The Ph. Eur. equivalence table is based on information from the following resources and tools:

1. Antec Scientific, Application Note # 217_045_07, '[18F] FDG – Fluorodeoxyglucose according EP method', https://antecscientific.com/wpcontent/muplugins/antecdownloads/files/apps/pharma/217_045_07%20%20FDG%20Fluorodeoxyglucose%20according%20EP.pdf
2. Antec Scientific, Application Note # 217_046_03, 'FDG long term stability', https://antecscientific.com/wpcontent/muplugins/antecdownloads/files/apps/clinical/217_046_03%20%20FDG%20long%20term%20stability.pdf
3. European Pharmacopoeia, monograph 01325, Fludeoxyglucose (18F) injection, EP 11.3 (2024), 5101 - 5103
4. European Pharmacopeia, Chapter 2.2.46, 'Chromatographic separation techniques, European Pharmacopeia', EP 11.6, (2025), 61156116
5. European Pharmacopeia, Chapter 4.1.1, 'Reagents', European Pharmacopeia', EP 11.0, (2025), 507—580
6. EDQM Online Knowledgebase, Monograph Details for monograph 01325, Fludeoxyglucose (18F) injection, https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/1325, accessed 30 June 2026
7. US Pharmacopeia, Chromatographic columns database, packing L46 search, https:// www.uspchromcolumns.com/, accessed 30 June 2026
8. Anthropic, Claude.ai, 2026, Claude for Windows version 1.15962.1, Large Language model Sonnet 4.6, https://claude.ai/

Claude.ai was used for the initial research and verification of all info in the abovementioned resources. In total 22 relevant method parameters & criteria were assessed.

Ordering information

ALEXYS FDG Analyzer (manual injector)	
180.0053WM	ALEXYS FDG Analyzer (incl. SenCell & Clarity CDS software#)

ALEXYS FDG Analyzer (AS 6.1L autosampler)	
180.0055W	ALEXYS FDG Analyzer - isocratic
116.4321	SenCell 2 mm Au HyREF
195.0035#	Clarity CDS single instr. incl LC, AS module

Columns	
260.0051	SweetSep AEX18, 2.1 x 185 mm column, 5 µm
260.0031	Borate ion trap, 2.1 x 50 mm column, 10 µm
260.0100*	Pre-column filter PEEK, 0.5 µm

#) The ALEXYS FDG Analyzer can also be fully controlled under Thermo Fisher Scientific ChromeleonCDS and Agilent OpenLab CDS. Please contact Antec for more details.

*) To protect the analytical column it is advised to use a precolumn filter. The pre-column filter PEEK, 0.5 µm (pn 260.0100) includes a starter pack of 4 replacement PEEK frits.

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For research purpose only. The information shown in this communication is solely to demonstrate the applicability of the ALEXYS system and DECADE Elite detector. The actual performance may be affected by factors beyond Antec's control. Specifications mentioned in this application note are subject to change without further notice.