

Supplement on validation studies performed.

Table 1 Validation results from the fractional elution method using NaOAc.

Validation parameter	GMP release criteria	Run 1	Run 2	Run 3
Visual appearance	Clear, colourless particle free	Pass	Pass	Pass
Radiochemical purity	$\geq 95\%$	100%	100%	100%
Chemical purity	Retention time = 10-11 min	10.63 min	10.65 min	10.54 min
Radionuclidic purity (half-life)	63-75 min	68.06 min	68.24 min	68.32 min
pH	4.0 – 8.0	7.5	7.5	7.5
Bacterial endotoxin	< 10 EU/ml	Pass	Pass	Pass
Filter integrity	≥ 3.45 bar	Pass	Pass	Pass
Ethanol content	< 10 %	Pass	Pass	Pass
Germanium breakthrough	< 0.001%	< 0.001%	0.001%	0.001%
Radio-yield	≥ 250 MBq at EOS	482 MBq	514 MBq	479 MBq
Sterility	No growth	Pass	Pass	Pass

Table 2 summarises the results for the automated synthesis method using a cationic pre-purification method.

Table 2 Validation results from the cationic purification method using NaOAc.

Validation parameter	GMP release criteria	Run 1	Run 2	Run 3
Visual appearance	Clear, colourless particle free	Pass	Pass	Pass
Radiochemical purity	≥ 95%	100%	100%	100%
Chemical purity	Retention time = 10-11 min	10.30 min	10.70 min	10.65 min
Radionuclide purity (half-life)	63-75 minutes	67.74 min	68.61 min	67.87 min
pH	4.0 – 8.0	7.5	7.5	7.5
Bacterial endotoxin	< 10 EU/ml	Pass	Pass	Pass
Filter integrity	≥ 3.45 bar	Pass	Pass	Pass
Ethanol content	< 10 %	Pass	Pass	Pass
Germanium breakthrough	< 0.001%	< 0.001%	<0.001%	<0.001%
Radio-yield	≥ 250 MBq at EOS	509 MBq	470 MBq	506 MBq
Sterility	No growth	Pass	Pass	Pass

Notes: EOS = End of synthesis