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Vrdnik Srbija

Aseptic Process Validation of [^{18}F]Fluorodeoxyglucose Production

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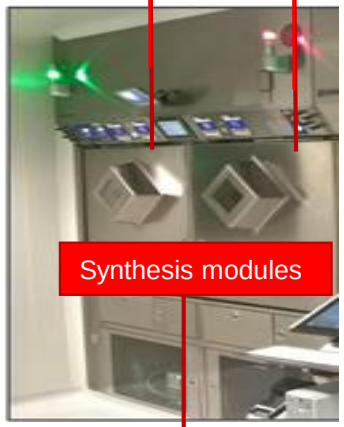
[^{18}F]Fluorodeoxyglucose Production Process

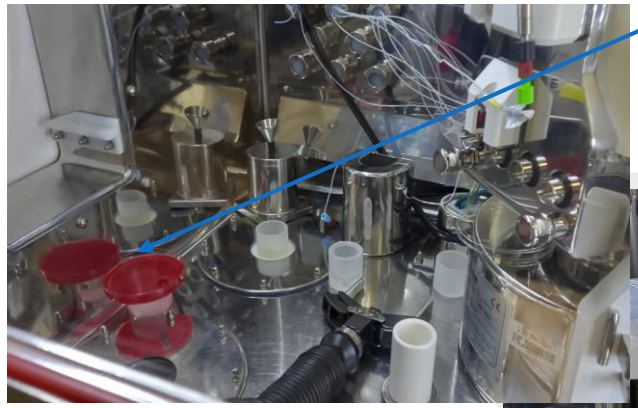
Synthesis hotcell BBS2-O

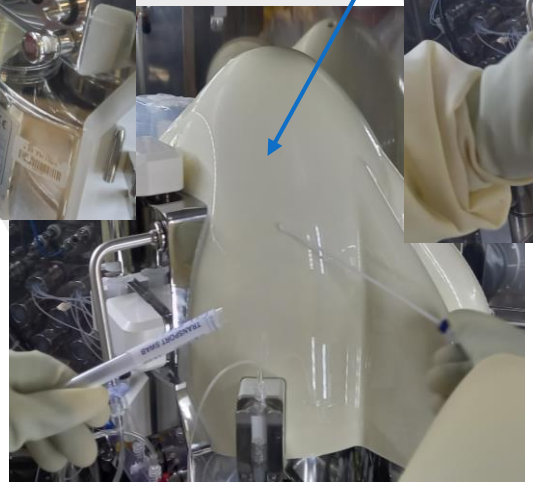
Dispensing hotcell Talia

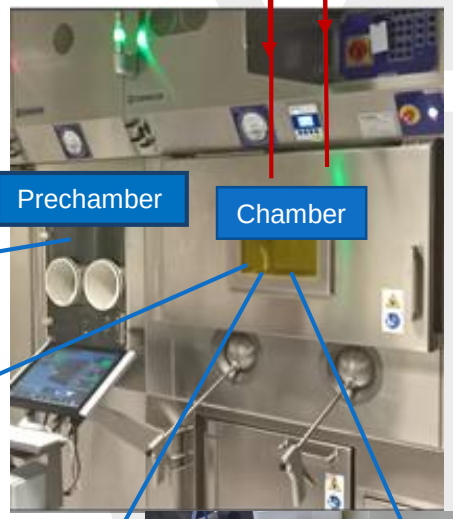
[^{18}F]FDG transfer lines



Synthesis modules







Prechamber

Chamber

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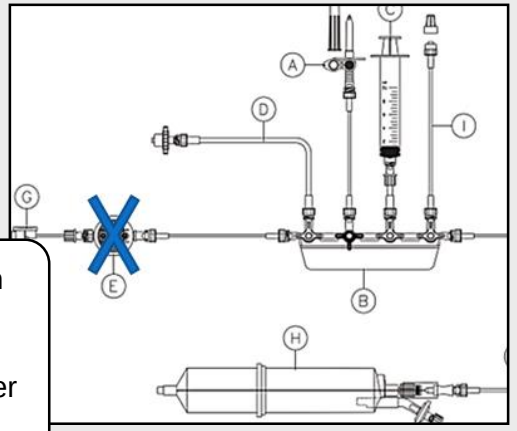

1. Bioburden

- without radioactivity
- without a filter for final sterilization

2. Media fill

- Tryptic Soy Broth (TSB) microbial growth medium, was used for process simulation

Results

	Bioburden testing			Media fill testing		
	1 batch	2 batch	3 batch	1 batch	2 batch	3 batch
Bacterial Endotoxins IU/ml (<17,5)	<5	<5	<5,46	5	6,38	<5,91
Sterility samples	All samples were sterile					

Microbiological monitoring during aseptic validation

		Settle plates (cfu/4 hours)			Glove print - 5 fingers (cfu/glove)			
	Positions	P3 (class B)	P5 (class A)	P11(class C)	FP1 (class B)	FP2 (class B)	FP3 (class A)	FP4 (class A)
Batch No.	1 Bioburden	0	0	0	0	0	0	0
	2 Bioburden	0	0	0	0	0	0	0
	3 Bioburden	0	0	0	0	0	0	0
	1 Media fill	0	0	0	0	0	0	0
	2 Media fill	0	0	0	0	0	0	0
	3 Media fill	0	0	0	0	0	0	0

Conclusion

The results of the operational process environmental monitoring (viable and non-viable) are within the criteria prescribed by EudraLex - Volume 4, Annex 1.

Aseptic Process Validation of [^{18}F]FDG has been completed successfully. It has been proven that even in the worst-case scenario, there is no microbiological growth during the processes of synthesis and aseptic dispensing.