

STABILITY STUDY OF [^{99m}Tc]Tc-EDDA/HYNIC-TOC and [⁶⁸Ga]Ga-DOTA-TOC IN SYRINGES



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OBJECTIVES

[^{99m}Tc]Tc-EDDA/HYNIC-TOC and [⁶⁸Ga]Ga-DOTA-TOC are two somatostatin analogues indicated in the diagnosis of somatostatin receptor bearing neuroendocrine tumours (NET). According to their Summary of Product Characteristics (SmPC), stability of the preparation have been demonstrated for 4 hours at temperature below 25°C in the original bottle.

But, what about the stability of a prolonged storage in propylene syringe?

MATERIAL AND METHODS

- Appearance, pH, radiochemical purity, particulate contamination, sterility and endotoxin tests were made in compliance with the monographs of the European Pharmacopoeia and the SmPC after **2h of storage in syringe**.
- Adsorption test : to compare the residual activity in syringe before and after storage (n=4). Comparisons between groups were performed using a paired t-test. The null hypothesis was rejected for p < 0.05.

3-piece syringe, **Polypropylene** (PP) barrel and piston, BD Emerald (ref : 307731)



Washed **3 times** with NaCl 0,9%



Activity measurement

RESULTS

Drug specifications and results after 2h storage

Recommandations (SmPC + Ph.Eur)	[^{99m} Tc]Tc-EDDA/HYNIC-TOC (Tektrotyd®)	Results	[⁶⁸ Ga]Ga-DOTA-TOC (Somakit-TOC®)	Results
Visual aspect	Clear, colorless	✓	Clear, colorless	✓
pH (pH-indicator strips)	unchanged	✓	3.2-3.8	✓
Radiochemical purity (Thin Layer Chromatography)	≥90%	✓	≥95%	✓
Particulate contamination (liquid particle counter system)	- Free of visible particles - Subvisible particles : (2.9.20 monograph) ≤ 6000 greater than 10µm and ≤ 600 greater than 25µm	✓	- Free of visible particles - Subvisible particles : (2.9.20 monograph) ≤ 6000 greater than 10µm and ≤ 600 greater than 25µm	✓
Sterility (liquid culture medium)	sterile	✓	sterile	✓
Endotoxin	In compliance with European Pharmacopoeia (5.1.10 monograph, with k=2.5 IU)	✓	In compliance with European Pharmacopoeia (5.1.10 monograph, with k=2.5 IU)	✓

Adsorption Test

	Without storage (immediate)	After 2 h storage in PP syringe
	A0 (MBq)	% Adsorption = Activity in washed medical device (Awd)/Activity in washing solution (Aws) x 100
Tektrotyd® (n=4)	495.9	1.6
	694	1.4
	512.2	1.6
	410.1	1.8
Somakit-Toc® (n=4)	143.7	1.9
	151.0	1.8
	157.2	1.7
	185.3	1.2

Paired t-test :

Tektrotyd® :

Mean without storage = 1.6% vs with storage = 1.75%
p=0,022<0.05 (significant)

Adsorption is more important with the storage but it remains minor

Somakit-toc®

Mean without storage = 1.65% vs with storage = 1.65%
p=1>0.05 (non significant)

There is no difference

DISCUSSION AND CONCLUSION

[^{99m}Tc]Tc-EDDA/HYNIC-TOC and [⁶⁸Ga]Ga-DOTA-TOC repackaged in PP syringes **retained their quality after dispensing and prolonged storage for up to 2h** subject to sufficient activity to perform an interpretable image.

