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Large-scale, GMP-compliant production and quality control of Al^[18F]F-NOTA-Octreotide

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Abstract:

Aim/Introduction: [⁶⁸Ga]Ga-DOTATATE is well established for PET/CT imaging of neuroendocrine tumors (NET). Al^[18F]F-NOTA-Octreotide is an emerging radiotracer for the same indication, allowing for large-scale, centralized production improving patient access to precision imaging for the same indication[1]. In this work, our objective was to evaluate the production capacity and the influence of starting activities on critical parameters such as radiochemical yields (RCY), purity (RCP), reliability and stability. **Materials and Methods:** A GMP-compliant production process for Al^[18F]F-NOTA-Octreotide was developed, optimized, and validated at two independent radiopharmacies. Briefly, [¹⁸F]fluoride was trapped on a QMA cartridge, rinsed with water, and eluted with EtOH/NaCl 0.9%. Subsequently, the precursor solution was added and heated to 100 °C for 10 minutes before standard workup and reformulation. Quality control was performed including appearance, pH, radionuclidic, radiochemical, and chemical purity, residual solvents, endotoxins, and sterility, compliant with the European pharmacopeia. We collected and analyzed 60 production records from executed between August 2022 and March 2023, applying the same methods for production and quality control. **Results:** From starting activities of 157,8 ± 47,5 GBq we obtained an overall average of 51,0 ± 23,5 GBq (31,8 ± 9,8 % RCY n.d.c., n=57) Al^[18F]F-NOTA-Octreotide with 96,5 ± 2,9 % RCP. The implemented process can provide up to 100 GBq of Al^[18F]F-NOTA-Octreotide with high RCPs and stability was confirmed of up to 10h EOS. Of a total of n=61 analyzed production batches, n=3 (5%) were out of specification, n=1 (1.6%) resulted in no product and from n=57 batches, 550 doses have been supplied to >10 PET imaging sites with excellent clinical results as previously published[3] **Conclusion:** Al^[18F]F-NOTA-Octreotide can be obtained in large amounts, with excellent and reliable radiochemical yields and purity, and improves patient access to precision diagnostic imaging of NETs. **References:** 1. Pauwels, E.; Cleeren, F.; Tshibangu, T.; Koole, M.; Serdons, K.; Boeckxstaens, L.; et al. (18)F-AIF-NOTA-octreotide outperforms (68)Ga-DOTA-TATE/-NOC PET in neuroendocrine tumor patients: results from a prospective, mul-ticenter study. J Nucl Med. 2022. Epub 2022/10/21. doi: 10.2967/jnumed.122.264563. PubMed PMID: 36265911. 2. Tshibangu, T.; Cawthorne, C.; Serdons, K.; Pauwels, E.; Gsell, W.; Bormans, G.; et al. Automated GMP compliant production of [(18)F]AIF-NOTA-octreotide. EJNMMI Radiopharm Chem. 2020;5(1):4. Epub 2020/01/31. doi: 10.1186/s41181-019-0084-1. PubMed PMID: 31997090; PubMed Central PMCID: PMC6989705. 3. Haeger A.; Soza-Ried C.; Kramer V. et al.; Al[18F]F-NOTA-Octreotide Is Comparable to [68Ga] Ga-DOTA-TATE for PET/CT Imaging of Neuroendocrine Tumours in the Latin-American Population. Cancers 15 (2), 439

Site	N° Prod.	[¹⁸ F]Fluoride / GBq	Al ^[18F] F-NOTA-OC / GBq	RCY / % (n.d.c.)	RCP / % EOS
A	n=39	176,2 ± 47,8	58,5 ± 24,4	33,0 ± 9,4	95,9 ± 3,0
B	n=18	121,5 ± 26,4	33,4 ± 14,5	27,9 ± 11,7	97,3 ± 1,6
All	n=57	157,8 ± 47,5	51,0 ± 23,5	31,8 ± 9,8	96,5 ± 2,9

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