99mTc-MAA for Lung Perfusion Scintigraphy: Impact of Counting Method on the Effective Number of Particles Administered and Particle Aggregation Over Time

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Introduction: 99mTc-MAA (macroaggregates of albumin) is the selected radiopharmaceutical for the Lung Perfusion Scintigraphy. It is retained in lung capillaries by mechanical blockage resulting in local microembolization. Care should be taken concerning not only particle size but also the number of particles administered to patients, particularly those who present with special conditions (pulmonary hypertension, shunt or lung transplant). European Pharmacopoeia only requires the assessment of particle size. This work aims to characterize particle size and particle aggregation of two commercial brands of MAA kits and to compare particle counting methods.

Material and Methods: Twenty kits of 99mTc-MAA from two distinct sources were labeled according to respective manufacturer’s instructions. Two aliquots of 1 ml from each kit were collected to pre-identified tubes. Particle counting was performed by at least three distinct observers using two distinct methods: the “empirical” (based on the relation between the total number of particles per vial and the correspondent administered volume) and the “experimental” (based on the hemocytometer determination). A “pool” of four independent observers was involved in the experimental approach, always using the same optical microscope and hemocytometer. Particle counting from each 1ml-aliquots was done in triplicate by each observer, resulting in 6 evaluations per observer/per kit, so 120 evaluations in total. Both methods were compared using linear regression to obtain the R² value.
(correlation coefficient) while simultaneously accessing the inter-observer variability at the hemocytometer determination. Results were compared using Student-t test.

**Results:** As an example of the already obtained results, it has been experimentally determined a mean number of particles of 1,05 millions/ml, to be compared with the correspondent value of 1,5 millions/ml empirically determined. Considering the inter-operator variability in the experimental calculation, it has been registered a variability superior to 5%. All samples complied with European Pharmacopoeia concerning particle size. No particles above 150 µm and no more than 0,2% of particles above 100 µm were observed.

**Discussion and Conclusion:** Obtained results show that the number of particles calculated by different methods could vary, and that the operator’s intrinsic characteristics are important in the experimental determination. Empirical method is easier to perform, less time consuming and does not require special equipment. On the other side, by choosing the experimental method, one has the opportunity to assess particle size simultaneously, as stated by the European Pharmacopoeia.
Foi decidido que não será apresentada a versão integral deste documento.

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