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Short Communication

Bio-Pharmaceutical Manufacturing Large Scale Production Process: The graphene - Derivates Role and mRNA Vaccine

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Aim of this work is to investigate the role played by graphene and its derivates in some relevant manufacturing process like purification and absorption.

The chemical physical properties of this innovative product make possible to understand why they are used in many bio-medical and other fields like biosensors, in water purifying, to remove heavy metals procedure, in diagnostic field but also in extraction, purifying DNA, RNA and other biomolecule, carrier, adjuvant, antibacterial and other biological and industrial use.

The large scale production is different from a laboratory scale but the same chemico-physical properties are used.

The classic drug manufacturing production as well as biopharmaceuticals need to verify the presence of impurity in the raw material and in the finished drugs for regulatory need and for patient safety.

For this reason, it is interesting to verify the use in some large scale manufacturing procedure of innovative products like mRNA Vaccine.

Because this products graphene oxide and other product related is recognized with toxicological properties it is strongly recommended by the authors if used in the manufacturing process to test in the final product the full absence of this molecule with written report inside the technical sheet approved.

Conclusion

Related the reference analyzed it is clear that because impurity was finded in various classic approved chemical drugs in past time as well as in some bio-pharmaceutical products.

it is interesting, related last evidence Giovannini., *et al*, P. Campra, Young RO and Young MI Lee., *et al*. to investigate the topic related the absence of graphene derivates and some m RNA covid-19 vaccine.

Many process and bio-technology use Graphene derivates product in example in purifying - extracting RNA (Or related the property of absorption, carrier, adjuvant, to increase RNA stability, magnetic micro-bead for improve extractions procedures).

Observing all this reported in references it is needed that regulatory agency as mandatory order require specific written report related certification about graphene derivates absence in the final bio-pharmaceutical products (every batch/lot) And This also for the raw material: it must to be certified and reported in the technical and security sheet.

This even if EMA have already verified absence of graphene and derivates like GO (P-00303/2022 (ASW).

It is necessary that regulatory agency provide written information about the pre-treatment method used by the controlling lab for lots release for the sample testing (before the assay with Raman spectroscopy it is used a destructive or not destructive method?).

Many time the final producers use raw materials coming from other provider: for this reason it is also needed to test for graphene derived this raw material.

It is not acceptable that the manufacturing procedure and techniques are not entirely knowed by regulatory agency, researcher and by the public opinion (what kind of extraction technique used and what materials used? for all the productive process phases).

And this even if are present patent and other rights for the industrial pharmaceuticals producers.

The fact that a new technology provides great advantages in efficiency of production not mean that the safety and security criteria it not must be followed.

To make of full knowledge by the public opinion of this fact make possible to share to all a wider safety perception useful in the vaccination strategy.

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