STERILIZATION PROCESS ON POLYMERIC NANOPARTICLES FOR USE IN BIOLOGICAL MEDIA

Y. S. Tapia-Guerrero[1,2], F.V. Borbolla-Jiménez[2], G. Leyva-Goméz[3] and J.J. MagañaAuthor[2]

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Polymeric NanoParticles (NP) have shown to be promising drug-delivery systems for use in pharmaceutical and biomedical applications. Among others, Poly-(ε-CaproLactone) (PCL) and Poly-(D, L-lactic-co-Glycolic) Acid (PLGA) are two of the most effective coating agents for both nanospheres and nanocapsules . The usefulness of these NP drug-based formulations and the medical implications for their in vivo administration requires that manufacturing conditions be sterile and non-toxic .

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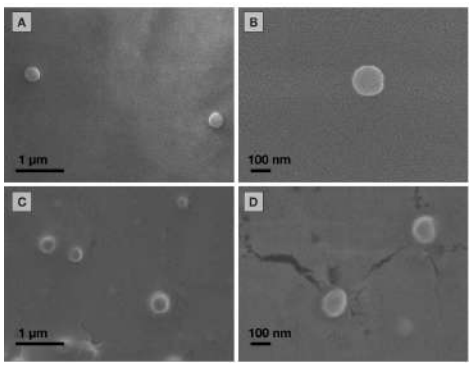


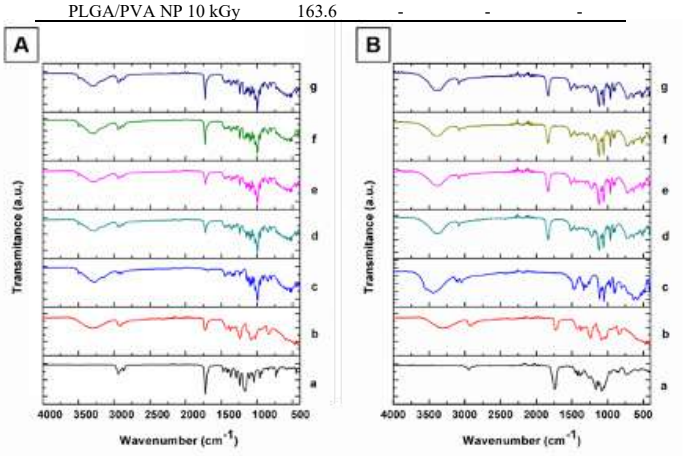
Sample	Size (nm)	PDI	Zeta Potential (mV)
PCL/PVA NP	228.8 ± 11.60	0.050 ± 0.10	−14.47 ± 1.76
PCL/PVA NP UV	232.5 ± 5.70	0.040 ± 0.06	−14.07 ± 0.25
PCL/PVA NP 5 kGy	213.6 ± 2.21*	0.080 ± 0.03	−18.53 ± 0.78*
PCL/PVA NP 10 kGy	208.8 ± 1.37**	0.110 ± 0.05**	−22.90 ± 0.66**
PLGA/PVA NP	243.1 ± 3.06	0.064 ± 0.02	−17.00 ± 0.17
PLGA/PVA NP UV	240.0 ± 1.55	0.070 ± 0.05	−18.16 ± 0.58
PLGA/PVA NP 5 kGy	209.6 ± 1.95***	0.046 ± 0.02	−17.00 ± 0.50
PLGA/PVA NP 10 kGy	217.0 ± 1.96***	0.028 ± 0.03**	−17.50 ± 0.40

**P ≤ 0.1, **P ≤ 0.01, and **P ≤ 0.001 compared with no irradiated system.

2

DSC

Sample	T_1 (°C)	T_2 (°C)	T_3 (°C)	T_4 (°C)
PCL	67.5	-	-	-
PVA	195.5	-	-	-
D-(+)-trehalose dehydrate	100.0	212.0	-	-
PCL/PVA NP	56.0	99.5	211.0	-
PCL/PVA NP UV	56.7	99.7	212.0	-
PCL/PVA NP 5 kGy	54.8	97.8	130.0	212.0
PCL/PVA NP 10 kGy	55.8	98.5	130.0	212.0
PLGA	50.4	241.4	-	-
Mannitol	167.0	-	-	-
PLGA/PVA NP	165.3	-	-	-
PLGA/PVA NP UV	165.5	-	-	-
PLGA/PVA NP 5 kGy	165.1	-	-	-
PLGA/PVA NP 10 kGy	163.6	-	-	-



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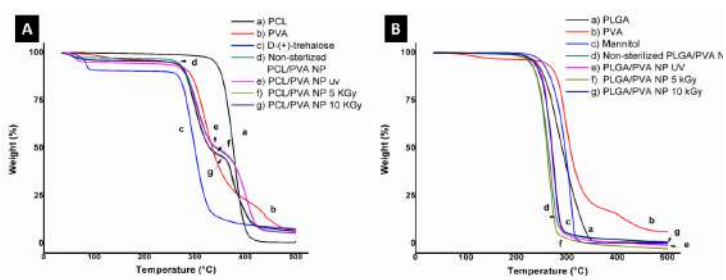

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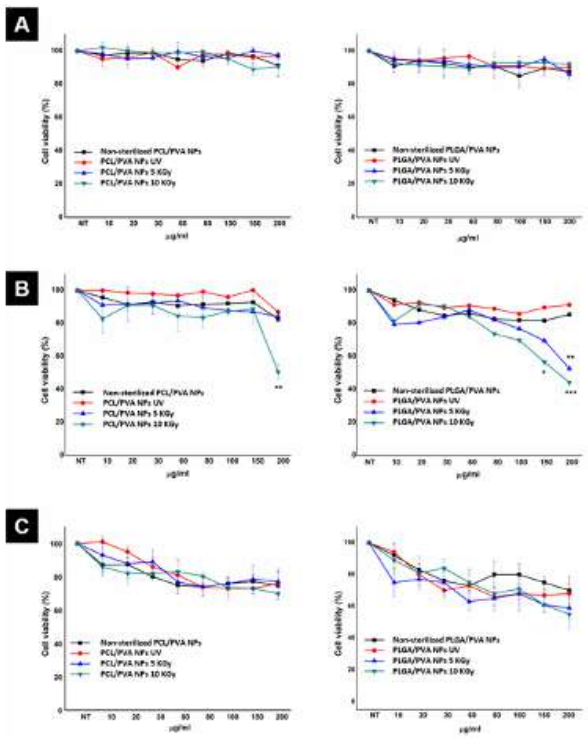

Conclusions: The 2 h UV radiation at (100 uJ/cm^3) could be highly effective and low-processing-time options for sterilizing NP for medical purposes. However, we suggest validating each NP system, because these generally are of different polymer-composition systems.

1. Morphology of nanoparticles by scanning electron microscopy (A) PCL/PVA 25,000×, (B) PCL/PVA 100,000×, (C) PLGA/PVA nanoparticles (NP) 25,000×, and (D) PLGA/PVA NP 100,000×., **2.** FTIR . (A) Spectra of the PCL/PVA NP system; (a) PCL, (b) PVA, (c) trehalose, (d) non-sterilized PCL/PVA NP, (e) PCL/PVA NP after 2 h UV radiation (100 uJ/cm^3), (f) PCL/PVA NP after 5 kGy of gamma radiation, and (g) PCL/PVA NP after 10 kGy of gamma radiation. (B) Spectra of the PLGA/PVA NP system; (a) PLGA, (b) PVA, (c) mannitol, (d) non-sterilized PLGA/PVA NP, (e) PLGA/PVA NP after UV radiation, (f) PLGA/PVA NP after 5 kGy of gamma radiation, and e) PLGA/PVA NP after 10 kGy of gamma radiation. **3.** Figure **3.** (A) Thermogram of the PCL/PVA NP system (B) Thermogram of the PLGA/PVA NP system. **4.** PCL/PVA and PLGA/PVA NP cell viability by MTT assay. Cells were treated for 24 h (A), 48 h (B), and 72 h (C) with 10-200 µg/mL of PCL/PVA NP and PLGA/PVA NP,