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Dear Colleagues,

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To finish, I hope that all of you will enjoy the Conference, and I wish our visitors from abroad will have a very pleasant stay in Paris.

Thank you

Prof. Mario Monzón Verona Ph.D.

Mechanical Engineering Department
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Preparation and characterization of nanoparticles containing cefaclor monohydrate by nano-spray drying method for extended release

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1. Introduction – Cefaclor monohydrate (CEF) belongs to cephalosporin antibiotic group for oral administration. The plasma half-life of CEF is 2.3 to 2.8 hours. As half-life is short, recurrent doses are needed in CEF-treated diseases [1].For these reasons; CEF is a candidate drug for extended-release dosage forms. Nanoparticles (NPs) are matrix systems that are prepared with natural or synthetic polymers with sizes in the range of 10 to 1000 nano-meter (nm) [2]. Eudragit® RS 100 (ERS) has been used for various applications such as extended release, bioavailability enhancement, NP production [3]. In this study NPs prepared with nano-spray drying methods and characterized for oral use aiming to extended release of CEF.

2. Experimental - NPs of CEF with the different ratios of CEF/ERS were prepared using Nano Spray-Dryer (B90, Büchi Labortechnik AG, Switzerland). For the preparation of NPs, ERS was dissolved in methanol prior to the addition of CEF. Spray-drying conditions and formulations ingredients are summarized in Table 1 and Table 2, respectively. Structures and characters of NPs were elucidated by particle size (PS), Polydispersity index (PDI) and zeta potential (ZP), encapsulation efficiency (EE%), in vitro dissolution in pH 6.8 PBS, release kinetics profiles by DDSolver software. EE% and *in vitro* release studies were carried out by UPLC method [1].

Inlet Temperature	Outlet Temperature	Pump Level	Spray Level
120°C	54°C	3	%100

Table II. Formulations ingredients

Code	ERS	CEF	Methanol
Blank	1.5 g	-	100 mL
NP-1	1.5 g	75 mg	100 mL
NP-2	1.5 g	150 mg	100 mL

Table III. Analysis Results

	Blank	NP-1	NP-2
PS (nm)	186.7□9.0	328.2□12.5	389.1□11.7
PDI	0.3□0.1	0.4□0.1	0.4□0.1
ZP (mV)	+40.2□	+39.7□	+36.80□
EE %	-	84.4□2.1	78.5□1.4

3. Results and Discussion - Table 3 are summarized the results of PS, PDI, ZP and EE %. It was observed that the PS increased and the EE % decreased as the amount of CEF into the nanoparticles increased. All NPs presented PDI values lower than 0.5 and therefore particle size distribution was decided to be monodisperse. Positive ZP values of NPs highlighted the presence of cationic ammonium group of ERS. *In vitro* release profiles of pure CEF and the NPs prepared are presented in Figure 1. At the end of the 3rd hour, pure CEF powder reached 96.3□2.4%(mean□SD) cumulative release rate while NP-1 and NP-2 coded formulations reached 38.4□3.4% and 51.6□2.7%, respectively. As seen in Figure 1, the release profiles of NPs showed the extended release of CEF from NPs. When the release results obtained according to **Table I.** Spray-Drying Conditions DDSolver criteria are examined; NP-1 and NP-2 coded formulations were fitted to KorsmeyerPeppas model (r^2= 0.995 and r^2=0.997 for NP-1 and NP-2 coded formulation, respectively).

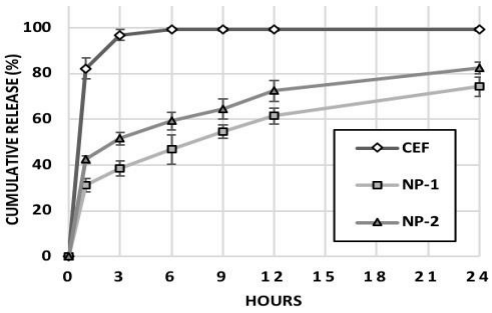

Figure 1. In vitro release profile of CEF and NPs

4. Conclusions - It can be concluded that CEF-loaded NPs are extended-release drug systems for oral administration.

5.References

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