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PREFORMULATORY STUDIES ON ROSMARINIC ACID-NLC FOR ORAL ADMINISTRATION

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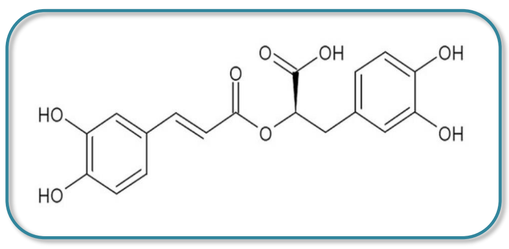
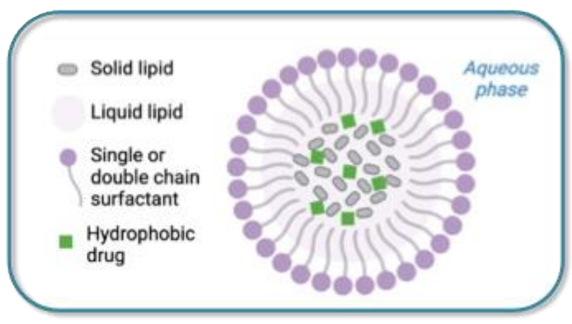
INTRODUCTION & AIM

Rosmarinic Acid (RA)
natural polyphenol from *Rosmarinus officinalis with*
antioxidant, anti-inflammatory, antidiabetic, antitumor, antimicrobial and antiviral properties.



Limited pharmaceutical application due to poor water solubility, low bioavailability, and rapid degradation in the gastrointestinal tract.
Fast metabolism and elimination further reduce RA efficacy[1].



This study aims to develop **nanostructured lipid carriers (NLCs)** to enhance oral bioavailability, to protect RA from gastric degradation, to allow for prolonged intestinal release, thereby improving its therapeutic potential.

METHOD

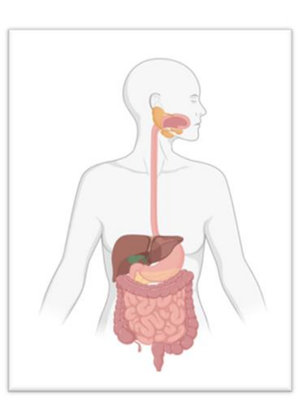
➢ ***HOT HOMOGENIZATION FOLLOWED BY ULTRASONICATION***

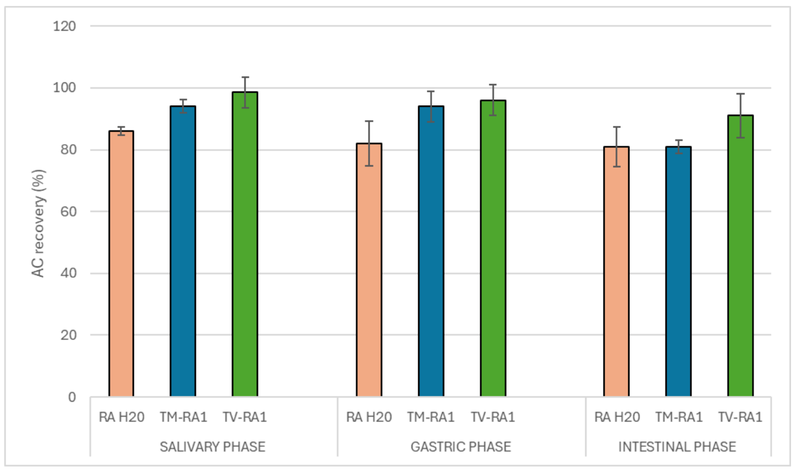
- **Lipid phase**
  Tristearin:Miglyol® (TM) or Vitamin E (TV) 2:1 w/w
- **Aqueous phase**
  Poloxamer 188 (2.5% w/w)
- **RA: 0.5, 1 or 2 mg/ml**

➢ **ANTIOXIDANT ACTIVITY: *PHOTOCHEMILUMINESCENSE* (PCL)**

FORMULATION	µmoliTE/ml
RA/H20	17.4
TM-RA$_1$	15.55 ± 0.35
TV-RA$_1$	15.80 ± 0.42

➢ **STATIC DIGESTION**

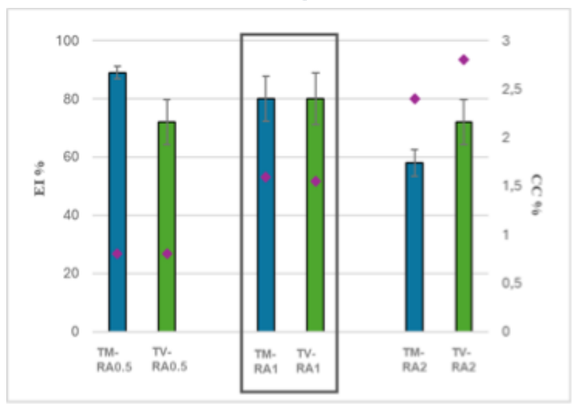




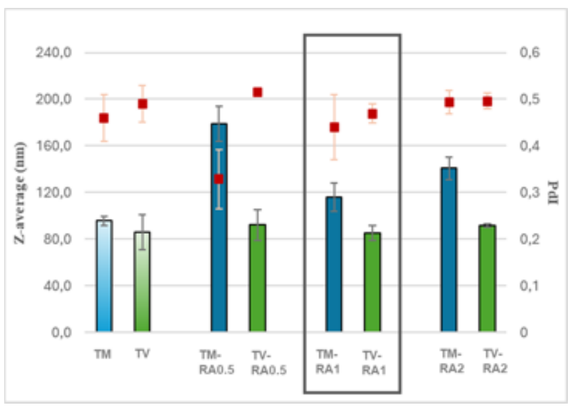
RESULTS & DISCUSSION

❖ ***PREFORMULATORY STUDY***

HPLC analysis

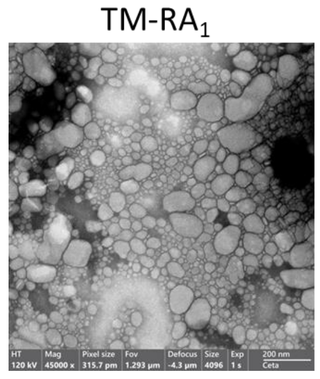


PCS analysis

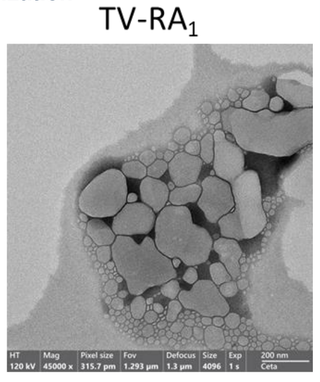


TEM visualization

TM-RA$_1$



TV-RA$_1$

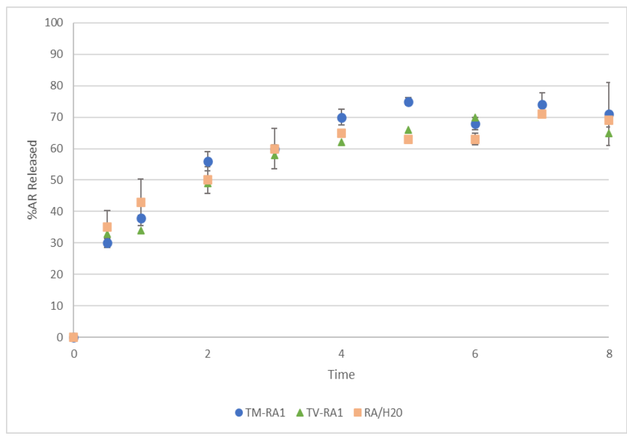


TM-RA$_1$ and **TV-RA$_1$**
(1 mg/ml of RA) were selected and subjected to morphological and charge characterization by TEM, Z-potential measurements, stability and *in vitro* studies.
Formulations remained stable up to 90 days post-production in terms of encapsulated RA (80%) and size, without significant variations in size distribution and polydispersity.

❖ **IN VITRO *STUDIES***

➢ **EQUILIBRIUM DIALYSIS**

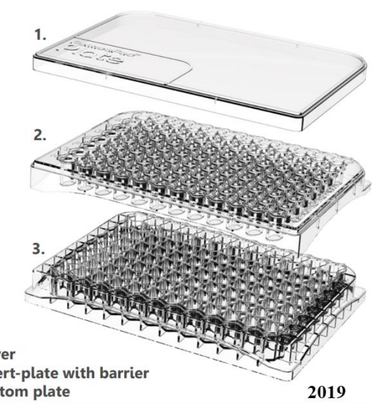
Nylon membrane
cut-off 10-12 kDa
Receiving phase H_2O:Etanol 70:30 v/v



FORMULATION	ORDER ZERO	FIRST ORDER	SECOND ORDER	KORSMEYER-PEPPAS	
		R^2		R^2	n
RA/H20	0,717	0,8309	**0,9235**	0,9767	**0,3**
TM-RA$_1$	0,850	0,959	**0,9852**	0,9890	**0,4**
TV-RA$_1$	0,807	0,915	**0,9649**	0,9492	**0,3**

➢ **PERMEAPAD® PLATE BIOMIMETIC BARRIER[2]**

Receiving phase PBS 73 mM pH 7,4



1: Cover
2: Insert-plate with barrier
3: Bottom plate

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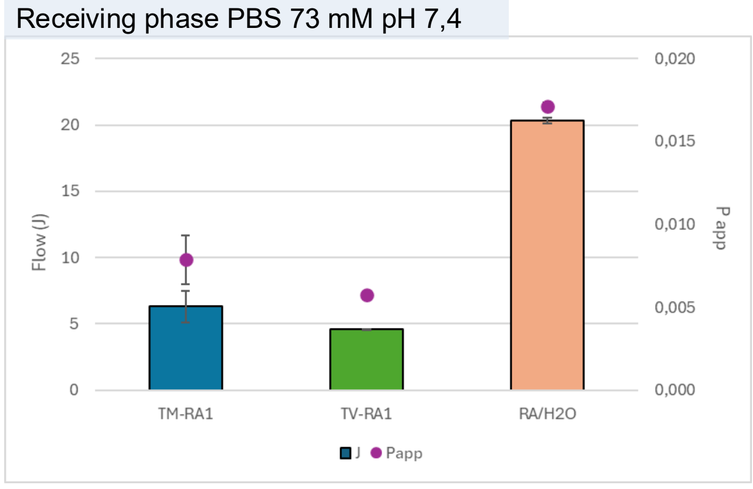

CONCLUSIONS

- ❑ RA, encapsulated in the nanoparticles, maintains unchanged antioxidant activity compared to the reference solution.
- ❑ *In vitro* release study by equilibrium dialysis showed a controlled, time-dependent release of RA, following second-order kinetics consistent with the Higuchi model.
- ❑ Permeability tests using the PermeaPad® Plate[2] revealed a five-fold reduction in RA diffusion compared to aqueous suspension, supporting sustained release.
- ❑ Static *in vitro* digestion confirmed that NLCs protect RA from gastric degradation, enabling intact delivery to the intestinal environment and promoting absorption.

FURTHER STUDIES/REFERENCES

- ❑ Further studies will be conducted including NLC in gel-based systems to improve mucosal adhesion

1. MK Azhar et al., *Nutrients*. **2023** (doi: 10.3390/nu15194297)
2. M Sguizzato et al., *Int J Pharm.* **2025** (doi:1 0.1016/j.ijpharm.2025.125170)