PROBLEM D

Sr. IDP

Bioavailability Enhancement of Palmitoylethanolamide(PEA)

Palmitoylethanolamide (PEA) is a promising anti-inflammatory and analgesic nutraceutical ingredient; however, its **extremely low aqueous solubility, high crystallinity, and poor dissolution rate** severely limit its oral bioavailability. These physicochemical challenges result in slow gastrointestinal dispersion, limited intestinal uptake, and high dose requirements. Existing approaches, such as micronization or simple blending, provide only partial improvement and do not sufficiently overcome solubility-driven absorption barriers.

The challenge is to develop a **scientifically justified, nutraceutical-acceptable (specifically for EU market), and scalable formulation strategy** that significantly enhances the solubility, dispersibility, and oral absorption of PEA while maintaining stability and safety.

The solution should propose:

- **A rational formulation, composition, and choice of excipients** suitable for nutraceutical use.
- **The mechanistic basis** for improved solubilization and absorption of PEA.
- **A scalable manufacturing process.**
- **Analytical and biopharmaceutical evaluation methods**, such as in-vitro dissolution, solubility profiling, or predictive modeling, to assess bioavailability enhancement.

The final deliverable must demonstrate a **practical, industry-ready formulation strategy** capable of enabling effective oral delivery of PEA.