

Drug Coated Capsules

Cerovene is the only company with drug-coated capsules technology which provides many benefits.

- Drug Coated Capsule is a “ **New Dosage Form**”
- Generic substitution is not allowed as drug coated capsules are not recognized by FDA as pharmaceutical equivalent to conventional capsules
- Product life cycle with no clinical studies needed
- Manufacturing uses conventional processes
- Possible application for both IR & ER dosage Forms
- Increase in bioavailability for poorly soluble drugs
- Suitable for incompatible drugs within Fixed Dose Combination (FDC) product



Dosage Form Definition

The US Pharmacopoeia provides a clear definition of Dosage Form, which the FDA refers to when approving new products.

- A 1999 FDA Draft Guidance for Industry states:
 "A dosage form is the way of identifying the drug in its physical form".
- In determining dosage form, FDA examines such factors as :
 - 1) Physical appearance of the drug product,
 - 2) Physical form of the drug product prior to dispensing to the patient,
 - 3) The way the product is administered,
 - 4) The frequency of dosing, and
 - 5) How pharmacists and other health professionals might recognize and handle the product."
- The FDA has consistently distinguished dosage forms on the basis of the physical appearance of the drug and hence, currently marketed Oracea® Capsule and coated Doxycycline capsule are **distinct dosage** forms.



Dosage Form IP

Cerovene's coated-capsule technology is patent protected.

- Patent filed in June 2009
- Formulation Patent about coated capsule technology
- Petition to accelerate the patent review would allow for 12-month review process
- Potential for additional IP
- Potential for filing a continuation in part for coated doxycycline capsules, claiming original priority date.

