



U.S. Type IV Drug Master Files The Facts

IPEC
AMERICAS

30
YEARS
OF EXCIPIENT
LEADERSHIP



Voluntary

Not mandatory
Not a registration



Confidential

Not shared with
customers or other
regulators



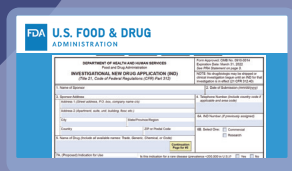
Reviewed with drug application

Not
independently
reviewed



Updated with significant change

Not static



eCTD format

Paper copies
not
accepted

DMFs support:

- Multiple applications
- Non-compendial excipients
- Excipient quality and safety
- Suitability for intended uses



find out more: ipeccamericas.org

