

# **DCGI Approval Process** (For BABE Studies)

## **BENOC and Test License:**

- New Molecule (Not Approved in India)
- Modified Release Formulation
- Molecule approved with-in 04 years

# **Documents requires for BENOC and Test License Application:**

- IEC Approved Study Documents (Protocol + Informed consent (ICF)
- Sponsor Documents (\*)

#### **Test License:**

- Old molecule approved more than 4 years

# **Documents requires for Test License Application:**

- Sponsor Related Documents (IP details including quaNtity to be imported and the pack size)

# **Filing of DCGI Application Online**

#### **DCGI BE-NOC Approval:**

4 to 6 weeks from the date of application

## **DCGIT License Approval:**

- 2 weeks from the date of application

## (\*) Document list requirements from Sponsor side:

- CoA of test and reference product
- Minimum 01 month (based on time between DCGI application and manufacturing date of test product) or 03 months stability data at accelerated & real time (R&D batch OR Bio batch).
- Chemical + pharmaceutical data
- Comparative dissolution profile (Test Vs Reference)
- Form 29 or GMP certificate
- IP details including quantities to be imported and the pack size