



(*) 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