

I. Preclinical Studies

1. Guideline on conduct of pharmacokinetic studies in target animal species
https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-conduct-pharmacokinetic-studies-target-animal-species-revision-1_en.pdf
2. In Vitro Drug Interaction Studies — Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions Guidance for Industry
<https://www.fda.gov/media/134582/download>
3. Q5A (R1) – *Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin* <https://www.ema.europa.eu/en/ich-q5a-r1-quality-biotechnological-products-viral-safety-evaluation-biotechnology-products-derived>
4. Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) (<http://cpcsea.nic.in/Auth/index.aspx>)
5. Organisation for Economic Co-operation and Development [Chemical safety and biosafety] (OECD) (<https://www.oecd.org/chemicalsafety/>)
6. OECD Guideline Test no. 420 Testing of chemicals- Acute Oral Toxicity – Fixed Dose Procedure <https://www.oecd-ilibrary.org/docserver/9789264070943-en.pdf?expires=1649147530&id=id&acname=guest&checksum=6AA5F504FC43CCBC40365E703A5ADD51>
7. OECD Guideline Test no. 425 Testing of chemicals- Acute Oral Toxicity – Up-and-Down-Procedure (UDP) <https://www.oecd-ilibrary.org/docserver/9789264071049-en.pdf?expires=1649147768&id=id&acname=guest&checksum=6F2A96CF4494A81BD44A112F8DCBE8F0>
8. OECD Guideline Test no. 423 Testing of chemicals- Acute Oral Toxicity Acute Toxic Class Method <https://www.oecd-ilibrary.org/docserver/9789264071001-en.pdf?expires=1649147874&id=id&acname=guest&checksum=8A041462C41924CE7E9F36571641AC6B>

9. OECD Guideline Test no. 407 Testing of chemicals - Repeated Dose 28-Day Oral Toxicity Study in Rodents <https://www.oecd-ilibrary.org/docserver/9789264070684-en.pdf?expires=1649147953&id=id&acname=guest&checksum=E54EB733FF8EABC4D3691E6558933F32>
10. OECD Guideline Test no. 422 Testing of chemicals - Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test <https://www.oecd-ilibrary.org/docserver/9789264264403-en.pdf?expires=1649148116&id=id&acname=guest&checksum=5C62AF77095A1D9C26D71504B93B1822>
11. OECD Guideline Test no. 421 Testing of chemicals - Reproduction/Developmental Toxicity Screening Test. <https://www.oecd-ilibrary.org/docserver/9789264264380-en.pdf?expires=1649148966&id=id&acname=guest&checksum=373A04AF660155632D9B6B5C3C11D1A2>