Pharmaceutical Research Summary: imatinib

Generated: 11 July 2025 at 08:05 UTC
AI Model: o1
Search Sources: EMA EPAR, EMA-PSBG, FDA Approvals, FDA-PSBG

Research Results

imatinib – Regulatory Dossier

EPAR (EMA)

• [Glivec: EPAR – Scientific Discussion](https://www.ema.europa.eu/en/documents/scientific-discussion/glivec-epar-scientific-discussion_en.pdf) – Scientific discussion, 2009-02-18
• Key points: Covers the initial assessment for imatinib (branded as Glivec in the EU); discusses pharmacology, clinical efficacy in chronic myeloid leukaemia (CML) and gastrointestinal stromal tumors (GIST), and overall benefit-risk assessment.

EMA-PSBG

• **Result:** No product-specific bioequivalence guidance found for imatinib

FDA Approvals

• NDA 021588 – approval date (2001-05-10)
• Dosage form/strength: Imatinib mesylate capsules and tablets (various strengths)
• Review path: Priority review
• Key letters:
• [Approval Letter](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2001/21588ltr.pdf)

FDA Review Package
• **Clinical Pharmacology Biopharmaceutics Review(s):**
• [Clinical Pharmacology and Biopharmaceutics Review – NDA 21-588 (Parts 1 & 2)](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/21-588_Gleevec_biopharmr_P1.pdf) – 2001-03-23
• [Additional Review Materials](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/21-588_Gleevec_biopharmr_P2.pdf) – 2001-03-23

FDA-PSBG
• **Result:** Guidance found
• [Draft Guidance on Imatinib Mesylate](https://www.accessdata.fda.gov/drugsatfda_docs/psg/Imatinib_mesylate_oral_tab_21335_RC05-16.pdf) – 2016-05

Clinical Trials

NCT	Phase	Primary Endpoint	Outcome Summary
NCT00006343	III	Major cytogenetic response at 18 months	Imatinib showed significantly higher

MCR rates vs interferon-α, leading to approval for CML. |

Summary of Key Regulatory Information
• First EMA approval: 2001-07-07
• First FDA approval: 2001-05-10
• Current EMA status: authorised
• Current FDA status: approved
• Orphan designations: granted in EU/US for CML and certain GIST indications
• Safety/risk-management highlights: Risk management plan (RMP) in EU; monitoring for cytopenias, hepatotoxicity, and fluid retention; periodic assessments required.

Source URLs
• https://www.ema.europa.eu/en/documents/scientific-discussion/glivec-epar-scientific-discussion_en.pdf
• https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2001/21588ltr.pdf
• https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/21-588_Gleevec_biopharmr_P1.pdf
• https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/21-588_Gleevec_biopharmr_P2.pdf
• https://www.accessdata.fda.gov/drugsatfda_docs/psg/Imatinib_mesylate_oral_tab_21335_RC05-16.pdf
• https://clinicaltrials.gov/ct2/show/NCT00006343