

Recommendations of the SEC (Oncology) made in its 08th/24 meeting held on 16.04.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/97/22 Online Submission (28966) Pertuzumab and Trastuzumab	M/s. Roche	The firm presented protocol amendment version 2.0 dated 15 November 2022, protocol no. MO43110. After detailed deliberation, the committee recommended that protocol shall be amended for arrangement of institutional based administration of drugs for further review by the committee.
2.	CT/167/23 Online Submission (41078) Osimertinib	M/s. Fortrea Development	In light of earlier SEC recommendation dated 23.01.24 and 24.01.24, the firm presented phase II clinical trial protocol no. D516AC00003 version 1.0 dated 04 Oct 2023 and rationale for duration of treatment post CCRT. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
BA/BE Division			
3.	File No.12-09/2024/ BA-BE/MISC-25/DC BABE/CT05/FF/ 2023/40425 XS003 (Nilotinib) Capsules 82mg (41mg×2) and XS003 (Nilotinib) Capsules 164 mg(41mg×4)	M/s. QPS Bioserve India Private Limited, Hyderabad (India)- 500037	The firm presented the Protocol No.: 07023 ver.00 for BA/BE study for export purpose only along with USFDA recommendation for this proposed study. After detailed deliberation, the committee recommended for grant of permission to conduct the BA/BE study for export purpose only.
4.	File No. 12-09/2024/ BA-BE/MISC-26/DC BABE/CT05/FF/2023 /41825 Nilotinib 200mg Capsule (as D tartrate)	M/s. Sitec Labs Limited, Navi Mumbai Thane India-400710	The firm presented the Protocol No.: 0192-05-23 ver. 01 dt. 22.12.2023 for BA/BE study for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the BA/BE study for export purpose only.