

Recommendations of the SEC (Oncology) made in its 05th/26 meeting held on 11.02.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/CT21/FF/2023/38264 SND/MA/23/000182 Ibrutinib Tablet 140 mg, 280 mg, 420 mg & 560 mg tablets	M/s. Natco Pharma Limited	The firm presented their proposal for manufacturing and marketing of Ibrutinib tablets 140mg/280mg/420mg/560mg based on BE study conducted with Ibrutinib tablets in US along with request for CT wavier. During the presentation, firm stated that Ibrutinib 560mg has been withdrawn globally and requested to grant the permission for Ibrutinib tablets 140mg/280mg/420mg based on BE study conducted in USA with Ibrutinib 560mg along CT wavier. After detailed deliberation the committee opined that firm should conduct BE study with Ibrutinib 420mg as 560mg strength is withdrawn. Accordingly, firm shall submit BE protocol with 420mg strength to CDSCO for further consideration.