

**Recommendations of the SEC (Analgesic & Rheumatology) made in its 95<sup>th</sup> meeting held on 13.04.2023 at CDSCO (HQ), New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>SND Division</b>			
1.	SND/CT/23/000001  Nimesulide Granules for oral suspension 100mg	M/s. Dr. Reddy's Laboratories Limited	The firm did not turn up for presentation.
2.	SND/MA/23/000005  Methadone oral solution 1mg/ml	M/s. Rusan Pharma Ltd	The firm presented the proposal for permission to manufacture and market Methadone oral solution 1mg/ml before the committee along with request for BA/BE study and clinical trial waiver.  After detailed deliberation, the committee recommended that clinical trial waiver might be considered however, firm is required to conduct BA/BE study of applied product (i.e Methadone oral solution 1mg/ml) with already approved product as reference. Accordingly, firm is required to submit BA/BE study protocol for further review by the committee.
<b>GCT Division</b>			
3.	CT/24/21 Online Submission (22468)  Tofacitinib Tablet	M/s. Pfizer	The firm has presented the changes made in protocol amendment 7 dated 22-August-2022.  After detailed deliberation, the committee recommended for approval of the proposed amendment with a condition that the washout period of Tacrolimus, Sulfasalazine and Azathioprine should be 4 weeks.
<b>Medical Device Division</b>			
4.	CI/MD/2023/89719  Knotless PEEK Anchor with Titanium Tip (Viplok) & Knotless PLDLA-BTCP Anchor with Titanium Tip (Viplok)	M/s. Healthium Medtech Limited	The firm presented the protocol for conducting the post market clinical investigation (Phase IV) before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the post market clinical Investigation (Phase IV) with proposed device in the country.