

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 07th/25 meeting held on 10.06.2025 at CDSCO HQ New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---------------------------|---|---|---|
| GCT Division | | | |
| 1. | CT/60/25 Online Submission (49587) Flomoxef (Flumarin) Fosfomycin (Fomicyt) | M/s Novotech Clinical Research India Private Limited | The firm presented phase III/IV clinical study protocol no. NeoSep1 version no. 3.0 dated 03 - OCT - 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: <ol style="list-style-type: none"> 1. Second randomization shall be done only if the cultures from the patient are available. 2. Data safety monitoring Board (DSMB) required to monitor actively and periodically reporting to Institutional ethics committee. |
| New Drugs Division | | | |
| 2. | ND/45/2025-eoffice Bedaquiline tablet 20 mg and 100 mg | M/s Johnson and Johnson Pvt. Ltd. | In light of earlier SEC recommendation dated 28.06.2023. The firm presented proposal for revision of Prescribing Information of drug Bedaquiline tablet 20 mg and 100 mg as per the CCDS dated 03.08.2023, before the committee. After detailed deliberation, the committee recommended for grant of approval for revision of Prescribing Information of Bedaquiline tablet 20 mg and 100 mg, as presented by firm |
| SND Division | | | |
| 3. | SND/CT/25/000050 Povidone Iodine Alcoholic Prep 10% w/v | M/s G. S. Pharmbutor Private Ltd | The firm presented the proposal for grant of permission to conduct Phase-IV clinical trial of Povidone Iodine Alcoholic Prep 10% w/v along with Phase-IV clinical trial protocol (Protocol No. CT-PVPI-ISP-01, Version:1.0, Dated: 14.02.2025) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-IV clinical trial of Povidone Iodine Alcoholic Prep 10% w/v as per protocol presented by the firm. |

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---------------------|--|------------------------------------|--|
| FDC Division | | | |
| 4. | FDC/MA/24/000272 Darunavir Ethanolate IP eq. to Darunavir 120mg + Ritonavir IP 20mg film coated tablet | M/s Laurus Labs Limited | <p>The firm presented the proposal along with BE study report conducted for export purpose before the committee.</p> <p>After detailed deliberation, the committee noted that:</p> <ol style="list-style-type: none"> 1. The firm did not present any scientific literature regarding essentiality and desirability of the FDC in proposed strength and indication. 2. The firm did not present any safety and efficacy data generated in Indian population for the proposed FDC. 3. Firm did not present any scientific literature/ data from peer reviewed journal regarding the unmet need of the proposed FDC. 4. Firm did not present any justification for the proposed indication of the FDC in pediatrics population. <p>Accordingly, the firm should submit the above data to CDSCO for further review by the committee in presence of experts from NACO.</p> |
| 5. | FDC/MA/25/000111 Rifapentine 300mg + Isoniazid IP 75mg + Moxifloxacin Hydrochloride IP eq. to Moxifloxacin 100mg film coated Tablet | M/s Lupin Limited | <p>The firm presented the proposal along with BE study report conducted for export purpose before the committee.</p> <p>After detailed deliberation, the committee opined that:</p> <ul style="list-style-type: none"> • The proposed FDC is not included in National TB Elimination Program (NTEP) guideline. • The firm did not present any data regarding unmet need of the proposed FDC in the country. <p>In view of above, the committee did not recommend for approval of the proposed FDC.</p> |
| 6. | FDC/MA/23/000106 Calcium Asparate 1120mg + Magnesium Hydroxide IP 180mg + | M/s Overseas Health Care Pvt. Ltd. | <p>As per the condition mentioned in Form CT-23 dated 25.10.2023, the firm presented Active PMS protocol before the committee.</p> |

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|-------|--|-------------------|--|
| | Vitamin D3 IP 1000 IU tablet | | <p>After detailed deliberation, the committee recommended for conducting the Active PMS study.</p> <p>The result of the study should be submitted to CDSCO for review by the committee.</p> |
| 7. | FDC/MA/25/000115 Rifapentine 300mg + Isoniazid IP 75mg + Pyrazinamide IP 375mg + Moxifloxacin Hydrochloride IP eq. to Moxifloxacin 100mg film coated Tablet | M/s Lupin Limited | <p>The firm presented the proposal along with BE study report conducted for export purpose before the committee.</p> <p>After detailed deliberation, the committee opined that:</p> <ul style="list-style-type: none"> • The proposed FDC is not included in National TB Elimination Program (NTEP) guideline. • The firm did not present any data regarding unmet need of the proposed FDC in the country. <p>In view of above, the committee did not recommend for approval of the proposed FDC.</p> |