

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 01st/24 meeting held on 24.01.2024 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/45/23 Online Submission (29879) Bemnifosbuvir Hemisulfate (BEM;AT-527) and Ruzasvir (RZR; AT-038)	M/s. IQVIA	The firm presented protocol amendment 2 dated 15 August 2023 protocol no. AT-01B-004. After detailed deliberation, the committee recommended for approval of the protocol amendment subject to the condition that at least 2 government sites shall be included in the study as presented by the firm.
BA/BE Division			
2.	File.No.12-09/2024/BA-BE/ MISC-01/DCBABE/CT05/FF/2023/40117 Isoniazid Tablets 75 mg + Moxifloxacin 100mg Tablets + Pyrazinamide Tablets 375 mg + Rifapentine Tablets 300mg	M/s. Veeda Clinical Research Limited, Ahmedabad - 380015	The firm presented Bioequivalence study protocol No. 23-VIN-0369, Version No. 01 dated 12-OCT-2023. After detailed deliberation, the committee recommended for grant of permission to conduct the BE Study as presented by the firm.
SND Division			
3.	SND/MA/21/000103 Polymyxin B for Injection IP 750000 Units (Lyophilized)	M/s. BDR Lifesciences Private Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Poymyxin B for injection IP 750000 units (Lyophhilized)/Vial along with justification for waiver of clinical trial before the Committee. It is informed that applied strength Poymyxin B for injection IP 750000 units has not approved anywhere in the world. After detailed deliberation, the Committee did not recommend for waiver of clinical trial and recommended to conduct phase III clinical trial for which the firm should submit Phase III clinical trial protocol to CDSCO for further review by the committee.
4.	Misc 12-44/2018-DC (Pt-ICMR-SND) Probiotic supplementation	ICMR	In light of the earlier SEC (Antimicrobial & Antiviral) meeting dated 16.01.2019, Phase III clinical trial permission was issued vide CT-NOC No.CT/SND/17/2019 dated 01.03.2019.

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	Lactic Acid bacteria and Bifidobacteria drop with Medium Chain Triglyceride (MCT) oil (Vivomixx Drop)		<p>Now, the applicant submitted their proposal for amendment in the Phase III Clinical trial protocol and accordingly presented the details of the proposed amendments.</p> <p>After detailed deliberation, the committee recommended for approval of the proposed amendments in the Phase III clinical trial protocol.</p>
5.	SND/IMP/21/000006 4 Klerwipe Low Residue Peroxide Wipes (Hydrogen Peroxide based disinfectant wipes)	M/s. Ecolab Food Safety & Hygiene Solutions Private Limited	<p>In light of the earlier SEC (Antimicrobial & Antiviral) meeting dated 31.01.2023, firm presented comparative data of the applied product with already approved disinfectants. The proposed disinfectant is registered in France, Germany, Spain, Switzerland, Ireland and freely sold in the United Kingdom.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and marketing of Klerwipe Low Residue Peroxide Wipes (Hydrogen Peroxide based disinfectant wipes) with condition that each product shall be supplied with MSDS and product shall be used for "Hospital Purpose" only.</p>
New Drugs Division			
6.	ND/MA/22/000100 Methenamine Hippurate 1gm Tablet	M/s. Lyrus Life Sciences	<p>In light with earlier SEC recommendation dated 31.10.2023, the firm presented repeated dose toxicity study data, published animal toxicity study data, published clinical study data on Indian/Asian population and bioequivalence study data before the committee.</p> <p>After detailed deliberation, the committee recommended for the grant of permission to manufacture and market of drug Methenamine Hippurate 1gm Tablet with condition that the firm should conduct Phase IV clinical trial for which the protocol should be submitted within 3 months of approval of the drug for review by the committee.</p>