

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 116th meeting held on 26.07.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/22/000030 Ayers and Co Hand Sanitiser 50ml, 375ml & 1L and Ayers and Co Hospital Grade Disinfectant 300ml & 1L	M/s. Adiro Labs Pvt. Ltd.	<p>The firm presented their proposal for import and marketing of the hand sanitizer and surface disinfectant before the committee.</p> <p>After detailed deliberation, the committee recommended for additional short term and long term safety data on adequate number of Indian subjects.</p> <p>The above data should be submitted to CDSCO for further review by the committee.</p>
2.	ND/MA/22/000089 FDC of Bictegravir, Emtricitabine, Tenofovir Alafenamide (50, 200, 25mg) Tablet	M/s. Cipla Ltd.	<p>The firm presented their proposal for permission to manufacture and market Bictegravir, Emtricitabine and Tenofovir Alafenamide (50, 200, 25mg) Tablet along with BE study results.</p> <p>After detailed deliberation, the committee opined that the firm should submit additional data on:</p> <ol style="list-style-type: none"> 1. Advantages and disadvantages of the proposed Bictegravir FDC over the marketed Bictegravir FDC. 2. Safety and drug interaction data in Indian subjects. <p>Accordingly, the firm should submit above data to CDSCO for further review by the committee.</p>
3.	ND/MA/22/000088 Doravarine tablets 100 mg	M/s. Emcure	<p>The firm presented their proposal for permission to manufacture and market Doravarine tablets 100 mg along with BE study protocol and local clinical trial waiver.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the protocol presented. However, the committee did not recommend local clinical trial waiver and opined that the firm should submit:</p>

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			<p>1. Data on Safety and Drug interaction studies in India population.</p> <p>2. Preclinical toxicity study data.</p> <p>Accordingly, the firm should submit above data to CDSCO for further review by the committee.</p>
SND Division			
4.	SND/MA/21/000368 Pidotimod Oral Liquid 400/800mg &Pidotimod Tablets 400/800 mg	M/s Wockhart Ltd.	The firm didn't turn up for presentation.
5.	SND/MA/22/000180 Biapenem for injection 300mg in Dual Chamber Bag	M/s. Gufic Bioscience	<p>The firm presented their proposal of Biapenem for injection 300mg in Dual Chamber Bag with local CT waiver before the committee.</p> <p>The firm presented advantages of the modified container closure system with respect to already approved glass vial and procedure of uses of this Dual Chamber Bag.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed Biapenem for injection 300mg in Dual Chamber Bag with approved indication.</p>
6.	SND/CT/22/000021 Thymosin Alpha 1 for injection 1.6 mg	M/s. Gufic Bioscience	<p>In light of earlier SEC recommendation (Antimicrobial & Antiviral) meeting dated 05.05.2022, the firm presented their proposal with revised Phase III clinical trial with respect to study design of Thymosin Alpha 1 for injection 1.6 mg in Sepsis patient before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the revised protocol presented subject to condition that the firm should submit the details of safety management plan for SAEs both expected and unexpected during the study to CDSCO before initiation of the study.</p>
FDC Division			

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7.	FDC/IMP/22/000025 Avibactam Sodium eq to Avibactam 0.5 gm + Ceftazidime 2 gm Powder for concentrate for solution for infusion	M/s. Pfizer Ltd.	<p>The firm presented their proposal for import and marketing of approved FDC in additional indication before the committee.</p> <p>The committee noted that product was already approved by CDSCO on 2018 & 2021 for different indications. Further, the firm informed the committee that the proposed additional indication are approved in countries like EU,UK, Russia etc.,</p> <p>After detailed deliberation, the committee opined that the firm should submit the justification along with efficacy & safety data on Indian patients for proposed indication before the committee for further review.</p>
8.	FDC/MA/22/000148 Sodium Chloride 2.6gm+Potassium Chloride 1.5gm+Dextrose Anhydrous 13.5gm+Sodium Citrate 2.9gm + Zinc Sulphate Monohydrate 0.0550gm sachets	M/s. FDC Ltd.	<p>The firm presented their proposal for manufacturing and marketing of the proposed FDC in indication i.e “for oral rehydration in various etiology for children above 1 month of age”.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> 1. The firm should submit the data on Indian patients for proposed indication i.e “for oral rehydration in various etiology for children above 1 month of age”. 2. The firm should submit the regulatory status in other countries for proposed indication. 3. The firm should submit the published literature of peer reviewed journal in proposed indication. 4. The firm should submit the data of synergetic effect study on zinc. <p>In view of above, the firm should submit the justification of aforesaid points before the committee for further review.</p>
9.	FDC/MA/22/000165 Zinc Sulphate Monohydrate 0.0110gm+Potassium Chloride 0.3gm+Sodium Chloride 0.52gm+Dextrose	M/s. Acme Diet Care Pvt. Ltd.	<p>The firm presented their proposal for manufacturing and marketing of the proposed FDC for indication as to replace fluid and electrolyte loss due to vomiting & diarrhoea.</p> <p>The committee noted that the FDC is already approved by CDSCO in liquid dosage form for oral rehydration in</p>

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	Anhydrous 2.7gm+Sodium citrate 0.58gm Oral Powders		various etiology. However, the proposed formulation is in powder dosage form. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC in approved indication. The firm should submit revised Form CT-21 accordingly to CDSCO.
10.	FDC/MA/20/000150 Zinc Citrate Trihydrate eq. to Zinc 10 mg +Ascorbic acid 1000 mg effervescent tablets	M/s. Kusum Healthcare Pvt. Ltd.	The firm didn't turn up for presentation.
BA/BE Division			
11.	BABE/CT05/FF/2022 (31543) Pretomanid, Moxifloxacin, Pyrazinamide and Bedaquiline Tablets 100 mg/ 200 mg/ 750 mg/ 100 mg	M/s Macleods Pharmaceuticals Ltd.	The firm presented their proposal for permission to conduct Bioavailability/Bioequivalence Study of Pretomanid, Moxifloxacin, Pyrazinamide and Bedaquiline Tablets 100 mg/ 200 mg/ 750 mg/ 100 mg for Export Purpose. After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the protocol presented.
12.	12-09/2022/BA- BE/Misc-13/DC Rifapentine, Isoniazid and Moxifloxacin Tablets 300 mg/75 mg/100 mg	M/s. Lupin Limited,	The firm presented their proposal for permission to conduct Bioavailability/Bioequivalence Study of Rifapentine, Isoniazid and Moxifloxacin Tablets 300 mg/75 mg/100 mg for Export Purpose. After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the protocol presented.
13.	12-09/2022/BA- BE/Misc-14/DC Rifapentin, Isoniazid, Pyrazinamide and Moxifloxacin Tablets 300mg/ 75mg/ 400mg/ 100mg	M/s. Lupin Limited,	The firm presented their proposal for permission to conduct Bioavailability/Bioequivalence Study of Rifapentin, Isoniazid, Pyrazinamide and Moxifloxacin Tablets 300mg/ 75mg/ 400mg/ 100mg for Export Purpose. After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the protocol presented.

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Additional Proposal- GCT Division			
14.	<p>CT/43/22 Online Submission (31821)</p> <p>Mino-Lok® -1 mg/mL of minocycline, 30 mg/mL of Na-ethylenediaminetetraacetate (EDTA) in 25% v/v ethanol (19.5% w/v).</p>	M/s. Biorasi	<p>The applicant has presented Phase III clinical trial protocol No. MDA 2013-0039, India specific version 7.1 dated 17-May-2022 before the committee.</p> <p>Risk versus benefit- The test drugs (minocycline, Sodium-ethylenediaminetetraacetate (EDTA) and ethanol) are approved individually and their safety profile may justify the conduct of the study.</p> <p>Innovations vs. Existing Therapeutic Option- The purpose of the study is to evaluate the efficacy and safety of Mino-Lok Therapy (MLT) in combination with systemic antibiotics in the treatment of Catheter-Related or Central Line-Associated Bloodstream Infection (CRBSI/CLABSI).</p> <p>Unmet need- The test may be useful for treatment of catheter related bloodstream infections.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed phase III study as presented.</p>