

**Recommendations of the SEC (Antimicrobial & Antiviral) made in its 124<sup>th</sup> meeting held on 22.03.2023 at CDSCO (HQ), New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drug Division</b>			
1.	ND/MA/22/000100  Methenamine Hippurate 1gm Tablet	M/s. Lyrus Life Science	<p>The firm presented the proposal for manufacture and marketing of the drug Methenamine Hippurate 1gm Tablet along with BE results and justification for local Phase III clinical trial waiver before the committee.</p> <p>The committee noted that the Methenamine Hippurate 1gm tablet is approved by Denmark, UK, USA and Australia in the year 1972, 1989, 1976 &amp; 1991 respectively.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the additional data on cell line study and animal model study.</p> <p>Accordingly, the firm should submit above data to CDSCO for further review by the committee.</p>
2.	ND/MA/21/000200  Squaric Acid 1.745 mg/ml Solution Spray	M/s. Vital Therapeutics & Formulations Pvt. Ltd	<p>In light of earlier SEC recommendation dated 29.11.2022, the firm presented sub-acute toxicity study report before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product of Squaric acid 1.745mg/ml solution (Spray) for proposed indication subject to the condition that the firm should provide a leaflet with every pack of the product for consumer highlighting do's and dont's including advisory in case of accidental exposure.</p>
3.	ND/MA/21/000201  Squaric Acid 0.748mg/ml Solution Fog	M/s. Vital Therapeutics & Formulations Pvt. Ltd	<p>In light of earlier SEC recommendation dated 29.11.2022, the firm presented sub-acute toxicity report before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product of</p>

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			Squaric acid 0.748 mg/ml solution (FOG) for proposed indication subject to condition that the firm should provide a leaflet with every pack of the product for consumer highlighting do's and dont's including advisory in case of accidental exposure.
<b>SND Division</b>			
4.	SND/MA/123/000022  Povidone Iodine Gargle 2% w/v	M/s. Stedman Pharmaceuticals Pvt. Ltd.	<p>The firm presented the proposal for manufacturing and marketing permission of Povidone iodine Gargle 2% w/v for the indication as oral antiseptic for infected inflammatory conditions of the mouth and pharynx such as tonsillitis, pharyngitis, stomatitis, traumatic ulcers etc. and for maintaining oral hygiene prior to, during and after dental and oral surgery along with therapeutic justification and published literature for clinical trial waiver.</p> <p>Committee noted that Povidone Iodine 0.5% gargle and FDC of Povidone Iodine 2.0% w/v + Ethyl Alcohol 8.30.5% liquid are already approved by CDSCO. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing permission of Povidone iodine Gargle 2 % w/v for proposed indication.</p>
5.	SND/MA/22/000358  Cefixime Oral suspension 200mg/5ml	M/s. Alkem Laboratories Ltd	<p>The firm presented the proposal for manufacturing and marketing permission of Cefixime oral suspension IP 200mg/5ml, in continuation with the earlier SEC recommendation dated 30.01.2023 for following proposed indications:</p> <ol style="list-style-type: none"> <li>1. Otitis media caused by Haemophilus influenzae, Moraxella catarrhalis, and Streptococcus pyogenes.</li> <li>2. Pharyngitis and tonsillitis caused by Streptococcus pyogenes.</li> <li>3. Acute exacerbations of chronic bronchitis caused by Streptococcus pneumoniae and Haemophilus influenza.</li> <li>4. Uncomplicated urinary tract infections caused by Escherichia coli and Proteus mirabilis.</li> <li>5. For the treatment of enteric (typhoid)</li> </ol>

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			fever. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product Cefixime Oral suspension 200mg/5ml for approved indications only i.e “For the treatment of enteric (typhoid) fever”.
<b>GCT Division</b>			
6.	CT/80/22 Online Submission (33469)  Aztreonam- Avibactam 1 Metronidazole	M/s Pfizer	The firm presented clarification /justifications for Phase- IIa study, in line with the earlier SEC recommendation dated 20.10.2022, before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the study.
<b>BA/BE Division</b>			
7.	12-09/2023/BA- BE/Misc-04/DC (Application No. BABE/CT05/FF/202 2/33817)  Flucytosine solution for infusion 2.5 gm/250 mL (10mg/mL)	M/s Cipla Limited, Mumbai.	The firm presented the proposal to conduct bioavailability study for product Flucytosine solution for infusion 2.5 gm/250 mL (10mg/mL) for export purpose.  After detailed deliberation, the committee recommended for grant of permission to conduct the study.
<b>FDC Division</b>			
8.	FDC/CT/22/000080  FDC Amoxicillin and Potassium Clavulanate Oral Suspension IP (600 mg + 42.9 mg) per 5ml.	M/s Sun Pharma	As per the condition mentioned in Form CT-23 dated 30.09.2022, the firm presented the Phase IV CT protocol before the committee. After detailed deliberation, the committee recommended for conducting the Phase IV CT. The result of the study should be presented before the committee for review.
9.	FDC/MA/22/000350  FDC of Rifaximin 200mg + Metronidazole Benzoate IP eq. to Metronidazole 400mg	M/s Mascot	In light of earlier SEC recommendation dated 14.07.2020 & 14.10.2020 as well as Technical Committee recommendation dated 26.04.2021, whereby committee did not recommend for approval of the FDC, the firm presented its proposal before the committee along with justification. After detailed deliberation, the committee opined that: 1. Dosing Schedule is not justified.

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			<p>2. Firm did not present any additional scientific literature or justification.</p> <p>3. The product is not approved internationally.</p> <p>4. There is no unmet need of the FDC.</p> <p>5. Firm has not presented any supportive guidelines.</p> <p>The committee did not recommend for approval of the FDC.</p>
10.	<p>FDC/MA/23/000054</p> <p>FDC of Alpha Lipoic Acid USP 100mg + Calcium Carbonate IP eq. to elemental Calcium 225mg + Magnesium Oxide IP eq. to Elemental Magnesium 50mg + Methylcobalamin IP 1500mcg + VitaminD3 IP 8000IU + VitaminK2-750mcg + Zinc Sulphate USP eq. to Elemental Zinc 7.5mg Capsule</p>	M/s Quality Pharma Products Pvt. Ltd.	The firm did not turn up for presentation.
11.	<p>FDC/IMP/22/000025</p> <p>FDC of Ceftazidime Pentahydrate eq. to Ceftazidime + Avibactam Sodium eq. to Avibactam Powder for concentrate for solution for infusion (powder for concentrate) (2gm + 0.5gm)</p>	M/s Pfizer	<p>In light of earlier SEC recommendation dated 28.02.2023, the firm presented its proposal before the committee along with academic trial data.</p> <p>After detailed deliberation, the committee reiterated its earlier recommendation.</p>