

**Recommendations of the SEC (Antimicrobial & Antiviral) made in its 108<sup>th</sup> meeting held on 21.01.2022 at CDSCO (HQ), New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	ND/MA/21/000200 Squaric Acid 0.1570mg/ml	M/s Vital Therapeutics & Formulations Pvt. Ltd	<p>The firm presented the proposal for manufacture and market disinfectant spray before the Committee.</p> <p>The Committee opined that the proposed product is indicated for antiviral &amp; antibacterial activity when sprayed on mask or other surfaces. The product is not approved /marketed anywhere in the world.</p> <p>After detailed deliberation, the Committee recommended that the firm should submit data on human safety for further consideration.</p>
2.	ND/MA/21/000201 Squaric Acid 0.6730 mg/ml	M/s Vital Therapeutics & Formulations Pvt. Ltd	<p>The firm presented its proposal to manufacture and market the disinfectant fog before the Committee.</p> <p>The Committee noted that the product is not approved/marketd anywhere in the world.</p> <p>After detailed deliberation, the Committee recommended that the firm should submit data on human safety for further consideration.</p>
3.	ND/IMP/21/0/00100 Polyhexamethylene guanidine Hydrochloride Uniko NEXT as Surface Disinfectant	M/s Water Freedom Revolution Industries Private Limited	<p>The firm presented its proposal to import and market the surface disinfectant.</p> <p>After detailed deliberation, the Committee recommended that the firm should submit the human safety data of proposed disinfectant for further consideration.</p>
4.	12-01/20-DC (Pt-279) C-Tb with QUANTIFERON-TB gold plus and 2 T.U. Tuberculin PPD	ICMR, RMRC Bhubaneswar	<p>The applicant presented their proposal to amend the protocol to include the pediatric population in the study before the Committee.</p> <p>After detailed deliberation, the Committee recommended for grant of approval for the proposed protocol amendment.</p>
5.	ND/CT04/FF/2021/29 273 Colloidal Nano silver	M/s. Biosphere clinical research Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 23.12.2021, the firm presented its justification before the Committee.</p>

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	Gel		<p>The Committee noted that the proposed formulation is vaginal nanosilver preparation.</p> <p>After detailed deliberation, the Committee reiterated its earlier recommendation.</p> <p>Accordingly, the firm should submit the protocol of Phase I clinical trial study for further review by the Committee.</p>
<b>SND Division</b>			
6.	SND/IMP/21/000096 Benzalkonium chloride Hand Sanitizer	M/s. Sunmed	The firm did not turn up for the presentation.
7.	SND/MA/21/000556 Feropenem sodium Extended release 300 mg	M/s. Sun Pharma	<p>The firm presented its proposal for manufacturing and marketing of Feropenem Sodium Extended Release Tablets 300mg along with BE Study report.</p> <p>After detailed deliberation, the Committee opined that the firm should present detailed pharmacokinetic data as per regulatory guidelines for review by the Committee.</p>
<b>FDC Division</b>			
8.	FDC/MA/20/000232 Tinidazole 100mg +Norfloxacin 100mg suspension	M/s. Rivpra Formulation Pvt. Ltd.	The firm didn't turn up for the presentation.
9.	FDC/IMP/20/000082 Composition of 'Intravenous Amino Acids Solutions 10% for Infant' (Brand name-Aminoven infant 10% (100.00mg/ml) solution for infusion)Per 1000ml solution for infusion contains: Active Ingredients Quantity L-isoleucine Ph.Eur 8.0 g L-leucine Ph.Eur. 13.0 g L-lysine monoacetatecorrespon	M/s. Fresenius Kabi India Pvt. Ltd.	<p>The firm presented its proposal before the Committee for import and marketing of the proposed FDC.</p> <p>After detailed deliberation, the Committee recommended continued import and marketing of the proposed FDC.</p>

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	<p>ding to L-lysine USP  12.0 g 8.51 g L-  methionine Ph.Eur  3.120 g N-acetyl-L-  cysteine  corresponding to L-  Cysteine Ph.Eur.  0.700 g 0.52 g L-  phenylalanine  Ph.Eur.3.750 g  L-threonine Ph.Eur  4.400 g L-tryptophan  Ph.Eur2.010 g L-  valine Ph.Eur 9.0 g L-  arginine Ph.Eur 7.500  g L-histidine Ph.Eur  4.760 g Glycine  Ph.Eur. 4.150 g L-  alanine Ph.Eur. 9.300  g L-proline Ph.Eur.  9.710 g L-serine  Ph.Eur. 7.670 g  Glacial acetic acid  Ph.Eur.4.42 g  Taurine0.400 g N-  acetyl-L-tyrosine  corresponding to L-  tyrosine Ph. Eur.  5.176 g 4.20 g L-  malic acid2.620 g  Other Excipients:  Water for injections  Ph. Eur.</p>		
10.	<p>FDC/IMP/20/000052  Composition of FDC  of Aminomix 1  Novum (Two  ChamberBag  containing Amino  Acid solution 5% and  Carbohydrates 20%  Solution  with electrolytes) for  Intravenous Infusion'  (Brand name-  Aminomix 1 Novum)  Per1000ml solution  for infusion contains:  Active Ingredients  Quantity Amino acid  Solution 500ml  Isoleucine Ph. Eur.</p>	M/s. Fresenius Kabi India Pvt. Ltd.	<p>The firm presented its proposal before the Committee for import and marketing of the proposed FDC.</p> <p>After detailed deliberation, the Committee recommended continued import and marketing of the proposed FDC.</p>

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	<p>2.50 g Leucine Ph. Eur. 3.70 g Lysine hydrochloride  Corresponding to Iysine Ph. Eur. 4.125 g 3.3 g Methionine Ph. Eur. 2.15 g Phenylalanine Ph. Eur. 2.55 g Threonine Ph. Eur. 2.20 g Tryptophan Ph. Eur. 1.00 g Valine Ph. Eur. 3.10 g Arginine Ph. Eur. 6.00 g Histidine Ph. Eur. 1 .50 g Glycine Ph. Eur. 5.50 g Serine Ph. Eur. 3.25 g Tyrosine Ph. Eur. 0.20 g Taurine 0.50 g Alanine Ph. Eur. 7.00 g Proline Ph. Eur. 5.60 g Sodium glyserophosphate hydrated Ph. Eur. 4.59 g Acetic acid, glacial Ph. Eur. 4.5 g Potassium hydroxide Ph. Eur. 1.981g Hydrochloric acid 25% Ph. Eur. 1.47 ml  Other Ingredients: Water for injections Ph. Eur. 353.0 ml Sodium Hydroxide Ph. Eur. 0-0.036 g Nitrogen Ph. Eur. q.s. Carbohydrate Solution 500ml Glucose monohydrate corresponding to anhydrous glucose Ph. Eur. 220.00 g 200.00 g Sodium chloride Ph. Eur. 1.169 g Calcium chloride dihydrate Ph. Eur. 0.294 g Magnesium chloride Hexahydrate Ph. Eur. 0.61 g Zinc chloride Ph. Eur. 0.00545 g Other Ingredients: Water for</p>		

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	in injections Ph. Eur. 353.0 ml Hydrochloric acid 25% Ph. Eur. 0 -0.117 ml Sodium Hydroxide Ph. Eur. 0 - 0.024 g		
11.	FDC/IMP/20/000048 Sodium acetate 3 H2O 8.17 g corresponding to Sodium acetate 4.9g E.P. Potassium chloride 5.97 g E.P. Magnesium sulphate 7H2O 3.29 g corresponding to Magnesium sulphate 1.6 g E.P. Active Sodium glycerophosphate Corresponding to Sodium glycerophosphate (anhydrous) 5.04gE.P. Active Calcium chloride 2 H2O 0.980g corresponding to Calcium chloride 0.74 g E.P. Active Valine 7.3gE.P. Active Tyrosine 0.23g E.P. Tryptophan 1.9g E.P. Threonine 5.6g E.P. Serine 4.5g E.P. Proline 6.8g E.P. Active Phenylalanine 7.9000g E.P. Active Methionine 5.6g E.P. Active Lysine hydrochloride 11.3 g corresponding to Lysine 9g E.P. Active Leucine =7.9g E.P. Isoleucine 5.6 g E.P.Histidine 6.8000g E.P. Glycine7.9000 g E.P. Glutamic acid 5.6000gE.P. Aspartic acid 3.4000g E.P. Arginine 11.3 g E.P. Alanine	M/s Fresenius Kabi India Pvt. Ltd.	The firm presented its proposal before the Committee for import and marketing of the proposed FDC.  After detailed deliberation, the Committee recommended continued import and marketing of the proposed FDC.

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	=16.0000gE.P. Purified soybean oil =200gE.P. Glucose monohydrate 209 g corresponding to Glucose (anhydrous) =190gE.P.Emulsion for infusion		
12.	FDC/IMP/20/000049 Sodium acetate 3 H2O 8.17 g corresponding to Sodium acetate 4.9 g E.P. Potassium chloride =5.97 g E.P. Magnesium sulphate 7H2O 3.29g corresponding to Magnesium sulphate 1.6000gE.P. Sodium glycerophosphate Corresponding to Sodium glycerophosphate (anhydrous) 5.04 g E.P. Calcium chloride 2 H2O 0.980g corresponding to Calcium chloride0.74g E.P. Valine 7.3 g E.P. Tyrosine0.23 g E.P. Tryptophan 1.9g E.P. Threonine 5.6gE.P.Serine 4.5 gE.P. Proline 6.8gE.P. Phenylalanine 7.9g E.P. Methionine 5.6g E.P. Lysinehydrochloride1 1.3g corresponding to Lysine9g E.P. Leucine 7.9 g E.P. Isoleucine 5.6 g E.P. Active Histidine 6.8 g E.P. Glycine 7.9gE.P. Glutamic acid 5.6g E.P. Aspartic acid =3.4g E.P. Arginine 11.3 gE.P. Alanine 1	M/s Fresenius Kabi India Pvt. Ltd.	The firm presented its proposal before the Committee for import and marketing of the proposed FDC.  After detailed deliberation, the Committee recommended continued import and marketing of the proposed FDC.

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	gE.P. Purified soybean oil 200g E.P. Glucose monohydrate 121 g corresponding to Glucose (anhydrous) =110 g E.P. Emulsion for infusion		
13.	FDC/MA/20/000144 Lamivudine USP 300mg + Dolutegravir (As Dolutegravir Sodium) 50mg film coated tablets.	M/s. Emcure Pharmaceuticals	The firm presented its proposal before the Committee along with justification for the Phase IV CT waiver.  After detailed deliberation, the Committee recommended that the opinion of NACO may be taken in this regard.
<b>GCT Division</b>			
14.	CT/48/15 (Offline Submission) Regimen of anti-tuberculosis Drugs with MDR-TB	National Institute for Research in TB	The applicant presented the proposed protocol amendment to Phase III STREAM protocol no.:ISRCTN-18148631, Version:11 dated 06-OCT-2021 before the Committee.  After detailed deliberation, the Committee recommended for conduct of the study as per the proposed protocol amendment.
<b>Medical Device Division</b>			
15.	MFG/MD/2021/4623 2 Thera PREP Pro PI Applicator	M/s Carenow Medical Pvt Ltd.	The firm presented its proposal before the committee.  After detailed deliberation, the Committee recommended for grant of permission for manufacturing and marketing of the product Thera PREP Pro PI applicator with composition 10% w/v Povidone Iodine and 90% w/v purified water, in the country
16.	MFG/MD/2021/4623 1 Thera PREP ProCHG IPA Applicator	M/s Carenow Medical Pvt Ltd.	The firm presented its proposal before the Committee.  After detailed deliberation, the Committee recommended for grant of permission for manufacturing and marketing of the product Thera PREP ProCHG IPA Applicator with composition 10% v/v Chlorhexidine

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			Gluconate IP and 70% v/v Isopropyl Alcohol IP solution in the country
17.	CI/MD/2021/43252 AM-301 (Nasal Spray)Permission for Pivotal clinical Investigation	M/s Ecron Acunova Limited	The proposal is deferred to the next meeting due to technical issues.
18.	IMP/MD/2021/44998 Fast acting, sporicidal ready-to use surface cleaning and disinfection wipe (IncidinOxyWipeS)	M/S. Ecolab Food Safety & amp; Hygine Solutions Hygiene Solution Pvt. Ltd.	The firm presented its proposal before the Committee.  After detailed deliberation, the Committee recommended for grant of permission for import & marketing of fast-acting, sporicidal ready to use surface cleaning and disinfection wipes, (Brand: Incidin <sup>TM</sup> Oxywipes) having Hydrogen peroxide 1.5 % in the country.