

**Recommendations of the SEC (Cardiovascular & Renal) made in its 107<sup>th</sup> meeting held on 11.08.2022 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>SND Division</b>			
1.	SND/MA/22/000083 Polystyrene Sulphonate Jelly 20% w/w	M/s. Pharose Remedies	The firm didn't turn up for presentation.
2.	SND/MA/21/000482 Ticagrelor SR Tablets 120/180mg	M/s. Theon Pharma	The firm didn't turn up for presentation.
<b>FDC Division</b>			
3.	FDC/MA/19/000106 Efonidipine Hydrochloride Ethanolate 20mg/20mg/40mg + Telmisartan IP 20mg/40mg/40mg uncoated bilayered tablet	M/s. Zuventus Healthcare Ltd	The firm didn't turn up for presentation.
4.	FDC/MA/21/000136 Efonidipine HCl 40mg + Telmisartan IP 40mg tablets	M/s. Ajanta	As per condition mentioned in the permission for manufacture and market which was issued to the firm on 07.02.2022, the firm presented the Phase IV CT protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV CT with condition that 2D Echo Cardiography should be included at the base line as well as at end of the study.
5.	FDC/IMP/22/000026 Modified Fluid Gelatin 4gm + Sodium Hydroxide 0.1360gm + Sodium Chloride 0.7010gm Parenteral Preparations	M/s. B. Braun Medical (India) Pvt. Ltd.	The firm didn't turn up for presentation.
6.	FDC/IMP/22/000027 Tryptophan 2gm + Threonine 6.35gm + Aspartic acid 5.25gm + Zinc	M/s. B. Braun Medical (India) Pvt. Ltd.	The firm didn't turn up for presentation.

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	acetate dehydrate 0.0176gm+Histidine HCl 9.45gm+Glucose monohydrate 396gm+Sodium dihydrogen Phosphate dehydrate 6.24gm+Serine 10.5gm+Magnesium acetate tetrahydrate 2.2740gm+Glutamic acid +12.27gm+Tyrosine 0.0gm+ Proline 11.9gm+Glycine 16.98gm+Alanine 16.98gm+Lysine hydrochloride 9.95gm+Soya-bean oil 80gm+Omega-3 acid triglycerides 20gm+Arginine 9.45gm+Sodium acetate trihydrate0.9460gm+S odium hydroxide 2.9280gm+Sodium chloride 0.9460 gm+ isoleucine 8.21gm+Medium chain triglycerides 100gm+Potassium acetate 9.2220gm+Phenylalan ine 12.29gm+ Methionine 6.84gm+Calcium chloride dehydrate 1.558gm+Valine 2gm+Leucine 10.96gm Parenteral preparation		
7.	FDC/IMP/22/000030  Valine 6.2gm+Serine 2.3gm+Aspartic acid 5.6gm+ +Water for injections 926gm+ Alanine 10.5gm+Sodium acetate trihydrate	M/s. B. Braun Medical (India) Pvt. Ltd.	The firm didn't turn up for presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	2.8580gm+Lysine HCl 8.56gm+Citric acid monohydrate 0.21 to 0.42gm+Potassium acetate 2.453gm+Acetyl cysteine 0.2gm+Tryptophan 1.6gm+Glycine 12gm+Magnesium chloride hexahydrate 0.508 gm +Isoleucine 5gm+Arginine 11.5gm+Phenylalanine 4.7gm+Nitrogen 15.8gm+Threonine 4.2gm+Methionine 4.4gm+Histidine 3gm+Disodium hydrogen phosphate dodecahydrate 3.581gm+sodium hydroxide 0.36gm+Proline 5.5gm+Glutamic acid 7.2gm+Leucine 8.9gm+Tyrosine 0.4gm Parenteral preparations		
8.	FDC/IMP/22/000031 Sodium acetate trihydrate 3.27gm+ magnesium chloride hexahydrate 0.2gm+Sodium Chloride5.55gm+Succinylated gelatine 40gm+Potassium Chloride 0.3gm+Calcium Chloride dehydrate 0.15gm Parenteral Preparations	M/s. B. Braun Medical (India) Pvt. Ltd.	The firm didn't turn up for presentation.
9.	FDC/IMP/22/000028 Valine 5.2gm+Serine 6gm+Aspartic acid 3gm+ Alanine 9.7gm+Sodium	M/s. B. Braun Medical (India) Pvt. Ltd.	The firm didn't turn up for presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	acetate trihydrate 1.088gm+Lysine HCl 5.68gm+Potassium acetate 5.886gm+Tryptophan 1.14gm+Glycine 3.3gm+Magnesium acetate tetrahydrate 1.288gm+Isoleucine 4.68gm+Arginine 5.4gm+Phenylalanine 7.02gm+ Threonine 3.64gm+Methionine 3.92gm+Histidine 3.38gm+sodium dihydrogen phosphate dihydrate 2.34gm+sodium hydroxide 1.6gm+Proline 6.8gm+Glutamic acid 7gm+Leucine 6.26gm+sodium chloride 2.162gm+zinc acetate dehydrate 0.0132gm+medium chain triglycerides 100gm+calcium chloride dehydrate 0.8820gm+soya-bean oil, refined 100gm+Glucose monohydrate 176gm Parenteral preparations		
10.	FDC/IMP/22/000029  Lysine acetate 10.6gm+Valine 10.6gm+Asparagine monohydrate 0.55gm+Acetylcysteine 0.8gm+Histidine 4.7gm+Phenylalanine 1.6gm+Serine 3.7gm+Arginine 8.8gm+Tryptophan 1.5gm+Isoleucine 8.8gm+Glycine 6.3gm+Methionine	M/s. B. Braun Medical (India) Pvt. Ltd.	The firm didn't turn up for presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	1.2gm+aspartic acid 2.5gm+alanine 8.3gm+Ornithine HCl 1.66gm+Leucine 13.6gm+proline 7.1gm+acetyltyrosine 0.86gm+threonine 4.6gm+glutamic acid 5.7gm Parenyeral preparations		
<b>GCT Division</b>			
11.	CT/06/22 Online Submission (30222)  Lanalumab (CVAY736)	M/s. Novartis	In light of earlier SEC recommendation dated 19/07/2022, the firm presented the Phase III clinical trial protocol no CVAY736K12301 before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that the volume of blood to be drawn at each time of sample collection and the frequency of sample collection during the study should be mentioned in protocol and Informed consent document.
12.	CT/35/22 Online Submission (31533)  Sibeprenlimab	M/s. George Clinical India	In light of earlier SEC recommendation dated 22.06.2022, the firm presented the safety and efficacy data from interim analysis of Phase II study before the committee.  After detailed deliberation, the committee recommended for grant of permission for conduct of the proposed Phase III clinical trial.
<b>FDC Division</b>			
13.	FDC/MA/22/000096  Clopidogrelbisulphate eq. to Clopidogrel 75mg + Atorvastatin Calcium eq. to Atorvastatin 40mgtablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 27.04.2022, the firm presented the BE study report before the committee.  After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC.
14.	FDC/MA/22/000149  Rosuvastatin Calcium eq.to Rosuvastatin 5mg/10mg/20mg/40mg+Bempedoicacid	M/s. Exemed Pharmaceuticals	The firm didn't turn up for presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	180mg/180mg/180mg /180mg tablets		
15.	FDC/MA/22/000094 Bempedoic acid 180mg/180mg/180mg /180mg+Atorvastatin Calcium eq.to Atorvastatin 10mg/20mg/40mg/80 mg tablets	M/s. Exemed Pharmaceuticals	The firm didn't turn up for presentation.