

Recommendations of the SEC (Cardiovascular & Renal) made in its 105th meeting held on 19.07.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
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/22/000169 Desidustat tablets 100 mg	M/s.Zydus Life science	The firm presented the proposal for manufacturing and marketing of the Desidustat Tablets 100 mg for the treatment of Anaemia in adult patients with chronic kidney disease(CKD) not on dialysis and on dialysis along with the justification of BE study waiver. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the Desidustat Tablets 100 mg for already approved indication.
FDC Division			
3.	FDC/MA/21/000136 EfonidipineHCl 40mg + Telmisartan IP 40mg tablets	M/s. Ajanta	The firm didn't turn up for presentation.
4.	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.
5.	FDC/IMP/22/000027 Tryptophan 2gm+Threonine 6.35gm+ Aspartic acid 5.25gm+ Zinc acetate dehydrate 0.0176gm+Histidine HCl 9.45gm+Glucose monohydrate 396gm+Sodium dihydrogen Phosphate dehydrate	M/s. B. Braun Medical (India) Pvt. Ltd.	The firm didn't turn up for presentation.

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	6.24gm+Serine 10.5gm+Magnesium acetate tetrahydrate 2.2740gm+Glutamic acid +12.27gm+Tyrosine 0.0gm+ Proline11.9gm+Glycine 16.98gm+Alanine 16.98gm+Lysine hydrochloride 9.95gm+Soya-bean oil 80gm+Omega-3 acid triglycerides 20gm+Arginine 9.45gm+Sodium acetate trihydrate 0.9460gm+Sodium hydroxide 2.9280gm+Sodium chloride 0.9460 gm+ isoleucine 8.21gm+Medium chain triglycerides 100gm+Potassium acetate 9.2220gm+Phenylalanine 12.29gm+Methionine 6.84gm+Calcium chloride dehydrate 1.558gm+Valine 2gm+Leucine 10.96gm Parenteral preparation		
6.	FDC/IMP/22/000030 Valine 6.2gm+Serine 2.3gm+Aspartic acid 5.6gm+ +Water for injections 926gm+ Alanine 10.5gm+Sodium acetate trihydrate 2.8580gm+Lysine HCl 8.56gm+Citric acid monohydrate 0.21 to 0.42gm+Potassium acetate 2.453gm+Acetyl cysteine	M/s. B. Braun Medical (India) Pvt. Ltd.	The firm didn't turn up for presentation.

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	0.2gm+Tryptophan 1.6gm+Glycine 12gm+Magnesium chloridehexahydrate 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 0.4gmParenteral preparations		
7.	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.
8.	FDC/IMP/22/000028 Valine 5.2gm+Serine 6gm+Aspartic acid 3gm+ Alanine 9.7gm+Sodium acetate trihydrate 1.088gm+Lysine HCl 5.68gm+Potassium acetate 5.886gm+Tryptophan 1.14gm+Glycine 3.3gm+Magnesium acetate tetrahydrate 1.288gm+Isoleucine	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
	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 176gmParenteral preparations		
9.	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 1.2gm+aspartic acid 2.5gm+alanine 8.3gm+Ornithine HCl 1.66gm+Leucine 13.6gm+proline 7.1gm+acetyltirosine 0.86gm+threonine 4.6gm+glutamic acid 5.7gm Parenyeral preparations	M/s. B. Braun Medical (India) Pvt. Ltd.	The firm didn't turn up for presentation.

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GCT Division			
10.	CT/42/18 Online Submission (18065) Semaglutide	M/s. Novo-Nordisk	<p>The firm presented protocol amendment 9 (version no 7.0) dated 09-02-2022 before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.</p>
11.	CT/149/21 Online Submission (17548) BI 690517	M/s. Parexel	<p>The firm presented protocol amendment version 3 dated 30-03-2022 before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of proposed protocol amendment with the following conditions-</p> <ol style="list-style-type: none"> 1. Exclusion criteria 26 under protocol section 3.3.3 - Abnormal laboratory value should be specified to exclude patient with hepatic cirrhosis or other liver disease rather than based on investigator's judgment. 2. ICF should be updated for genetic testing/bio specimens as per protocol section 3.1.
12.	CT/06/22 Online Submission (30222) Ianalumab (CVAY736)	M/s. Novartis	<p>The firm presented Phase III clinical trial protocol before the committee.</p> <p>The committee noted that applicant has not presented the protocol in a proper way, missed some inclusion/exclusion criteria as submitted to CDSCO in their dossier.</p> <p>Accordingly, the committee opined that the applicant should present the protocol in details in upcoming SEC.</p>