

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 05th/24 meeting held on 14.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/20/000083 Ursodeoxycholic Acid Tablets IP 150mg/300mg/ 450mg/600mg (Additional Indication)	M/s. Abbott limited	<p>In light of earlier recommendation dated on 15.02.2024, the firm has presented their Phase III clinical trial protocol for the product Ursodeoxycholic acid tablets IP 150mg/300mg/450mg/600mg before the committee.</p> <p>After detailed deliberation, the committee opined to revise the protocol as follows:</p> <ol style="list-style-type: none"> 1) The study shall be carried out with standard of care treatment and preferably a comparative clinical trials in Non alcoholic Fatty Liver Disease (NAFLD). 2) The sample size shall be statistically significant and around 150-200 evaluable subjects. 3) The proposed duration of trial is too short and shall be increased to 6 months to ascertain the efficacy and safety in the proposed indication i.e. NAFLD. <p>Accordingly, the firm shall submit revised protocol for further review by the committee.</p>
2.	SND/MA/22/000051 Rabeprazole Sodium Oral disintegrating tablets 20 mg	M/s. Dr. Reddy's Laboratories Limited	<p>In light of earlier recommendation dated on 13.04.2022, the firm was granted permission to conduct BE study for Rabeprazole Sodium orally disintegrating tablet 20 mg. Now the firm has submitted the BE study report and presented the same before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of manufacture and market of Rabeprazole orally disintegrating tablets 10mg & 20mg with a condition to the conduct Phase IV study.</p> <p>Accordingly, the firm shall submit Phase IV study protocol within 3 months from the date of grant of permission to CDSCO for further review by the committee.</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
3.	FDC/MA/24/000072 Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg/15mg + Ezetimibe IP 10mg/5mg Tablets	M/s. Mankind Pharma Ltd.	<p>The firm presented the proposal before the committee.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> 1. The firm should present rationality and justification from scientific literature in peer-reviewed journal or any proof of concept study w.r.t applied FDC for proposed indication i.e. for the treatment of Non-Alcoholic Steatohepatitis (NASH)/ Non-Alcoholic fatty liver disease (NAFLD). 2. The firm should present International approval status of the FDC and its proposed indication (NASH/NAFLD). 3. The firm should present justification and supporting literature for proposed indication (NASH/NAFLD) of FDC vis-a-vis approved indication of individual drugs of FDC. <p>Accordingly, the firm should submit above data to CDSCO for further review by the committee.</p>
4.	FDC/MA/24/000085 L-Isoleucine U.S.P 0.6g + L-Leucine U.S.P. 0.73g + L-Lysine hydrochloride U.S.P. 0.58g + L-Methionine U.S.P. 0.4g + L-Phenylalanine U.S.P. 0.56g + L-Threonine U.S.P. 0.42g + L-Tryptophan U.S.P. 0.18g + L-Valine U.S.P. 0.5800g + L-Arginine U.S.P. 1.15g + L-Histidine U.S.P. 0.48g + Glycine U.S.P. 1.03g + L Alanine U.S.P. 2.07g	M/s. Aculife Healthcare Private Limited	<p>The firm did not turn up for the presentation.</p>

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	+ L Proline U.S.P. 0.68g + L Serine U.S.P. 0.5g + L Tyrosine U.S.P. 0.04g solution for infusion		
5.	FDC/MA/24/000086 L-Isoleucine U.S.P. 0.3300 % w/v + L- Leucine U.S.P. 0.4020 % w/v + L- Lysine hydrochloride U.S.P. 0.3190% w/v + L-Methionine U.S.P. 0.2200 % w/v + L-Phenylalanine U.S.P. 0.3080 % w/v + L-Threonine U.S.P. 0.2310 % w/v + L- Tryptophan U.S.P. 0.0990 % w/v + L- Valine U.S.P. 0.3190 % w/v + L-Arginine U.S.P. 0.6320 % w/v + L-Histidine U.S.P. 0.2640 % w/v + Glycine U.S.P. 0.5660 % w/v + L-Alanine U.S.P. 1.1380 % w/v + L-Proline U.S.P. 0.3740 % w/v + L- Serine U.S.P. 0.2750 % w/v + L-Tyrosine U.S.P. 0.0220 % w/v solution for infusion	M/s. Aculife Healthcare Private Limited	The firm did not turn up for the presentation.
6.	FDC/MA/24/000087 L-Isoleucine U.S.P. 0.33 % w/v + L- Leucine U.S.P. 0.4020 % w/v + L- Lysine hydrochloride U.S.P. 0.3190% w/v + L-Methionine U.S.P. 0.2200 % w/v + L-Phenylalanine U.S.P. 0.3080 % w/v + L-Threonine U.S.P. 0.2310 % w/v + L-Tryptophan	M/s. Aculife Healthcare Private Limited	The firm did not turn up for the presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	U.S.P. 0.0990 % w/v + L-Valine U.S.P. 0.3190 % w/v + L-Arginine U.S.P. 0.6320 % w/v + L-Histidine U.S.P. 0.2640 % w/v + Glycine U.S.P. 0.5660 % w/v + L-Alanine U.S.P. 1.1380 % w/v + L-Proline U.S.P. 0.3740 % w/v + L-Serine U.S.P. 0.2750 % w/v + L-Tyrosine U.S.P. 0.0220 % w/v solution for infusion		
7.	FDC/MA/24/000088 L-Isoleucine U.S.P. 0.6g + L-Leucine U.S.P. 0.73g + L-Lysine hydrochloride U.S.P. 0.58g + L-Methionine U.S.P. 0.4g + L-Phenylalanine U.S.P. 0.56g + L-Threonine U.S.P. 0.42g + L-Tryptophan U.S.P. 0.18g + L-Valine U.S.P. 0.5800 g + L-Arginine U.S.P. 1.15g + L-Histidine U.S.P. 0.48g + Glycine U.S.P. 1.03g + L Alanine U.S.P. 2.07g + L Proline U.S.P. 0.68g + L Serine U.S.P. 0.5g + L Tyrosine U.S.P. 0.04g solution for infusion	M/s. Aculife Healthcare Private Limited	The firm did not turn up for the presentation.