

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 06<sup>th</sup>/25 meeting held on 25.03.2025 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/22/23 Online Submission (36953) TP-102	JSS Medical Research Asia Pacific Private Limited	In light of earlier SEC recommendation dated 06.02.2025, the firm presented the proposed for Increase in the number of subjects from India (10) protocol no.TP-102 _102.  After detailed deliberation, the committee recommended the approval for recruitment of 10 additional subjects from India as presented by the firm.
<b>Biological Division</b>			
2.	BIO/CT18/FF/2024/4 3161  Semaglutide tablets (1.5mg, 4mg & 9mg)	M/s Novo Nordisk India Pvt Ltd	In light of earlier SEC recommendations dated 11.09.2024, the firm presented the difference in the manufacturing process of approved formulation of Semaglutide tablets 3 mg, 7 mg & 14 mg and proposed new formulation of Semaglutide tablets 1.5 mg, 4 mg, 9 mg along with regulatory approval status of Semaglutide tablets 1.5 mg, 4 mg, 9 mg of new formulation.  The committee noted that Semaglutide tablets 3 mg, 7 mg & 14 mg is approved for marketing in India. The firm has claimed that Semaglutide tablets 1.5 mg, 4 mg, 9 mg of new formulation are equivalent to the approved doses of Semaglutide tablets 3 mg, 7 mg & 14 mg respectively.  The firm is seeking approval for Semaglutide tablets 1.5 mg, 4 mg, 9 mg of new formulation based on the BE studies conducted in USA and Canada.  After detailed deliberation, the committee recommended to conduct clinical trial in India to establish safety and efficacy of Semaglutide tablets 1.5 mg, 4 mg, 9 mg of new formulation in Indian population.  Dr Rajesh Khadgawat did not participate in the deliberation.

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3.	File No. r-DNA-11016(13)/8/2024-eoffice(E-64487)  Velaglucerasealfa 400 units/vial powder for solution for infusion	M/s Takeda Biopharmaceuticals India Pvt. Ltd	The firm did not turn up for the presentation.
<b>BA/BE Division</b>			
4.	BABE/CT05/FF/2024/45919  Carbamizole 30mg Tablet	M/s Accutest Research Laboratories (I) Pvt. Ltd.	The firm presented the Protocol No. ARL-23-054; Version No.: 01, dated 08-Oct-2024 of the BA/BE study for Export purpose only.  After detailed deliberation, the committee noted that the firm not presented satisfactory w.r.t. rational for the proposed dose and any published literature for safety and tolerability of Carbamizole 30 mg tablets as single dose. Therefore, the committee did not recommend the proposed BABE study in healthy human subjects.
<b>SND Division</b>			
5.	SND/MA/25/000019  Semaglutide Tablets 3mg, 7 mg & 14 mg (Synthetic origin)	M/s. Torrent Pharmaceuticals Limited	The firm presented bioequivalence study report (Protocol No. 22-143 Amendment no. 01 dated 04-Dec-2023) as per BE NOC No. BE/SND/12/2023 dated 15.05.2023 (amendment dated 05.03.2024) along with Phase III clinical trial protocol (Protocol No.: CT/SEMA/DM/2024/3_1, Version No.: 2, Date: 01-Mar-2025) before the committee.  After detailed deliberation, the committee recommended to accept the bioequivalence study report and recommended for grant of permission to conduct Phase III clinical trial study with following change in the study protocol: <ul style="list-style-type: none"> <li>• In the exclusion criteria “Subjects with the diagnosis of retinopathy” should be replaced with “Subjects with the diagnosis of unstable retinopathy or maculopathy”.</li> </ul>

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6.	SND/MA/22/000363  Cholecalciferol aqueous injection 600000 IU/2 ml	M/s Akums Drugs & Pharmaceuticals Pvt. Ltd.	<p>The firm presented the proposal of PK/PD study protocol CHOL-23-007 ver.00 dated 25<sup>th</sup> Nov.2024 of drug product Cholecalciferol aqueous injection 600000 IU/2ml before the committee.</p> <p>The committee noted that adequate safety measures are not incorporated in proposed protocol i.e. Urinary Calcium/ Creatinine ratio, long term follow-up and GFR.</p> <p>After detailed deliberation, the committee did not recommend the proposed Study Protocol.</p>
7.	SND/MA/24/000062 Semaglutide solution for Injection (Synthetic origin) 0.25mg/0.5ml, 0.5 mg/0.5ml, 1 mg/0.5 ml, 1.7 mg/0.75 ml and 2.4 mg/0.75 ml	M/s SUN Pharma Limited	<p>In light of earlier SEC recommendations dated 13.01.2025, the firm presented the BE study report along with revised CT protocol no. ICR/23/013 ver. 3.0 dated 16<sup>th</sup> Jan.2025 before the committee.</p> <p>After detailed deliberation, the committee recommended to accept the bioequivalence study report and recommended for grant of permission to conduct Phase III clinical trial study as per revised protocol presented.</p>
<b>FDC Division</b>			
8.	FDC/MA/22/000315  Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Pioglitazone Hydrochloride IP eq. Pioglitazone 15 mg film coated tablet	M/s Windlas Biotech Limited	<p>In light of the earlier SEC recommendation dated 22.02.2024, the firm presented the proposal along with justification regarding Individual pharmacokinetic data and inter-subject variability of BE report.</p> <p>After detailed deliberation, the Committee opined that the BE study raw data requires further perusal with the clinical pharmacologist for further review by the committee.</p>