

Recommendations of the SEC (Endocrinology & Metabolism) made in its 11th/26 meeting held on 05.05.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/23/26 Online Submission (55030) Orforglipron (LY3502970)	M/s. IQVIA RDS (India) Private Limited	The firm presented phase IIIb clinical study protocol no.: J2A-MC-GZPV version no. Initial protocol dated 28-OCT-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/49/26 Online Submission (55749) Zinc-Desferrioxamine B	M/s. Spectrum Clinical Research Private Limited	The firm presented phase II clinical study protocol no.: CBL-ZYG-50 version no. 1.0 dated 26-FEB-2026. After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee. <ol style="list-style-type: none"> 1) Justification for inclusion of subjects with serum creatinine up to 2 mg/dL. 2) Scientific justification for the proposed BMI criteria (27 -35). 3) Justification for restricting the study population to the age group of 30–60 years instead of including adult subjects ≥ 18 years. 4) Reconsideration and justification of the proposed HbA1c inclusion range (7.5%–11%), particularly for subjects at the higher end, from an ethical and clinical perspective. 5) Justification for the use of HbA1c as a monitoring parameter, with consideration of alternative measures such as fructosamine, if appropriate. 6) Clear specification of the standard of care (SoC) to be provided in the study and its integration in the double-blind design. 7) The firm shall submit complete Pre-clinical and Phase I clinical study report of IMP (Zinc-Desferrioxamine B), 900 mg capsule to support progression to Phase II. 8) Provide a clear reason for using the investigational drug for treating Type 2 Diabetes Mellitus, along with expected benefits (such as improvement in blood

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			sugar levels). 9) Justification for dose selection and safety margins, along with available safety and efficacy data in the target population.
3.	CT/50/26 Online Submission (55812) Paltusotine	M/s. Allucent (India) Private Limited	<p>The firm presented Post Trial Access clinical study protocol no.: CRN00808-411 version no. 1.0 dated 23-DEC-2025.</p> <p>After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee.</p> <ol style="list-style-type: none"> 1) Paltusotine (CRN00808) is a selective somatostatin receptor subtype 2 (SST2) agonist administered orally once daily; the sponsor is required to provide a clear justification for its use as (Paltusotine) a treatment of choice instead of other drugs currently available in India. 2) The firm shall submit the Efficacy data of Paltusotine (CRN00808) study. 3) In the initial trial (CRN00808), the inclusion criteria focused on patients who had not responded adequately to other available medications, thereby justifying the use of the investigational medicinal product (IMP), paltusotine, as a potentially beneficial treatment option for this population.
New Drugs Division			
4.	ND/MA/25/000136 Tofogliflozin Tablets 20mg	M/s. Hetero Labs Limited	<p>The firm presented the proposal for grant of permission to manufacture and market Tofogliflozin Tablets 20 mg along with phase III Clinical Trial protocol (Protocol ID: HCR/III/TOFGDM/08/2025. Version no.: 1.0, Dated: 08-08-2025) and BE waiver before the committee.</p> <p>The committee noted that the firm did not present the justification w.r.t. BE waiver. Hence, the committee did not consider BE waiver.</p> <p>After detailed deliberation, committee recommended that the firm should revise the Phase-III CT protocol with the following points:</p>

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			<ol style="list-style-type: none"> 1. The upper limit of Hb1AC to be mentioned in inclusion criteria. 2. Drug naïve patients to be mentioned in inclusion criteria. 3. The exclusion criteria to be revised to remove the hypercortisolemia. 4. The patient with urinary calculi to be introduced in exclusion criteria. <p>Accordingly, the firm should submit the revised protocol to CDSCO for further review by the committee</p>
FDC Division			
5.	<p>FDC/MA/23/000139 FDC-11012(14)/4/2025-eoffice</p> <p>Linagliptin 2.5 mg + Metformin Hydrochloride IP (ER) 500 mg film coated bilayered tablets</p>	M/s. Synokem Pharmaceuticals Ltd	<p>In light of the condition mentioned in permission in Form CT-23 dated 29.01.2024; the firm presented the Active PMS protocol before the committee.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> 1. Firm should revise the inclusion criteria to include patients with HbA1c between 8% to 10%. 2. Firm should include the same indication as approved by the CDSCO. <p>Accordingly, the revised Active PMS study protocol should be submitted to CDSCO, for review.</p> <p>Further, after approval from CDSCO the firm should submit Active PMS study report for further review by the committee.</p>
6.	<p>FDC/CT/25/000062</p> <p>Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin IP + Metformin Hydrochloride (SR) IP + (10mg + 20mg + 500mg & 10mg + 20mg + 1000mg) film coated bilayered tablet</p>	M/s. Mascot Health Series Pvt. Ltd.	<p>In light of the condition mentioned in permission in Form CT-23 dated 27.12.2023 and earlier SEC recommendation dated 25.02.2026; the firm presented the revised Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial.</p> <p>Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.</p>
7.	FDC/CT/25/000063	M/s. Mascot Health Series Pvt.	In light of the condition mentioned in permission in Form CT-23 dated

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	Glimepiride IP + Voglibose IP + Metformin HCl IP (ER) (1 mg + 0.2 mg + 500 mg, 2 mg + 0.2 mg + 500 mg, 1 mg + 0.2 mg + 1000 mg & 2mg + 0.2 mg + 1000 mg) uncoated bilayered tablet	Ltd	<p>09.01.2023 and earlier SEC recommendation dated 25.02.2026; the firm presented the revised Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial.</p> <p>Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.</p>
8.	FDC/MA/26/000054 Imeglimin Hydrochloride (ER) + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin (1000mg + 50mg & 1000mg + 100mg) film coated bilayer tablet	M/s. Exemed Pharmaceutical	<p>The firm presented their proposal along with BE study protocol under both Fasting and Fed condition & Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee considered the rationality of the proposed FDC and recommended for grant of permission to conduct BE study (Fasting and Fed condition) with the proposed FDC.</p> <p>As regard to Phase III clinical trial protocol, the committee opined the following:</p> <ol style="list-style-type: none"> 1. Patients with history of pancreatitis should be excluded from the study. 2. Patients taking probiotics should be excluded from the study. <p>Accordingly, revised Phase III CT protocol should be submitted to CDSCO. Further, after approval from CDSCO, NOC may be issued.</p> <p>The result of the BE study (Fasting and Fed condition) should be submitted to CDSCO for further review by the committee before initiation of the Phase III clinical trial.</p>