

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 03<sup>th</sup>/26 meeting held on 05.02.2026 at CDSCO HQ New Delhi:**

<b>S. No</b>	<b>File Name &amp; Drug Name, Strength</b>	<b>Firm Name</b>	<b>Recommendations</b>
<b>GCT Division</b>			
01	CT/188/25 Online Submission (53981)  LY3841136	M/s Clinical Trials Eli Lilly and Company India Pvt. Ltd.	<p>The firm presented phase III Clinical study Protocol Number: J3R-MC-YDAG, Amendment Number: Initial protocol dated 16 September 2025.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that measuring glucagon is highly desirable when testing the efficacy and safety of amylin receptor agonists.</p>
<b>Medical Devices Division</b>			
02	IMP/MD/2024/143435  Parathyroid Detection System	M/s. India Medtronic Private Limited	<p>The proposal of the firm for import of the applied device (PTeye- Parathyroid Detection System) has been further deliberated with the experts from Parathyroid surgeon and Biomedical Engineer.</p> <p>After detailed deliberation, the committee opined that the firm shall submit the following data for further deliberation:</p> <ol style="list-style-type: none"> <li>1. Data demonstrating the utility of the device in assessing the vascularity of parathyroid tissues.</li> <li>2. Data on clinical utility in form of reduction of post-operative hypoparathyroidism with use of this technology during thyroid surgery.</li> </ol> <ol style="list-style-type: none"> <li>1. Also, the applicant need to provide adequate justification with baseline reference for the statements mentioned in the Instructions for use (Warning) section of the device viz point no 09 –do not use the system in the presence of flammable materials. This includes anesthetics, gases, disinfecting agents, cleaning products, or any similar materials susceptible to igniting due to electrical sparking and point no 14 – do not use in an oxygen-rich environment.</li> </ol>

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<b>BABE Division</b>			
03	BABE/CT05/FF/2025/49439  Thyrod Tablets, USP (low, medium, high) (Contains Levothyroxine (T4) and Liothyronine (T3)+Thyroid Tablets)	M/s Veeda Clinical Research Limited	<p>Firm presented the BA/BE study Protocol No.: 25-VIN-0096, Version No.:02 Date: 07-Nov-2025 for export purpose only before the committee.</p> <p>After detailed deliberation, the committee opined that firm should submit the following data / informations:</p> <p>(i) Regulatory approval status of the proposed dose (<i>i.e.</i> 380 µg T4 and 90 µg T3; total thyroid hormone potency of 740 µg T4) of the Thyroid Tablets of porcine origin in Globally including by USFDA,</p> <p>(ii) More safety data and published literature demonstrating safety and tolerability in healthy subjects for the proposed dose of the Thyroid Tablets of porcine origin and</p> <p>(iii) Antigenicity data for the Thyroid powder / extract Tablets of porcine origin.</p> <p>Accordingly, the firm should submit above data for further review by the committee.</p>
<b>Biological Division</b>			
04	BIO/CT04/FF/2025/51855  Insulin Aspart Injection I.P 100 units/ml	M/s G.C Chemie Pharmie LTD.	<p>The firm presented the proposal to conduct Phase I clinical trial titled "A double blind, balanced, randomized, two-treatment, two-sequence, two-period, single dose, crossover, pharmacokinetic and pharmacodynamics bioequivalence research of Insulin Aspart Injection I. P. 100 units/mL of G. C Chemie Pharmie Limited, India comparing with NovoRapid 100 units/ml solution for injection of Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark, in healthy, adult, human male participants using Euglycemic clamp technique under fasting conditions." vide Protocol No. AR 156-24, Version 02 dated 21-Aug 2025.</p> <p>After detailed deliberation, the committee recommended the firm to submit the following:</p> <ul style="list-style-type: none"> <li>Justification for 22% inter-subject</li> </ul>

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			<p>variability in the proposed study in 26 healthy volunteers.</p> <ul style="list-style-type: none"> <li>• The validation data of the ELISA method proposed to be used for the estimation of C-peptide and insulin.</li> <li>• Revised protocol including male and female healthy volunteers in the ratio of 70:30.</li> </ul> <p>Accordingly, the firm should submit the revised protocol along with the data to CDSCO for further evaluation by the committee.</p>
05	<p>BIO/CT04/FF/2025/51 826</p> <p>Biphasic Insulin Aspart Injection I.P (30:70) 100 units/ml</p>	M/s G.C Chemie Pharmie LTD.	<p>The firm presented the proposal to conduct Phase I clinical trial titled "A double blind, balanced, randomized, two-treatment, two-sequence, two-period, single dose, crossover, pharmacokinetic and pharmacodynamic bioequivalence research of Biphasic Insulin Aspart Injection I. P. 30/70 (Mixture of insulin aspart and protamine crystallised insulin aspart) suspension for injection 100 units/mL of G. C Chemie Pharmie Limited, India comparing with NovoMix 30 100 units/ml suspension for injection (Biphasic insulin aspart I.P. (Mixture of insulin aspart and protamine crystallised insulin aspart) of Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd, Denmark, in healthy, adult, human male participants using Euglycemic clamp technique under fasting conditions" vide Protocol No. AR 157-24, Version 02 dated 21-Aug 2025.</p> <p>After detailed deliberation, the committee recommended the firm to submit the following:</p> <ul style="list-style-type: none"> <li>• Justification for 22% inter-subject variability in the proposed study in 26 healthy volunteers.</li> <li>• The validation data of the ELISA method proposed to be used for the estimation of C-peptide and insulin.</li> <li>• Revised protocol including male and female healthy volunteers in the ratio of 70:30.</li> </ul>

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			Accordingly, the firm should submit the revised protocol along with the data to CDSCO for further evaluation by the committee.
06	BIO/CT18/FF/2025/50 951  Velaglucerase Alfa (r-DNA Origin)	M/s Takeda Biopharmaceutica ls India Pvt. Ltd	The firm did not turn up for the presentation.
<b>SND Division</b>			
07	SND/MA/25/000230  Semaglutide Injection 2 mg/1.5 ml,(1.34 mg/ml), 4 mg/3 ml (1.34 mg/ml), and 8 mg/3 ml,(2.68mg/ml)	M/s Cipla Limited	<p>The firm presented the Proposal for manufacturing and marketing Semaglutide Injection along with BE study report before the Committee.</p> <p>The Committee was informed that firm submitted Phase III Clinical trial Protocol, however firm sought for CT waiver for applied indication and strength.</p> <p>After detailed deliberation, the Committee accepted the BE study results and opined that firm should conduct Phase III Clinical trial.</p> <p>Accordingly, the firm should present Phase III Clinical trial Protocol before the Committee for further review.</p>
08	SND/CT21/FF/2024/4 6165 SND/MA/24/000214  Semaglutide Tablets 3 mg/ 7 mg/14 mg,	M/s Macleods Pharmaceuticals Ltd.	<p>In light of earlier SEC recommendation dated 06.02.2025, the firm presented BE report of Semaglutide Tablets 14 mg along with justification for Phase III CT waiver for Type 2 Diabetes Mellitus before the Committee.</p> <p>After detailed deliberation, the committee recommended to accept the BE study report and also opined that firm should conduct Phase III CT Study.</p> <p>Accordingly, firm shall submit Phase III Clinical trial protocol to CDSCO for further review by committee.</p>

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<b>FDC Division</b>			
09	FDC/MA/25/000107  Empagliflozin + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP (ER) (10 mg + 100 mg + 500 mg, 25 mg + 100 mg + 500 mg) film coated bilayer tablet	M/s Exemed Pharmaceuticals	<p>The firm presented their proposal along with BE study protocol under both Fasting and Fed condition &amp; Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee considered the essentiality and desirability of the proposed FDC and recommended for grant of permission to conduct the BE study (Fasting and Fed condition) &amp; Phase III clinical trial.</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>