

Recommendations of the SEC (Endocrinology & Metabolism) made in its 24th/26 meeting held on 22.10.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	File No. r-DNA/7/2026-eoffice (E Comp. No.: 39359) E-Receipt: 157935/2026/CRU Recombinant Human growth Hormone (Somatropin) Injection	M/s Reliance Life Sciences Pvt. Ltd.	The firm presented the Clinical Study Report (CSR) of the Phase IV clinical trial of SomatoRel® (recombinant human growth hormone), conducted as per Protocol No. RLS/PMS/2019/03, Version 2.0, dated 02 August 2019. After detailed deliberation, the Committee noted the results of the study.
2.	BIO/CT04/FF/2026/57591 Insulin degludec and Insulin aspart Injection 100 units/ml (Insulin Degludec 70% and Insulin Aspart 30% Injection)	M/s. G.C. Chemie Pharmie Ltd.	The firm presented the Phase I Clinical Study Report for CT titled: “A double blind, balanced, randomized, two-treatment, two-sequence, two-period, single dose, crossover, pharmacokinetic and pharmacodynamic bioequivalence study of insulin degludec and insulin aspart injection 100 units/mL of G. C Chemie Pharmie Limited, India comparing with Ryzodeg (Insulin degludec/Insulin aspart) 100 units/mL of Novo Nordisk A/S, Novo All, DK-2880 Bagsvrd, Denmark, in healthy, adult, human male subjects using Euglycemic clamp technique under fasting conditions”, Study No.: AR136-24. The firm also presented the proposal for grant of permission to conduct the Phase III Clinical Trial titled “A Prospective, Multi-center, Randomized, Open-Label, Parallel group, Active-controlled, Phase III clinical study to evaluate the Efficacy, Safety and Immunogenicity of Insulin degludec and Insulin aspart Injection 100 units/ml (Insulin Degludec 70% and Insulin Aspart 30% Injection) (Investigational drug) of G.C. Chemie Pharmie Limited, India, with Ryzodeg100 units/ml (Insulin degludec 70% /Insulin aspart Injection 30%) (Reference drug) of Novo Nordisk India Private Limited, in adult participants with Type II Diabetes Mellitus. Protocol Number: CT26-002, Version 1.0: & Dated-06 Jun 2026. After detailed deliberation, the committee

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			noted the Results of Phase I Clinical Study and further recommended the grant of permission to conduct the proposed Phase III Clinical Trial as per the presented protocol.
3.	BIO/CT04/FF/2026/57469 Insulin Degludec Injection 300 Units/3ml (100 Units/ml)	M/s. Mankind Pharma Ltd.	<p>The firm presented the proposal to conduct a Phase I clinical trial titled “A double blind, balanced, randomized, two-treatment, two-sequence, two-period, single-dose subcutaneous injection, crossover, pharmacokinetic and pharmacodynamic bioequivalence study of Insulin Degludec (100 units/mL) injection of Mankind Pharma Limited, India comparing with Tresiba® Insulin Degludec inj. 100 units/mL of Novo Nordisk, India in healthy, adult, human male participants using Euglycemic clamp technique under fasting condition” with Protocol No. AR066-26, Version No.: 01, dated 29.05.2026 Amendment 01 dated 03.09.2026.</p> <p>After detailed deliberation, the committee recommended the grant of permission to conduct the proposed Phase I clinical trial as per the presented protocol.</p>
New Drugs Division			
4.	ND/CT/26/000011 ND/CT04/FF/2026/55071 (Inosine+ Nicotinamide+ Riboflavin+ Succinic Acid enteric coated tablet and intravenous solution for infusion)	M/s. Invitro Research Solutions Private Limited.	<p>In light of earlier recommendation dated 24.06.2026, firm presented the revised Phase III Clinical Trial Protocol (Protocol No: iVRS-CD-25-029, Version: 02, Dated: 15 Jul 2026) of drug (Inosine + Nicotinamide + Riboflavin + Succinic Acid enteric coated tablet and intravenous solution for infusion) before the committee.</p> <p>After detailed deliberation, committee recommended for grant of permission to conduct Phase III clinical trial as per the revised protocol presented by the firm.</p> <p>Accordingly, the firm should submit Phase III clinical trial report to CDSCO for further review by the committee.</p>