

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 04th/26 meeting held on 09.04.2026 at CDSCO HQ New Delhi:

| S.No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---------------------|---|---|--|
| GCT Division | | | |
| 1. | CT/170/25 Online Submission (53262) LY4268989 (MORF-057), LY3074828 (Mirikizumab) | M/s Clinical Trials Eli Lilly and Company India Pvt. Ltd. | In light of earlier SEC recommendation dated 08.01.2026, the firm presented phase II clinical study protocol no.: J6E-MC-KWAN amendment. b dated 27-OCT-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Vineet Ahuja didn't participate in the discussion. |
| 2. | CT/35/26 Online Submission (55316) Efimosfermin Alfa | M/s IQVIA RDS (India) Private Limited | The firm presented phase III clinical study protocol no.: 301160 Amendment 1 Final dated 21-JAN-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more geographically distributed government site shall be included in the study. |
| 3. | CT/39/26 Online Submission (55469) Efimosfermin Alfa | M/s IQVIA RDS (India) Private Limited | The firm presented phase III clinical study protocol no.: 306246 Amendment 1 Final dated 21-JAN-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more geographically distributed government site shall be included in the study. |

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| 4. | CT/43/26 Online Submission (55476) LY4268989 | M/s Clinical Trials Eli Lilly and Company India Pvt. Ltd. | <p>The firm presented phase II clinical study protocol no.: J6E-MC-KWAM amendment a dated 12-FEB-2026.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.</p> <p>Dr. Vineet Ahuja didn't participate in the discussion.</p> |
| FDC Division | | | |
| 5. | FDC/MA/25/000228 Co-Pack of Each blister card contains: a) Vonoprazan Fumarate Eq. to Vonoprazan 20 mg (2 Tablets) film coated tablet b) Amoxicillin Trihydrate IP Eq. to Amoxicillin Capsules 500 mg (6 Capsules) hard gelatin capsule | M/s Hetero Labs Limited | <p>The firm presented their proposal along with justification for BE & Phase III CT waiver before the committee.</p> <p>The committee noted that the proposed Combikit is already approved in USA and individual drugs are already approved by CDSCO.</p> <p>After detailed deliberation, the committee considered the request for BE and Phase III CT waiver and recommend for grant of permission to manufacture and market the proposed Combikit with the condition that Active PMS should be conducted.</p> <p>Accordingly, the firm should submit Active PMS protocol to CDSCO within 3 months of approval of the Combikit for review by the committee.</p> |