

**Recommendations of the SEC (Cardiovascular) made in its 17<sup>th</sup>/24 meeting held on 11.09.2024 at CDSCO HQ New Delhi:**

| S. No                 | File Name & Drug Name, Strength   | Firm Name                                    | Recommendations  |
|-----------------------|---|--|--|
| <b>GCT Division</b>   |   |  |  |
| 1.                    | CT/118/23<br>Online Submission<br>(32309)<br><br>Survodutide  | M/s. IQVIA RDS<br>(India) Private<br>Limited | In light of earlier SEC recommendation on 22.05.2024, the firm presented protocol amendment version 2.0 dated 22 November 2023 and protocol amendment version 3.0 dated 12 January 2024 protocol no. 1404-0040.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.   |
| 2.                    | CT/37/23<br>Online Submission<br>(34649)<br><br>Milvexian   | M/s. IQVIA RDS<br>(India) Private<br>Limited | The firm presented protocol amendment 1 dated 31 March 2023 and protocol amendment 2 dated 07 February 2024 protocol no. 70033093AFL3002.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.   |
| <b>BA/BE Division</b> |   |  |  |
| 3.                    | BABE/CT05/FF/<br>2024/41882<br><br>Diltiazem<br>Hydrochloride<br>Topical Gel (4%w/w)                                      | M/s. Veeda<br>Clinical Research<br>Limited   | In light of the earlier SEC recommendation dated 07.05.2024, the firm presented preclinical & safety data of the applied product and rationale for study design in which comparing test product Diltiazem Hydrochloride Topical Gel (4%w/w) Vs Reference product CARDIZEM Tablets 120 mg in healthy subjects.<br><br>After detailed deliberation, the committee opined that the firm need to present the proposal again alongwith evidence of ethical clearance/ approval of animal toxicity study conducted in China. |
| 4.                    | BABE/CT05/FF/<br>2024/42949<br><br>FDC of 24 mg<br>Extended Release<br>(ER) Toremide and<br>8 mg Dapagliflozin<br>Tablets | M/s. Syngene<br>International<br>Limited     | The firm presented the Protocol No.: SYNCD-022-24, Version No. 1.00, Date 12-APR-2024 for BA/BE study for export purpose only.<br><br>After detailed deliberation, the committee did not recommend the permission to conduct the BABE study for export   |

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|                     |   |                                       | purpose as the proposed FDC of 24 mg Extended Release (ER) Toremide and 8 mg Dapagliflozin Tablets is not rational.   |
| 5.                  | BABE/CT05/FF/2024/43905<br><br>FDC of Telmisartan and Chlortalidone Tablets 80mg + 12.5mg   | M/s. Dr Reddy's Laboratories Limited  | <p>The firm presented the Protocol No. 035-24, Version No.: 01, Dated: 29 Apr 2024 &amp; 036-24, Version No.: 01, Dated: 29 Apr 2024 for BA/BE study for Export purpose only.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for the export purpose only with condition that the firm shall revise the protocol with respect to following changes:</p> <p>(i) Inclusion of type of study in the protocol title as PILOT,</p> <p>(ii) Inclusion of Serum Pregnancy test for the female volunteer at the time of Screening and end of the study.</p> <p>(iii) Inclusion of the other Pharmacokinetics Parameters for Chlortalidone.</p> <p>Accordingly, the firm should submit the revised Protocol to the CDSCO for review.</p> |
| 6.                  | BABE/CT05/FF/2024/42574<br><br>FDC of Empagliflozin 10 mg and Bisoprolol Fumarate Tablet 10 mg  | M/s. Dr. Reddy's Laboratories Limited | The firm didn't turn up for presentation.   |
| <b>FDC Division</b> |   |                                       |   |
| 7.                  | FDC/MA/24/000188<br><br>Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg/10mg + Bisoprolol fumarate IP 1.25mg/2.5mg film coated tablet | M/s Eris Lifesciences Limited         | <p>The firm presented the proposal along with justification for BE and Phase III CT waiver before the committee for lower strengths based on their Clinical Trial report of higher strength i.e. Dapagliflozin 10mg/10mg + Bisoprolol fumarate IP 5mg/10mg tablet before the committee.</p> <p>After detailed deliberation, the committee considered the request for BE and Phase</p>   |

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|-------|---------------------------------|-----------|---|
|       |                                 |           | <p>III CT waiver and recommended for grant of permission for manufacturing and marketing of the FDC in both the strengths with the condition to conduct the Phase IV clinical trial.</p> <p>Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.</p> |