

Recommendations of the SEC (Endocrinology & Metabolism) made in its 15th/24 meeting held on 22.08.2024 at CDSCO (HQ), New Delhi:

| S. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---------------------|--|--------------------------------|---|
| FDC Division | | | |
| 1. | FDC/MA/23/000228 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Pioglitazone Hydrochloride IP eq. Pioglitazone 15 mg film coated tablet | M/s. Eris Lifesciences Limited | In light of earlier SEC recommendation dated 24.01.2024, the firm presented the proposal along with Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of the proposed FDC. |
| 2. | FDC/MA/23/000236 Empagliflozin 10mg/10mg/25mg/25 mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/100mg/50mg/100mg film coated Tablet | M/s. Exemed Pharmaceuticals | The firm presented the proposal along with Phase III clinical trial report for two strengths i.e. Empagliflozin 10mg/25mg + Sitagliptin 100mg/100mg film coated Tablet before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of the proposed FDC. |