Recommendations of the SEC (Endocrinology & Metabolism) made in its 04th /24 SEC meeting held on 22.02.2024 at CDSCO (HQ) New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/21/000290 Nano Carrier Entrapped Vitamin D3 Oral Dispersion 60000 IU per 5 ml	M/s. Pulse Pharmaceuticals Private Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Nano Carrier Entrapped Vitamin D3 oral dispersion 60000 IU per 5 ml along with Phase III clinical trial report before the committee. After detailed deliberation, the committee opined that the firm should submit casualty assessment data of all adverse events as per WHO scale and clarification regarding major discrepancy observed in the laboratory value with respect to 25-hydroxy cholecalciferol to CDSCO for further review by the Committee.
2.	SND/MA/23/000295 Eliglustat sublingual Film 16mg (orphan drug)	M/s. Kashiv biosciences	The firm presented their proposal for grant of permission to manufacture and marketing of Eliglustat sublingual film 16 mg along with justification for waiver of clinical trial and bioequivalence study before the committee. The firm has informed that Eliglustat capsules 84 mg is already approved by CDSCO on 31.01.2017. However, Eliglustat sublingual film 16mg not yet approved anywhere. After detailed deliberation, the committee opined that the firm should submit PK/PD data in healthy voluntary from proposed manufacturing site with Eliglustat sublingual film 16 mg to the CDSCO for further review by the committee.
FDC Division			
3.	FDC/MA/22/000315 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Pioglitazone Hydrochloride lP eq.	M/s. Windlas Biotech Limited	The firm presented their proposal along with BE study report before the committee. After detailed deliberation, the committee opined that firm should submit the following:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Pioglitazone 15 mg film coated tablet		1. Individual Pharmacokinetic data. 2. Justification for inter-subject variability. Accordingly, the firm should submit above data for further review by the committee.
4.	FDC/MA/22/000325 Linagliptin + Dapagliflozin Propanediol monohydrate eq to Dapagliflozin + Metformin HCl eq to Metformin (as sustained release) 5mg+5mg+500mg/ 5mg+5mg+1000mg/ 10mg+5mg+500mg/ 10mg+5mg+1000mg film coated bilayered tablets	M/s. Theon Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 18.07.2023, the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC in which Phase III clinical trial has been conducted i.e. FDC of Linagliptin10mg/10mg+ Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin5mg/5mg + Metformin Hydrochloride eq. to Metformin (as sustained release)500mg/1000mg tablets.
5.	FDC/MA/23/000085 Lobeglitazone sulfate 0.25mg/0.25mg + Sitagliptin Phosphate Monohydrate IP Eq. to Sitagliptin 50mg/100mg film coated tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation 15.06.2023 & 16.06.2023, the firm presented their proposal along with justification before the committee. However, after detailed deliberation the committee reiterated its earlier recommendation.
6.	FDC/MA/23/000141 Metformin HCl IP 500mg/500mg + Glimepiride IP 1mg/2mg + Sitagliptin phosphate monohydrate IP 50mg/50mg Tablets	M/s. Mascot Health Series Pvt. Ltd	The firm presented their proposal along with request for CT waiver & BE waiver of proposed strength based on BE report of higher strength i.e. FDC of Metformin Hydrochloride IP 1000 mg + Glimepiride IP 2 mg + Sitagliptin phosphate monohydrate IP 50 mg tablets before the committee. After detailed deliberation, the committee recommended for submission of data including dissolution data and justification for BE waiver as per the BE study guideline for further review by the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
7.	FDC/MA/24/000018 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg/10mg + Gliclazide IP (SR) 30mg/60mg + Metformin Hydrochloride IP (SR) 500mg/500mg film coated bilayered tablet	M/s. Eris Lifesciences Limited	The firm presented their proposal along with BE study protocol and justification for CT waiver before the committee. After detailed deliberation, the committee considered the request for CT waiver with the condition to conduct Phase IV CT study. Further, the committee recommended for conducting the BE study as per presented protocol. Accordingly, the firm should submit the BE study report to CDSCO for further review by the committee.
8.	FDC/MA/22/000339 Glimepiride 1mg/2mg/1mg/2mg + Sitagliptin Phosphate Monohydrate IP eq to Sitagliptin 50mg/50mg/100mg/100mg tablet	M/s. Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 18.07.2023, the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC of Glimepiride 1 mg/ 2 mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg / 100 mg tablet.
9.	FDC/MA/24/000023 Metformin Hydrochloride IP (sustained release) + Glimepiride IP + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 500mg/500mg/1000mg/1000mg + 1mg/2mg/1mg/2mg + 50mg/50mg/50mg/50mg film coated bilayered tablet	M/s. Mascot Health Series Pvt. Ltd	The firm presented their proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, firm should submit BE study report for review by the committee to take further decision on the Phase III clinical trial protocol.
10.	FDC/MA/24/000027 Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg/10mg + Lobeglitazone sulfate	M/s. Akums Drugs and Pharmaceuticals Ltd.	The firm did not turn up for the presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	0.25mg/0.25mg film coated tablet		