

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 02<sup>nd</sup>/24 meeting held on 24.01.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/03/24 Online Submission (41209)  Cagrisema 2.4 mg/2.4 mg	M/s. Novo-Nordisk	The firm presented Phase II clinical study protocol No. NN9388-7700.  After detailed deliberation, the committee recommended that the firm should submit detailed safety data from Phase I study for further review by the committee. Also the firm should include the Nephrologists as PI /Co –PI from the same site/institute where the study is planned.
<b>SND Division</b>			
2.	SND/MA/23/000235  Dapagliflozin Tablet 5mg & 10mg	M/s. Biocon Limited	The firm presented their proposal for grant of permission to manufacture and market of Dapagliflozin 2,3 Butanediol monohydrate 5mg & 10 mg tablets along with BE study report and justification for waiver of clinical trial before the committee.  The firm informed that applied Dapagliflozin 2, 3 Butanediol monohydrate has not been approved in India.  After detailed deliberation, the committee opined that firm should submit more clinical safety data of proposed formulations of Dapagliflozin 2,3 Butanediol monohydrate vis-a-vis Dapagliflozin propanediol monohydrate formulation to CDSCO for further review by the committee in presence of at least two pharmacologists.
<b>FDC Division</b>			
3.	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 Life Sciences Limited	The firm presented their proposal along with BE study report before the committee.  After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission was already granted by CDSCO.  The Phase III clinical trial report should be submitted to CDSCO for further

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			review by the committee.
4.	FDC/MA/23/000358  Empagliflozin + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP (SR) (10mg+100mg+500mg/10mg+100mg+1000 mg/25mg+100mg+500mg/25mg+100mg+1000mg) film coated tablet	M/s Synokem Pharmaceuticals Ltd.	The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the BE study with the condition that Doctor (MD Medicine) should be present during study.  Accordingly, firm should submit BE study report for review by the committee to take further decision on the Phase III clinical trial protocol.
5.	FDC/MA/23/000362  Empagliflozin 10mg/25mg + Vildagliptin IP (SR) 100mg/100mg tablet	M/s Exemed Pharmaceuticals	The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the BE Study.  Accordingly, the firm should submit BE study report for review by the committee and for taking further decision on the Phase III clinical trial protocol.
6.	FDC/MA/23/000367  Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg/10mg + Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg/ 20mg film coated tablet	M/s Pure & Cure Healthcare Pvt. Ltd.	The firm presented its proposal along with BE study and Phase III clinical trial protocol.  After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study.  The committee opined that the Phase III CT protocol should be adequately modified w.r.t. study period, list of Principal investigator etc.  Accordingly, BE study report should be presented before the SEC along with revised Phase III clinical trial protocol.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
7.	FDC/MA/23/000372  Sitagliptin phosphate monohydrate IP eq. to Sitagliptin + Voglibose IP + Metformin Hydrochloride IP (SR) (50mg+0.2mg+500mg )/ (50mg+0.2mg +1000mg)/ (100mg+ 0.2mg+500mg)/ (100mg/0.2mg+ 1000mg) film coated bilayered tablet	M/s Mascot Health Series Pvt. Ltd	The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the BE study & Phase III clinical trial study.  The result of the BE study should be presented for review by the SEC before initiation of the Phase III clinical trial.
8.	FDC/MA/23/000375  Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin 5mg/5mg/5mg/5mg + Glimepiride IP 1mg/2mg/1mg/2mg + Metformin Hydrochloride IP (As ER) 500mg/500mg/1000mg/1000mg film coated bilayered tablet	M/s Akums Drugs & Pharmaceuticals Ltd.	The firm presented their proposal along with BE report of higher strength of proposed FDC (Dapagliflozin 10mg + Glimepiride 2mg + Metformin ER 1000mg tablet) before the committee.  After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product after submission of data including dissolution data and justification for BE waiver as per the BE Study guideline with the condition that the firm should conduct Active PMS study.  Accordingly, the firm should submit Active PMS study protocol to CDSCO within 03 months of approval for review by the committee.
9.	FDC/MA/23/000376  Sitagliptin Phosphate Monohydrate IP Eq. to Sitagliptin 50mg/100mg /50mg/100mg/50mg/ 100mg + Glimepiride IP 2mg/2mg/1mg/1mg/0.	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, BE study report should be presented before the SEC along with Phase III clinical trial protocol.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	5mg/0.5mg film coated tablet		