Recommendations of the SEC (Endocrinology & Metabolism) made in its 89th meeting held on 14.06.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/20/000142 Metformin HCL IP(SR)500mg/1000mg/500mg/1000mg + Vildagliptin SR 50mg/50mg/ 100mg/100mg Tablets	M/s Mascot	In light of earlier SEC recommendation dated 18.02.2021, the firm presented the BE study report before the committee. After detailed deliberation, the committee recommended for initiation of Phase III CT study for which permission was already granted to the firm.
2.	FDC/MA/20/000131 Pioglitazone 30mg/15mg + Vildagliptin(SR)100mg/100mg film coated bilayered tablet	M/s. Synokem Pharmaceuticals	The firm presented their proposal before the committee. The committee noted that earlier the firm was already granted permission for conducting the BE and CT study for FDC of Pioglitazone 30mg/15mg + Vildagliptin (SR)100mg/ 100mg film coated bilayered tablet. However, now the firm presented revised BE & CT protocol for lower strength i.e FDC of Pioglitazone **15mg** + Vildagliptin (SR) **100mg** film coated bilayered tablet only. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE & CT study of the lower strength.
3.	FDC/MA/21/000016 Dapagliflozin 5mg/10mg +Teneligliptin Hydrobromide hydrate20mg/20mg film coated tablet	M/s. Inventia Healthcare Limited	In light of earlier SEC recommendation dated 18.02.2021, the firm presented the BE study report before the committee. After detailed deliberation, the committee recommended for initiation of Phase III CT for which permission was already granted to the firm.
4.	FDC/MA/22/000079 Pioglitazone HCl IP eq. to Pioglitazone 7.5/15 mg+ Vildagliptin 50/50 mg Tablets	M/s Mascot Health	The firm presented their proposal before the committee. The firm informed that CT and BE study permission were already granted to the firm for higher strength with Vildagliptin in SR dosage form. After detailed deliberation, the committee opined that the firm should conduct BE study on the proposed FDC and accordingly, protocol should be submitted for further deliberation by the committee.

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5.	FDC/MA/22/000017 Dapagliflozin IP 10mg + Metformin Hydrochloride IP (as sustained release) 1000mg + Sitagliptin Phosphate Monohydrate IP 100mg tablet	M/s. Mascot Health Series Pvt. Ltd.	The firm presented their proposal along with BE & CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE and CT study with following conditions: 1. HbA1c criteria should be defined in discontinuation criteria. 2. Dose of Metformin ≥ 1000mg should be clearly mentioned.
6.	FDC/MA/22/000155 Metformin Hydrochloride (as extended release) 500mg/1000mg/500mg/1000mg /500mg/1000mg/500mg/1000mg+ Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg/50mg/50mg/50mg/100mg/100mg/100mg/100mg+ Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/5mg/10mg/10mg /5mg/5mg/10mg/10mg tablets	M/s. Logos Pharma	The firm did not turn up for presentation.
7.	FDC/MA/22/000139 Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg/50mg+ Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/10mg tablets	M/s. Logos Pharma	The firm did not turn up for presentation.
8.	FDC/MA/22/000145 Linagliptin 2.5mg/5mg/5mg + Metformin Hydrochloride (ER)	M/s. Alkem Laboratories Ltd.	The firm presented their proposal before the committee along with BE study protocol. The committee noted that FDC of Linagliptin + Metformin Hydrochloride

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	1000mg/500mg/1000 mgfilm coated bilayered tablet		(ER) (2.5mg + 1000mg & 5mg + 1000mg) tablets is approved recently on 08.04.2022. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The result of the study should be presented before the committee for consideration.
9.	FDC/MA/22/000150 Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg/50mg+ DapagliflozinPropanediol Monohydrate eq. to Dapagliflozin 5mg/10mg tablets	M/s. Theon Pharmaceuticals Ltd.	The firm did not turn up for presentation.
10.	FDC/MA/22/000158 DapagliflozinPropanediol Monohydrate Eq. to Dapagliflozin 5mg/5mg + Sitagliptin Phosphate monohydrate IP eq. to Sitagliptin 50mg/50mg +_Metformin Hydrochloride IP 500/1000mg tablets	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented their proposal before the committee along with justification for BE study waiver and Phase III CT protocol. Based on BCS classification, the committee considered the justification for BE study waiver. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III CT. The result of the study should be presented before the committee for further consideration.
11.	FDC/MA/21/000235 Vildagliptin SR + Metformin (SR) (50mg/50mg/100mg/100mg 500mg/1000mg/500mg/1000mg) Tablet	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm presented their proposal before the committee along with revised Phase III CT protocol for FDC of Vildagliptin SR + Metformin (SR) (50mg + 500mg & 50mg + 100mg) tablet. After detailed deliberation, the committee recommended for grant of permission to conduct the second Phase III CT.
12.	FDC/MA/21/000146 Teneligliptin IP 20 mg/20mg + Metformin HCl IP (SR) 500MG/1000MG/Pioglitazone HCl IP 15 mg/15 mg	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal before the committee along with BE study protocol and justification for CT waiver. The committee noted that FDC of Teneleglipti n + Pioglitazone is approved by CDSCO recently based on Phase III clinical trial conducted on the patients who were already on Metformin therapy. The firm presented the results of Phase III

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			clinical trial on the FDC of Teneleglitin + Pioglitazone with Metformin background therapy. As regard to Phase III clinical trial waiver, the committee considered the same with condition that the Phase IV CT should be conducted after approval of the FDC. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study for further consideration.
13.	FDC/MA/21/000256 Sitagliptin phosphate monohydrate 50 mg/100mg+ Dapagliflozin propanediol monohydrate 5 mg/10 mg tablets	M/s. Exemed Pharmaceuticals	The firm presented their proposal along with Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
14.	FDC/MA/22/000143 Vildagliptin (as sustained release) 100mg/100mg+ Pioglitazone Hydrochloride eq. to Pioglitazone IP 15 mg/30 mg	M/s. Exemed Pharmaceuticals	The firm presented their proposal along with BE & CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE and CT study.
15.	FDC/MA/21/000283 Sitagliptin 100mg/100mg + Metformin ER 500mg/1000mg tablets	M/s. Optimus Pharma Private Ltd	The firm presented their proposal along with the result of BE study. After detailed deliberation, the committee opined that complete BE study report including the analytical graphs/ data etc. should be sent to the Pharmacologist of the expert committee for review and recommendations to CDSCO in the matter.
16.	FDC/MA/22/000168 Linagliptin 5 mg /5mg+Dapagliflozin 10 mg/ 5 mg tablets	M/s Alkem Health Science	The firm presented their proposal along with justification for BE study waiver and Phase III CT protocol for higher strength before the committee. As regard to BE study waiver, the committee considered the justification for BE study waiver on the basis of BCS

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			classification. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III CT for FDC of Linagliptin 5 mg +Dapagliflozin 10 mg tablets with condition that patients who are on the stable dose of Metformin ≥ 1000 mg at least 06 weeks should be enrolled in the study. The results of the study should be presented before the committee for further consideration.
Biological Division			
17.	05/PhaseIV/Shire/19-BD(Pt-I)(diary no. 2361) Velaglucerase Alfa	M/s Shire Biotech Pvt.Ltd	In light of the SEC recommendations dated 18.02.2022, the firm presented justification for amendment in their PMS protocol. After detailed deliberation, the committee recommended to include the data of any patient who enter the study as GD-1, and at a later date are diagnosed as GD-3, to be followed for full one-year and their data to be included in the amended PMS protocol.
18.	BIO/CT/18/FF/2022/30813 Technosphere insulin inhalation powder	M/s Cipla Ltd.	The firm presented the proposal for the amendment in the Phase III CT protocol. After detailed deliberation, the committee recommended for approval of the amendment in protocol version 2.0 dated 08.04.2022
19.	BIO/CT04/FF/2020/19709 Biphasic Isophane Insulin	M/s Hinge Clinica	The firm presented the proposal to conduct Phase III CT protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial vide protocol no JUSL-0220 version 1.0 dated 20 March 2020 subject to the following conditions: 1. The firm should conduct ketone bodies assessment in the patients. 2. Glucometer should be provided to the subjects in the study. Accordingly, the firm should submit revised protocol to CDSCO.