Recommendations of the SEC (Endocrinology & Metabolism) made in its 103rd meeting held on 18.07.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2023/ 35910 Insulin Injection IP 100 IU/mL	M/s. Regenix Biosciences Limited	In light of earlier SEC recommendation dated 19.05.2023, the firm presented the revised protocol vide protocol no. CT23-001 version 02 dated 31.05.2023. After detailed deliberation, the committee recommended for conduct of the Phase III clinical trial as per the presented revised protocol.
2.	BIO/CT04/FF/2023/ 36555 Insulin Glargine Injection 100 units/mL	M/s. Regenix Biosciences Limited	The firm presented the PK/PD study protocol titled "A double blind, balanced, randomized, two-treatment, two-sequence, four-period, single-dose, full replicate crossover pharmacokinetic and pharmacodynamic bioequivalence study of Insulin Glargine injection 100 units/mL of Regenix Biosciences Limited, India comparing with Lantus 100 units/ml solution for injection in a vial of Sanofi Aventis, in healthy male, adult, human subjects using Euglycaemic clamp technique under fasting conditions" vide protocol No. 23-014 version 1.0 dated 04.03.2023. After detailed deliberation, the committee recommended for conduct of the PK/PD study as per the presented protocol.
SND Division			
3.	SND/MA/22/000070 Cholecalciferol Granules 60000 IU (Mouth Dissolving Granules)	M/s. Tirupati Medicare	In light of earlier SEC recommendation dated 18.05.2023, the firm presented the proposal for manufacturing and market of Cholecalciferol granules 60000 IU (mouth dissolving granules) along with justification, supporting data/ literature for waiver of BE study and clinical trial before the committee. After detailed deliberation, the committee considered the request of the firm for clinical trial waiver. However, the committee recommended that firm should conduct the BE study and accordingly, the firm should submit the BE study protocol for review by the committee.

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4.	SND/MA/23/ 000018 Liraglutide 6mg/ml Solution for injection PFP (18mg/3ml PFP)	M/s. Sun Pharma	The firm presented proposal for manufacturing and market Liraglutide 6mg/ml solution for injection PFP (18mg/3ml PFP) synthetic origin along with pharmacokinetic data along with justification for Phase III clinical trial waiver. After detailed deliberation, the committee did not consider the request for clinical trial waiver. Accordingly, the committee recommended that the firm should conduct Phase III trial to ensure the safety and efficacy of the applied Synthetic product and therefore, the firm should submit the Phase III clinical trial protocol for review by the committee.
5.	SND/MA/23/ 000031 Cholecalciferol Tablets 2000 IU	M/s. Stedman Pharmaceuticals Pvt. Ltd.	In light of earlier SEC recommendation dated 21.03.2023 & 22.03.2023, the firm presented their proposal for manufacturing and market of Cholecalciferol granules 2000 IU (mouth dissolving granules) along with justification, supporting data/ literature for waiver of BE study and clinical trial before the committee. After detailed deliberation, the committee considered the request of the firm for clinical trial waiver. However, the committee recommended that the firm should conduct the BE study and accordingly, the firm should submit the BE study protocol for review by the committee.
6.	SND/MA/23/ 000033 Cholecalciferol Oral granules 60,000 IU	M/s. Stedman Pharmaceuticals Pvt. Ltd.	In light of earlier SEC recommendation dated 21.03.2023 & 22.03.2023, the firm presented the proposal for manufacturing and market of Cholecalciferol granules 60000 IU (mouth dissolving granules) along with justification, supporting data/ literature for waiver of BE study and clinical trial before the committee. After detailed deliberation, the committee considered the request of the firm for clinical trial waiver. However, the committee recommended that the firm should conduct the BE study and accordingly, the firm should submit

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			the BE study protocol for review by the committee.
FDC Division			
7.	FDC/MA/22/000301 Glimepiride 1mg IP + Lobeglitazone sulfate 0.5mg Tablets	M/s. Akums Drugs and Pharmaceuticals Ltd.	In light of earlier recommendation dated 16.09.2022, 20.04.2023 & 21.04.2023, the firm presented the BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The results of the BE study should be presented before the committee for further review.
8.	FDC/MA/22/000333 Metformin HCl IP as extended release 500mg/500mg/1000 mg/1000mg+Glimepiride IP 1mg/2mg/1mg/2mg +Sitagliptin phosphate monohydrate eq. to Sitagliptin IP 50mg/50mg/50mg/50 mg Tablets	M/s. Innova Captab Limited	The proposal was deferred for next meeting.
9.	FDC/MA/23/000056 Metformin HCl IP (As ER) 1000mg/500mg/1000 mg + Sitagliptin Phosphate Monohydrate IP Eq. to Sitagliptin 100mg/100mg/ 100mg + Empagliflozin 10mg/25mg/25mg tablets	M/s. Pure & Cure	The firm presented their proposal along with BE study protocol and justification for Phase III clinical trial waiver. After detailed deliberation, the committee recommended for grant of permission to conduct the BE Study. Further, the committee did not consider the request for clinical trial waiver. Accordingly, the firm should submit the Phase III clinical trial protocol alongwith BE study report for review by the committee.
10.	FDC/MA/23/000139 Linagliptin 2.5mg + Metformin HCL 500mg (ER) Tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal before the committee along with request for Phase III clinical trial and BE waiver based on earlier approved strengths of the FDC. After detailed deliberation, the committee recommended for grant of permission to

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			manufacture and market the proposed FDC subject to the condition that the firm should conduct active PMS study in the country with adequate number of subject for which protocol should be submitted to CDSCO within 03 months from the date of approval, for review by SEC.
11.	04-12/2016-DC Canagliflozin + Metformin HCL (50mg + 500mg, 50mg + 850mg, 150mg+ 500mg, 150mg+ 850mg, 50mg + 1000mg, 150mg+ 1000mg)	M/s. Johnson & Johnson	In light of earlier SEC recommendation dated 04.09.2019, the firm presented Phase IV clinical trial report for FDC of Canagliflozin + Metformin HCl film coated tablets (50mg + 500mg, 50mg + 1000mg) The committee noted that Phase IV clinical trial NOC was issued for 6 strengths of the FDC. After detailed deliberation, the committee recommended that the firm should submit Phase IV clinical trial report for all the strengths as per earlier SEC recommendation for further review by the committee.
12.	FDC/MA/22/000325 Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Linagliptin + Metformin HCl eq. to Metformin (as sustained release) (5mg/5mg/10mg/10mg+5mg/5mg/5mg/5mg+500mg/1000mg/500mg/1000mg) tablets	M/s. Theon Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 18.05.2023 & 19.05.2023, the firm presented BE study report. After detailed deliberation, the committee considered the BE study report and recommended for grant of permission to conduct the Phase III clinical trial for which the Phase III CT protocol has already been approved by SEC dated 18.05.2023 & 19.05.2023. The result of Phase III clinical trial should be presented before the committee for review.
13.	FDC/MA/22/000339 Glimepiride + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin (1mg/2mg/1mg/2mg +50mg/50mg/100mg/100mg) tablets	M/s. Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 19.01.2023 & 20.01.2023, the firm presented BE study report. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial for which permission has already been granted by CDSCO. The result of Phase III clinical trial should be presented before the committee for review.

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14.	FDC/MA/23/000182 Linagliptin 2.5mg/2.5mg + Imeglimin HCL 500mg/1000mg film coated tablets	M/s. Synokem Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
15.	FDC/MA/22/000422 Dapagliflozin Propanediol Monohydrate + Linagliptin (5mg/10mg/5mg/ 10mg+2.5mg/2.5mg/ 5mg/5mg) Tablets	M/s. Windlas	The proposal was deferred for next meeting.
16.	FDC/MA/21/000166 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Glimepiride IP + Metformin Hydrochloride IP (as extended release Tablets)	M/s. Sun Pharma Laboratories Ltd.	The proposal was deferred for next meeting.
17.	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 didn`t turn up for presentation.
18.	FDC/MA/23/000036 Metformin Hydrochloride IP (as extended release) 500mg/1000mg/500 mg/1000mg + Sitagliptin Phosphate Monohydrate IP eq to Sitagliptin	M/s Akums Drugs & Pharmaceuticals	The proposal was deferred for next meeting.

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	100mg/100mg/50mg/ 50mg + Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 5mg/5mg/10mg/10m g Tablets		
19.	FDC/MA/22/000298 Linagliptin + Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin (5mg + 10mg) Tablets	M/s. Theon Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
20.	FDC/MA/23/000013 Metformin HCl IP 500mg/1000mg +Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 10mg/10mg + Linagliptin 5mg/5mg Tablets	M/s. Mascot Health Series Pvt. Ltd	The firm didn`t turn up for presentation.
21.	FDC/MA/20/000131 Pioglitazone + Vildagliptin(30mg/10 0mg + 15mg/100mg) film coated bilayered tablet	M/s. Synokem Pharmaceuticals	The proposal was deferred for next meeting.
GCT Division			
22.	CT/73/22 Online Submission (25991) LY3209590	M/s. Eli Lilly	The proposal was deferred for next meeting.
23.	CT/22/23 Online Submission (36574) TP-102	M/s. JSS	The proposal was deferred for next meeting.

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24.	CT/53/23 Online Submission (37599) LY3437943	M/s. Eli Lilly	The proposal was deferred for next meeting.
25.	CT/71/22 Online Submission (26126) Cagrilintide S.C. 2.4mg + Semaglutide S.C. 2.4mg (CagriSema S.C. 2.4 mg/2.4mg)	M/s. Novo - Nordisk	The proposal was deferred for next meeting.