

Recommendations of the SEC (Endocrinology & Metabolism) made in its 102th meeting held on 15.06.2023 & 16.06.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/23-DC (Pt-89) Thiamine Hydrochloride Injection 100mg/mL	Dr. Alisha Khan UCMS & GTB Hospital, Delhi.	The Principal Investigator presented the proposal of academic clinical trial “Thiamine supplementation in the management of Diabetic Ketoacidosis: an open label, randomized controlled trial” before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the academic clinical trial as per the protocol presented by the applicant.
2.	ND/MA/22/000169 Carglumic Acid 200mg Tablets	M/s. Laurus Labs Ltd.	In light of earlier SEC recommendation dated 16.02.2023 and 17.02.2023, the firm presented the revised Bioequivalence study protocol along with Phase III clinical trial waiver in the country for the grant of permission to manufacture and market the Carglumic acid 200mg dispersible tablets before the committee. After detailed deliberation, the committee recommended to conduct the BE study and to submit the report along with the additional data w.r.t. the orphan drug status in US and Europe and published clinical trial data for further consideration.
Biological Division			
3.	BIO/CT04/FF/2023/3 5984 Insulin Glargine Injection IP 100 IU/mL	M/s. Regenix Biosciences Limited	The firm presented their proposal for grant of permission to conduct Phase III clinical trial titled as “A prospective, multi-center, randomized, double blind, parallel-group, active-controlled, Phase III study to compare the efficacy, safety and immunogenicity of Regenix Biosciences Limited, India, Insulin Glargine 100 units/mL (U-100) (Investigational drug) with Lantus® (Insulin Glargine) of Sanofi-aventis, India, (Reference drug) in Type I and Type II Diabetes” vide protocol No. CT-23-002 Version 02 dated 31.05.2023. After detailed deliberation, the committee recommended for grant of permission to

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			conduct the Phase III study as per the presented protocol.
4.	BIO/CT21/FF/2023/36566 Liraglutide injection 5.4 mg/mL	M/s. Levim Biotech	The firm presented their proposal for grant of permission to manufacture and market Liraglutide 5.4 mg/ml solution for injection based on the Phase III clinical trial results conducted in India. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Liraglutide 5.4 mg/ml solution for injection subject to the condition that the firm shall conduct Phase IV study in the country. Accordingly, protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization.
SND Division			
5.	SND/MA/23/000135 Cholecalciferol Oral Drops 800 IU/ml	M/s. Zuventus Healthcare Limited	The firm presented the proposal for grant of manufacture and marketing permission of Cholecalciferol Oral Drops 800 IU/ml for the treatment of Vitamin D3 deficiency and insufficiency along with therapeutic rationale and justification for BE study waiver, before the committee. The committee noted that Chplecalciferol Oral drops 800IU/ml is already approved in India "For the treatment of Vitamin D3 deficiency" on 08.03.2021. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of Cholecalciferol Oral Drops 800 IU/ml for the approved indication.
FDC Division			
6.	FDC/MA/23/000041 Rosuvastatin Calcium IP eq. to Rosuvastatin + Linagliptin (5mg/10mg/20mg+5 mg/5mg/5mg) Tablets	M/s. Exemed Pharmaceuticals	The firm did not turn up for the presentation.
7.	FDC/MA/23/000057	M/s. Exemed	The firm did not turn up for the presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Rosuvastatin calcium IP eq. to Rosuvastatin 5mg/10mg/20mg + Sitagliptin phosphate monohydrate IP eq. to sitagliptin 100mg/100mg/100mg Tablets		
8.	FDC/MA/22/000264 Sitagliptin Phosphate monohydrate 100mg I.P. + Pioglitazone HCl 15mg IP tablet	M/s. Synokem	In light of earlier SEC recommendation dated 18.05.2023 & 19.05.2023, the firm presented justification for Phase III clinical trial waiver. After detailed deliberation, the committee reiterated its earlier recommendation dated 18.05.2023 & 19.05.2023. Accordingly, the firm should present the Phase III clinical trial results for which clinical trial NOC was already issued to the firm on 18.11.2022.
9.	FDC/MA/22/000301 Glimepiride 1mg IP + Lobeglitazone sulfate 0.5mg Tablets	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm did not turn up for the presentation.
10.	FDC/MA/23/000085 Lobeglitazone sulfate 0.25mg/0.25mg + Sitagliptin Phosphate monohydrate 50mg/100mg tablets	M/s. Akums	The firm presented its proposal along with justification for BE & Phase III clinical trial waiver. After detailed deliberation, the committee recommended that: 1. The firm should present the justification and rationality for combining this FDC and its significant benefit. 2. Justification on dose titration. 3. International approval status. 4. Scientific literature available from peer reviewed journal in support of combining the two drugs in this FDC. Accordingly, the firm should submit justification to CDSCO for review by SEC.
11.	FDC/MA/23/000083 Vildagliptin (as sustained release)100mg/100mg /100mg/ + Rosuvastatin calcium	M/s. Exemed	The firm did not turn up for the presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	IP eq. to Rosuvastatin 5mg/10mg/20mg tablets		
12.	FDC/MA/22/000333 Metformin Hcl IP as extended release 500mg/500mg/1000m g/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 firm did not turn up for the presentation.
13.	FDC/MA/23/000129 Lobeglitazone Sulfate 0.5mg I.P. + Sitagliptin 50mg I.P. + Metformin HCL 500mg/1000mg ER Tablets	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm presented its proposal along with the BE study protocol before the committee. After detailed deliberation, the committee noted that: 1. The firm has not presented any scientific justification with rationality along with published literature. 2. There is insufficient data on long term safety of Lobeglitazone to be used as frontline drug. 3. There is no unmet need. Accordingly, the firm should submit the detailed justification in light of the above points to CDSCO for review by SEC.
14.	FDC/MA/23/000136 Pioglitazone HCL 15mg I.P + Vildagliptin 50mg/100mg/100mg I.P. + Metformin HCL 500mg/500mg/1000m g I.P. SR Tablet	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm presented its proposal along with BE & Phase III clinical trial study protocol before the committee. After detailed deliberation, the committee recommended that firm should justify the following points before presenting the protocol: 1. International approval status. 2. Proof of Synergistic benefit of the combination need to be established. 3. Scientific literature available from peer reviewed journal in support of combining the three drugs in this FDC.
15.	FDC/CT/23/000026 Glimipride +	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented its proposal along with BE study protocol for grant of permission to conduct BE study before the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Sitagliptin + Metformin ER (2mg+50mg+1000mg) Tablets		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 further review.
16.	FDC/MA/23/000158 Sitagliptin Phosphate Monohydrate 50mg/50mg I.P. + Pioglitazone 15mg/15mg + Metformin HCL 500mg/1000mg Sustained Release Form	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm presented its proposal along with justification of BE & Phase III clinical trial waiver based on BE study already conducted on higher strengths of the proposed FDC. The committee noted that the FDC in higher strength i.e. FDC of Sitagliptin Phosphate Monohydrate 100mg/100mg + Pioglitazone 15mg/15mg + Metformin HCL 500mg/1000mg (SR) is already approved by CDSCO on 20.01.2023. 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 of BE study waiver as per the BE Study guideline.
17.	FDC/MA/23/000096 Lobeglitazone Sulfate 0.5mg/0.5mg + Dapagliflozin Propanediol Monohydrate 5mg/10mg	M/s. Akums drugs & Pharmaceuticals Ltd.	The firm presented its proposal along with Phase III clinical trial protocol as well as justification for BE study waiver. After detailed deliberation, the committee recommended that the request of the firm for BE study waiver can be considered, if the firm conduct the Phase III clinical trial as per the clinical trial protocol. The result of the Phase III clinical trial study should be presented before the committee for review.
18.	FDC/MA/23/000026 Sitagliptin Phosphate 100mg I.P. + Lobeglitazone Sulfate 0.5mg	M/s. Synokem Pharmaceuticals	In light of earlier SEC recommendation dated 20.04.2023 & 21.04.2023, the firm presented their proposal along with BE & 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. The result of the BE study should be presented for review by SEC before initiation of the clinical trial.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
19.	FDC/MA/23/000161 Glimepiride 0.5mg + Voglibose 0.2mg + Metformin HCl (SR) 500mg tablets	M/s. Windlas	<p>The firm presented its proposal along with justification of BE & Phase III clinical trial waiver based on BE study already conducted on higher strengths of the proposed FDC.</p> <p>The committee noted that the FDC in higher strength i.e. FDC of Glimepiride 1mg/2mg + Voglibose 0.2mg/0.2mg + Metformin HCl (ER) 500mg/500mg tablets is already approved by CDSCO on 14.01.2020.</p> <p>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.</p>
20.	FDC/MA/23/000061 Glimepiride 1mg/1mg/2mg/2mg + Vildagliptin 50mg/50mg/50mg/50 mg + Metformin HCL 500mg/1000mg/500m g/1000mg Film Coated Tablets	M/s. Synokem Pharmaceuticals	<p>In light of earlier SEC recommendation dated 20.04.2023 & 21.04.2023, the firm presented their proposal along with BE & Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study & Phase III clinical trial.</p> <p>The result of the BE Study should be presented for review by SEC before initiation of the clinical trial.</p>
21.	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 proposal was deferred for next meeting.
22.	FDC/MA/23/000139 Linagliptin 2.5mg + Metformin HCL	M/s. Synokem	The proposal was deferred for next meeting.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	500mg (ER) Tablets		
23.	04-12/2016-DC Canagliflozin + Metformin HCL (50mg + 500mg, 50mg + 1000mg) film coated tablets	M/s. Johnson & Johnson	The proposal was deferred for next meeting.
24.	FDC/MA/22/000325 DapagliflozinPropane diol 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.	The proposal was deferred for next meeting.
25.	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.	The proposal was deferred for next meeting.
GCT Division			
26.	CT/112/22 Online Submission (25219) LY3298176	M/s. Eli Lilly	The firm presented protocol amendment 18F-MC-GPJ (a) dated 02 March 2023 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented.