

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 105<sup>th</sup> meeting held on 19.09.2023 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drug Division</b>			
1.	ND/MA/22/000054 Lobeglitazone sulphate 0.5mg + Glimeperide 1mg Tablet	M/s. Glenmark Pharmaceuticals Ltd.	The firm didn't turn up for presentation.
<b>SND Division</b>			
2.	SND/MA/23/000070 Cholecalciferol Granules 60000IU (mouth dissolving Granules)	M/s. Tirupati Medicare	<p>The firm presented their proposal earlier on 18.05.2023 &amp; 18.07.2023 for manufacturing and marketing permission of Cholecalciferol granules 60000IU (mouth dissolving Granules), before the committee wherein after detailed deliberation, the committee recommended that firm should conduct the BE study and granted clinical trial waiver, accordingly, the firm should submit the BE study protocol for review by the committee.</p> <p>Now the firm has submitted the therapeutic rationale and justification for the waiver of Bioequivalence study.</p> <p>After detailed deliberation, the committee did not consider the firm's request for BE waiver and recommended to conduct the BE study. Accordingly, the firm should submit the BE study protocol for review by the committee.</p>
<b>FDC Division</b>			
3.	FDC/MA/23/000233 Sitagliptin phosphate monohydrate IP eq. to Sitagliptin + Voglibose IP + Metformin HCl IP (ER) (50mg+0.2mg + 500mg)/(50mg+0.2mg+1000mg)/(100mg+0.2mg+500mg)/(100mg/0.2mg+1000mg) film coated bilayered tablet	M/s. Pure and Cure Healthcare Pvt. Ltd.	<p>The firm presented their proposal along with BE study protocol &amp; 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 &amp; Phase III clinical trial study.</p> <p>The result of the BE study should be presented for review by SEC before initiation of the Phase III clinical trial.</p>

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4.	FDC/MA/23/000249  Empagliflozin + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin HCl IP (ER) (10mg+100mg+500mg/10mg+100mg+1000mg/25mg+100mg+500mg/25mg+100mg+1000mg) tablet	M/s. Exemed Pharmaceuticals	<p>The firm presented their proposal along with BE study protocol &amp; 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 &amp; Phase III clinical trial study.</p> <p>The result of the BE study should be presented for review by SEC before initiation of the Phase III clinical trial study.</p>
5.	FDC/MA/23/000220  Metformin HCl IP (As extended release form) 500mg/1000mg + Glimepiride IP 1mg/1mg + Lobeglitazone sulfate 0.5mg/0.5mg tablets	M/s. Glenmark Pharmaceuticals Ltd.	<p>The firm presented their proposal along-with request for BE study and Phase III clinical trial study waiver.</p> <p>The committee noted that the proposed FDC is not approved internationally.</p> <p>After detailed deliberation, the committee opined that firm should submit BE study protocol as well as Phase III clinical trial protocol for the proposed FDC for further review.</p>
6.	FDC/MA/23/000248  Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/50mg + Metformin Hydrochloride IP 500mg/500mg + Glimepiride IP 1mg/2mg film coated tablet	M/s. Sun Pharma Laboratories Ltd.	<p>The firm presented their proposal for BE study and Phase III clinical trial waiver for lower strength i.e. Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/50mg + Metformin Hydrochloride IP 500mg/500mg + Glimepiride IP 1mg/2mg film coated tablet based on Phase III clinical trial and BE study results presented for higher strength i.e. Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/50mg + Metformin Hydrochloride IP 1000mg/1000mg + Glimepiride IP 1mg/2mg film coated tablet.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product in the lower strength.</p>
7.	FDC/MA/22/000276  Gliclazide SR IP + Dapagliflozin (30mg+10mg/	M/s. Eris Lifesciences Limited	<p>In light of earlier SEC recommendation dated 19.10.2022 &amp; 20.10.2022, the firm presented the BE study report as well as Phase III clinical trial study report before the committee.</p>

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	60mg+10mg) tablet		After detailed deliberation, the committee recommended that the firm should resubmit the data for ADR events reported after detailed causality assessment as per WHO scale along with details of 05 hypoglycemic cases reported for further review by the committee.
8.	FDC/MA/21/000093 Remogliflozin etabonate 100mg/100mg+ Vidagliptin 50mg/50mg + Metformin Hydrochloride 500mg/1000 mg tablet	M/s. Glenmark Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 18.02.2022 and as per condition of Form CT-23 dated 21.09.2021, the firm presented Phase IV clinical trial report before the committee.  After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.
9.	FDC/MA/21/000259 Metformin Hydrochloride IP + Glimepiride IP + Dapagliflozin propanediol monohydrate 500mg/500mg/1000mg/1000mg+1mg/2mg/ 1mg/2mg+5mg/5mg/5mg/5mg	M/s. Sun Pharma Laboratories Ltd.	In light of earlier SEC recommendation dated 24.11.2021 & 25.11.2021, the firm presented their proposal along with Phase III clinical trial study report and BE study report before the committee.  After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
<b>GCT Division</b>			
10.	CT/152/21 Online Submission (26746)  Semaglutide 1.34 mg/ml	M/s. NovoNordisk	The firm presented protocol amendment version 7.0 dated 18 April 2023 for protocol no, NN9535-4533.  After detailed deliberation, the committee recommended for protocol amendment as presented by firm.
11.	CT/14/22 Online Submission (26737)  Paltusotine	M/s. Pharm-Olam International	The firm presented notification of revised CRN00808-08 protocol version 3.0 dated 08 July 2022.  After detailed deliberation, the committee recommended for protocol amendment as presented by firm.