

Recommendations of the SEC (Endocrinology & Metabolism) made in its 106th meeting held on 27.09.2023 & 29.09.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000031 Cholecalciferol Tablets 2000IU	M/s. Stedman Pharmaceuticals Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 21.03.2023 & 22.03.2023 the firm presented specific justification and data along with published literatures in support of Bioequivalence study and Phase-III clinical trial waiver before the committee.</p> <p>The committee noted that CDSCO has been approved Cholecalciferol 60000 IU orally disintegrating strips (in 2017), Cholecalciferol oral drops 800 IU/ml (in 2021), Cholecalciferol 2000 IU orally disintegrating strips (in 2015), Cholecalciferol 60000 IU chewable tablets (in 2022) and Cholecalciferol 60000 IU Oral solution (in 2022).</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacturing and marketing of Cholecalciferol Tablets 2000IU with BE & CT waiver subject to condition that the firm should conduct Phase-IV clinical trial study. However, the firm should fulfil the requirements of CMC data before approval of the product.</p> <p>Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of drug for further review by the committee.</p>
2.	SND/MA/23/000033 Cholecalciferol Oral Granules 60,000IU	M/s. Stedman Pharmaceuticals Pvt. Ltd.	<p>The firm presented their proposal for grant of permission to manufacture and marketing of Cholecalciferol Granule 60000 IU (additional indication and additional dosage form) along with justification for waiver of Bioequivalence study before the committee.</p> <p>The committee noted that CDSCO has been approved Cholecalciferol 60000 IU orally disintegrating strips (in 2017), Cholecalciferol oral drops 800 IU/ml (in 2021), Cholecalciferol 2000 IU orally</p>

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			<p>disintegrating strips (in 2015), Cholecalciferol 60000 IU chewable tablets (in 2022) and Cholecalciferol 60000 IU Oral solution (in 2022).</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacturing and marketing of Cholecalciferol Oral Granules 60,000IU with BE & CT waiver subject to condition that the firm should conduct Phase-IV clinical trial study. However, the firm should fulfil the requirements of CMC data before approval of the product.</p> <p>Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of drug for further review by the committee.</p>
3.	<p>SND/MA/22/000254</p> <p>Semaglutide injection 2mg/1.5ml (1.34mg/ml) & 4mg/3ml (1.34mg/ml)</p>	M/s. Dr. Reddy's Labs Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 20.04.2023 & 21.04.2023, the firm presented Bioequivalence protocol and Justification for Phase-III clinical trial waiver before the committee.</p> <p>The Committee noted that the proposed drug formulation is under consideration by USFDA.</p> <p>After detailed deliberation, the Committee recommended for grant of permission to conduct bioequivalence study as per protocol presented by the firm. However, Phase-III clinical trial waiver can be considered based on the review of bioequivalence study report by the SEC committee.</p>
4.	<p>SND/MA/23/000115</p> <p>Metformin Hydrochloride 500mg, 1000mg, SR Tablets IP</p>	M/s.USV Pvt. Ltd.	<p>The firm presented their proposal for grant of permission to update the statement in the prescribing information (in fertility, pregnancy and lactation part) i.e. if clinically needed, the use of metformin can be considered during pregnancy and in the periconceptional phase as an addition or an alternative to insulin before the Committee.</p> <p>It was informed by the firm that</p>

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			<p>Metformin hydrochloride PR/SR tablets for pre-diabetes indication already approved in UK and some EU countries.</p> <p>After detailed deliberation, the proposal should be deliberated in presence of Gynecologist and Neonatologist experts in the next SEC meeting for further consideration.</p>
5.	SND/MA/22/000365 Nitisinone Tablets (2mg, 5mg, 10mg)	M/s. Brawn Laboratories Limited	<p>The firm presented their proposal for grant of permission to manufacture and marketing of Nitisinone Tablets 2mg, 5mg and 10mg for additional dosage form along with justification for waiver of bioequivalence study and Phase-III clinical trial before the committee.</p> <p>The committee noted that Hereditary Tyrosinemia Type I is a very rare disease and there is unmet medical need in the country. The committee also noted that the drug is already approved in US, EU and Australia as an Orphan drug for treatment of Hereditary Tyrosinemia Type I disease and the drug falls under BCS I.</p> <p>Further, Nitisinone capsule 2mg, 5mg, 10mg is already approved by CDSCO India on 09.06.2022 indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and Phenylalanine.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Nitisinone 2mg, 5mg and 10mg Tablets with waiver of Bioequivalence study and Phase-III clinical trial subject to condition that the drug should be sold by retail under prescription of Neonatologist, Pediatrician/Endocrinologist.</p>
FDC Division			
6.	FDC/MA/23/000134 Ferrous Fumarate IP	M/s. Hindustan Laboratories Limited	In light of earlier SEC (Analgesic & Rheumatology) recommendation dated 07.06.2023, the firm presented their

SEC (Endocrinology & Metabolism) meeting dated 27.09.2023 & 29.09.2023

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	30mg + Niacinamide IP 10mg + Pyridoxine Hydrochloride (Vit B6) IP 1mg + Folic Acid IP 250mcg + Riboflavin IP 1.2mg + Zinc Sulphate Monohydrate eq. to elemental Zinc 20mg + Thiamine Mononitrate IP 1.2mg + Cyanocobalamin (Vit B12) 2.5mcg + Ascorbic Acid (Coated) (Vit.C) 40mcg Capsules		<p>proposal along with justification on rationality before the committee.</p> <p>After detailed deliberation, the committee reiterated its earlier recommendation dated 07.06.2023.</p> <p>The committee also opined that firm should present the point wise justification along with supporting literatures /data as suggested in SEC (Analgesic& Rheumatology) dated 07.06.2023.</p>
7.	FDC/CT/23/000045 Empagliflozin + Sitagliptin Phosphate Monohydrate IP Eq. to Sitagliptin + Metformin hydrochloride IP ER tablet (10 mg + 100 mg + 1000 mg/ 25 mg + 100 mg + 1000 mg) tablets	M/s. Dr. Reddy's Laboratories Limited	<p>The firm presented their proposal along with BE study protocol as well as Phase III CT Protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study and Phase III CT Study.</p> <p>The committee also recommended that BE study report should be presented in SEC meeting before initiation of the clinical trial.</p>
8.	FDC/MA/23/000234 Linagliptin + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin (2.5mg+10mg/ 5mg+5mg/ 2.5mg+5mg) Tablets	M/s. Exemed Pharmaceuticals	<p>The firm presented their proposal along with justification for BE study as well as CT study waiver for lower strength based on the CT report of higher strength i.e. Dapagliflozin 10 mg + Linagliptin 5 mg tablet.</p> <p>After detailed deliberation, the committee opined that more evidence and supporting literature regarding efficacy and safety of proposed FDC in lower strengths should be submitted for further review.</p>
9.	FDC/MA/23/000222 Empagliflozin + Sitagliptin Phosphate Monohydrate IP eq. Sitagliptin (10mg+100mg/25mg +100mg) film coated tablet	M/s. Torrent Pharmaceuticals Ltd.	<p>The firm presented their proposal along with Phase III CT Protocol and requested for BE study waiver.</p> <p>After detailed deliberation, the committee considered the request for BE study waiver.</p> <p>Further the committee recommended modification in inclusion criteria of CT protocol- "to include the patient who are inadequately controlled on Metformin</p>

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			<p>monotherapy in atleast 1.5 gm/day and level of HbA1c between 8% -10.5 %''</p> <p>Accordingly, revised CT Protocol should be submitted for review by committee.</p>
10.	<p>FDC/MA/23/000225</p> <p>Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Metformin Hydrochloride IP (SR) (10mg+500mg/10mg+1000mg) film coated tablets</p>	M/s. Abbott Healthcare Pvt. Ltd.	<p>The firm presented their proposal along with BE study waiver justification.</p> <p>The committee noted that the proposed FDC is already approved by CDSCO on 16.10.2017.</p> <p>After detailed deliberation, the committee recommended to conduct the BE study with the proposed FDC.</p>
11.	<p>FDC/MA/23/000223</p> <p>Empagliflozin 25mg + Sitagliptin Phosphate Monohydrate IP eq. Sitagliptin 100mg + Metformin Hydrochloride IP (as extended release form) 1000mg film coated tablets</p>	M/s. Torrent Pharmaceuticals Ltd.	<p>The firm presented their proposal along with BE study Protocol under fasting and fed condition.</p> <p>After detailed deliberation, the committee recommended to conduct the proposed BE study under fasting and fed condition.</p> <p>The results of the BE study should be presented before the committee along with Phase III CT protocol.</p>
GCT Division			
12.	<p>CT/56/23 Online Submission (37706)</p> <p>Icosema&Insulin glargine 100 units/ml</p>	M/s. Novo-Nordisk	<p>The firm Presented Phase IIIb Clinical trial Protocol no. NN1535-4988, Version: 01 Final, dated 12 April 2023, before the committee</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the trial.</p>
13.	<p>CT/68/23 Online Submission (37918)</p> <p>LY3502970</p>	M/s. Elli Lilly	<p>The firm Presented Phase III Clinical trial Protocol no. J2A-MC-GZGQ, before the committee</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the Clinical trial.</p>
14.	<p>CT/62/23 Online Submission (37839)</p> <p>LY3502970</p>	M/s. Elli Lilly	<p>The firm Presented Phase III Clinical trial Protocol no. J2A-MC-GZGP amendment number: b, before the committee</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the trial.</p>

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15.	CT/70/23 Online Submission (38007) CRN04894	M/s. PPD	<p>The firm Presented Phase II Clinical trial Protocol no. CRN04894-03, Version: 2.0 Protocol date 23 February 2023 , before the committee</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the trial with condition that Classic 21-hydroxylase deficiency cases should be preferred for recruitment.</p>
FDC Division			
16.	FDC/MA/22/000254 Gliclazide SR + Sitagliptin 30mg/60mg + 100mg/100mg tablets	M/s. Eris Lifesciences Ltd.	<p>In light of earlier SEC recommendation dated 16.02.2023 &17.02.2023 the firm presented Phase III CT report before the committee.</p> <p>The firm informed that BE report has already been presented and the same was considered by the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with condition to conduct Phase IV CT study.</p> <p>Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC by the committee.</p>