

Recommendations of the SEC (Endocrinology & Metabolism) made in its 56th meeting held on 20.06.2019 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory remarks			
Biological Division			
1.	BIO/Form44/FF/2019/14218 (BIO/CT/19/000026) Somatropin	Reliance Life Sciences Pvt Ltd	Firm presented their Phase IV protocol before the committee. After detailed deliberation, committee recommended for grant of permission to conduct the study with following conditions: i. The study should be conducted in females less than 12 years and in males less than 11 years with growth hormone deficiency. ii. The sample size should be at least 275 subjects.
2.	BIO/Form44/FF/2019/14371 (BIO/CT/19/000028) Long-acting Recombinant Growth Hormone (ALT-P1)	Accutest Research Laboratories (I) Pvt. Ltd	Firm presented their PK/PD protocol for export purpose. The drug is in the early phase of development and is not approved internationally including country of origin. The committee noted that it is a recombinant technology derived drug. The technology used for development of this product is not approved for marketing in any other drug. The application is for generation of data for export purpose only and the firm has not submitted adequate data with respect to CMC, preclinical and toxicity. After detailed deliberation, the committee did not recommend for grant of permission to conduct of the study.
SND Division			
3.	04-232/2007-DC(Pt-Sun) Exenatide injection 250mcg/ml	M/s Sun Pharma Ltd.	In light of recommendation of the SEC meeting held on 20.12.2016, the firm presented the results of anti-Exenatide antibody assessment of the available patients of the phase III clinical trial. The committee noted the same for pre-closure of the study.
4.	SND/MA/18/000025 Cholecalciferol aqueous injection 600000 IU (add. Dosage form)	M/s Cadila Pharmaceuticals Ltd	Firm presented the PK study results and toxicity data. After detailed deliberation the committee recommended that firm should carryout human PK/PD studies for which protocol should be submitted for review by the committee.

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5.	SND/MA/18/000028 Vildagliptin SR Tablet 100mg(New Dosage form)	M/s Wockhardt	In light of recommendation of the 44 th TC meeting held on 05.09.2018, the firm presented their proposal for single dose and multiple dose BA/BE study. After detailed deliberation the committee recommended for grant of permission to conduct the proposed studies subject to condition that DPP IV inhibition should be assessed up to 72 hours post dose instead of 24 hours proposed. However, this committee recommends that Phase III clinical trial should also be conducted
FDC Division			
6.	FDC/MA/19/000047 VogliboseIP+RepaglinideIP (0.3mg/0.3mg/0.2mg/0.2mg+1.0mg/ 0.5mg/1.0mg/0.5mg)Film coated bilayered Tablet	M/s.Ajanta Pharma	The firm presented their proposal for conducting CT/BE study for the proposed FDC before the committee After detailed deliberation, committee recommended that firm should include one more arm of Repaglinide alone in BE study. Further the w.r.t CT protocol the committee recommended that the protocol should be revised in respect of study design including inclusion-exclusion criteria, no. of study arms, sample size justification, discontinuation criteria and hypoglycemia management protocol etc. Accordingly the firm should submit revised CT & BE study protocols for review by the committee.
7.	FDC/MA/19/000040 Gliclazide IP 60mg (as extended release form) + Metformin HCl IP 1000mg (as extended release form) uncoated bilayer tablet	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented their proposal for conducting BE study for the proposed FDC before the committee After detailed deliberation, committee recommended for grant of permission to conduct the proposed BE study. As regard to clinical trial waiver, firm should present the BE study data before the committee for further consideration.
8.	FDC/MA/19/000041 Vildagliptin 50mg/50mg + Metformin Hydrochloride IP 500/1000mg (sustained release)	M/s. Reddy's Laboratories Ltd.	The firm presented their proposal for conducting BE study for the proposed FDC before the committee After detailed deliberation, committee recommended for grant of permission to conduct the proposed BE study. firm should present the BE study data before the committee for further consideration. Nevertheless, Phase III Clinical trial is also required to be conducted for this FDC, as it is proposed for type 2 diabetic patients with moderate renal impairment (CKD stage 3a-

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			3b with eGFR between 30-59). Accordingly Phase III CT protocol should be submitted for review by the committee.
9.	FDC/MA/19/000039 FDC of Naltrexone Hydrochloride + Zonisamide (32mg + 91mg, 32mg + 182mg, 32mg + 273mg & 32mg + 364mg)	Dr. Reddy's Laboratories Ltd.	The firm presented their proposal for Phase II clinical trial with PK / BA assessment along with animal toxicity data for the FDC. Committee noted that neither Zonisamide nor Naltrexone alone has been approved in any country for the treatment of obesity. Therefore dose of Zonisamide and Naltrexone individually for the said indication as well as proof of concept of the proposed FDC for the proposed indication are not established. Committee after detailed deliberation recommended that the firm should generate data in animal obesity models to address the above mentioned concerns and submit the same to the committee for review.

