Recommendations of the SEC (Neurology & Psychiatry) made in its 03rd/24 SEC meeting held on 23.02.2024 at CDSCO (HQ) New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/20/000368 Midazolam Nasal Spray 0.5% w/v & 1.25% w/v	M/s. Biodeal Pharma	In light of earlier SEC recommendation dated 12.12.2023, the firm presented the analytical test report of proposed formulation at NABL accredited laboratory along with justification for CT waiver before the committee. It is informed by the firm that USFDA has already approved Midazolam nasal spray 0.5% w/v (5mg/0.1 ml) as single unit dose inhaler for acute treatment of seizures in patients 12 years of age and older who require control of intermittent episodes of increased seizure activity. The proposed formulation is multi-dose Nasal spray as against Single dose which is approved in other country. The committee noted that such nasal spray formulation is indeed/ very useful for the patient undergo seizure & epilepsy episodes. However, the committee opined that firm shall provide that the proposed formulation will have same efficacy / safety vis-à-vis to already approved single product. Therefore, firm is required to provide the clinical trial data to prove the efficacy & safety or a bridging clinical trial data study protocol.
2.	SND/MA/22/000052 Midazolam Nasal Spray 0.5% w/v & 1.25% w/v	M/s. Savi Health Science	In light of earlier SEC recommendation dated 13.09.2023, the firm presented their study protocol SB-IND-CT-082 ver. 1.0 dated 21.12.2023 along with justification before the committee. The firm informed the committee that the proposed indication for preoperative sedation for conscious sedation prior to short diagnostic or endoscopic procedure/ General anesthesia. This proposed indication is not approved for nasal spray formulation. After detailed deliberation, the committee

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			opined that the clinical trial presented by firm is not clear in respect of sample size, efficacy and safety criteria. Therefore, the firm is required to submit revised clinical trial protocol for the proposed product for further review by the committee.
3.	SND/MA/23/000172 Nicotine Polacrilex Sachet (Pouch) 2 mg, 4mg	M/s JHMG Pharma Drugs Private limited	The firm presented the proposal along with justification for BE and CT waiver before the committee. The firm informed the committee that the proposed formulation is containing Catechin as excipient which is also used in herbal drug. After detailed deliberation, the committee opined that the firm should give more data in respect safety of Nicotine Polacrilex with Catechin formulation
FDC Division			
4.	FDC/MA/23/000298 Clonazepam IP (as uncoated tablet) 0.5mg + Duloxetine Hydrochloride IP eq. to Duloxetine (as Gastro-resistant pellets) 20mg capsule	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 12.10.2023, the firm presented the proposal along with justification and rationality before the committee. After detailed deliberation, the committee reiterated its earlier recommendation the committee did not recommend for approval of the FDC.
5.	FDC/MA/24/000007 Gabapentin IP (as SR) 300mg/400mg/600mg + Nortriptyline Hydrochloride IP eq.to Nortriptyline 10mg/10mg/10mg + Methylcobalamin IP 1500mcg/1500mcg/1500mcg Film Coated Tablets	M/s. Pure and Cure Healthcare Pvt. Ltd.	The firm presented the proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, the result of the BE study should be presented along with Phase III clinical trial protocol for review by the committee.
6.	FDC/MA/24/000016 Polmacoxib 2mg + Pregabalin (SR) 82.5mg film coated bilayered tablet	M/s. Synokem Pharmaceuticals Ltd	The firm presented the proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended that the reference product should be changed to individual innovator

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			drug in the BE study. Accordingly, the revised BE study protocol should be submitted to CDSCO for review. Further, the firm should submit the Phase III CT study protocol along with BE study result for review by the committee.
7.	FDC/MA/23/000187 Pregabalin IP 75mg/75mg + Duloxetine Hydrochloride IP eq. to Duloxetine (as gastro resistant pellets) 20mg/30mg + Mecobalmin IP 1500mcg/1500mcg Hard gelatin capsules	M/s. Synokem Pharmaceuticals Ltd.	The firm presented the proposal along with BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission has already been granted by CDSCO. The Phase III clinical trial report should be submitted to CDSCO for further review by the committee.
8.	FDC/MA/22/000417 Bupropion Hydrochloride (ER) IP 105mg + Dextromethorphan Hydrobromide IP 45mg tablets	M/s. Exemed Pharmaceutical	The firm did not turn up for presentation.
9.	FDC/MA/23/000256 Pregabalin + Duloxetine Hydrochloride eq. to Duloxetine (as delayed release pellets) + Mecobalmin (75mg+30mg+1500mcg/ 75mg+20mg+1500mcg/ 75mg+10mg+ 1500mcg/ 50mg+10mg+1500mcg/ 50mg+20mg+1500mcg) Hard gelatin capsules	M/s. Ravenbhel Healthcare Pvt. Ltd.	The firm presented the proposal along with BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission has already been granted by CDSCO. The Phase III clinical trial report should be submitted to CDSCO for further review by the committee.