

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 229th meeting held on 06.06.2022 at CDSCO (HQ), New Delhi:

| Agenda No | File Name & Drug Name, Strength | Firm Name | Recommendation |
|--------------------------|--|------------------------------|--|
| New Drug Division | | | |
| 1. | ND/CT/21/FF/20225/30074 Combi pack of Nirmatrelvir Tablets 150 mg + Ritonavir Tablets 10mg in india | M/s Optimus Pharma Pvt. Ltd. | In light of earlier SEC (COVID-19) recommendation dated 05.05.2022, the firm presented their proposal along with the clarification for inter-subject variability in the BE results before the committee. During the presentation committee observed variation in C max values between the test product and reference product and requested the firm to submit additional data. As requested by the firm the proposal was deferred for the next meeting for further deliberation. |
| SND Division | | | |
| 2. | SND/MA/22/000146 Niclosamide Tablets 500mg | M/s Laxai Life Science | The firm presented the results of phase II clinical trial before the committee. After detailed deliberation, the committee recommended that the firm should submit Phase III CT protocol to CDSCO for further review by the committee. |
| 3. | SND/CT/21/000084 1. Nitazoxanide Tablet 2000mg/day 2. Inhaled ciclesonide 640mcg/day 3. Artesunate and Amodiaquine (ASAQ) Tablet (Artesunate 200 mg/day and Amodiaquine 540mg/day) 4. Ivermectin Tablet 0.4mg/kg/day 5. Paracetamol 500mg upto 2g/day | M/s Qascent Research | The firm presented their proposal for inclusion of the new study arm of Fluoxetine 40mg/day + inhaled budesonide 400mcg bid for 7 days in the study. After detailed deliberation, the committee recommended for approval of inclusion of the study arm subject to the condition that the study should be conducted initially on 50 patients to generate data as proof of concept and results of the same should be submitted for further consideration. |

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| GCT Division | | | |
| 4. | CT/100/21 Anti-COVID-19 AKS-452 Vaccine | M/s. Veeda | The applicant presented protocol amendment version 3 dated 28/01/2022 before the committee. After detailed deliberation, the committee opined that the applicant should present the proposed protocol amendment in details in upcoming SEC meeting. |
| 5. | CT/99/21 Ad26.COVS.S | M/s. Johnson & Johnson | The applicant presented protocol amendment version 3 dated 28/02/2022 along with proposal for revision of no. of subjects from India before the committee. The committee after detailed deliberation, agreed for the revision of no of subjects from India as proposed by the applicant. The committee also opined that the applicant should present result of ongoing clinical trial before the committee for further consideration of proposed protocol amendment. |
| 6. | CT/155/21 Alteplase | M/s. Parexel | The applicant presented protocol amendment version 4 dated 17/02/2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment with condition that the applicant should define upper normal limit of D-Dimer for Indian subjects and defined limit should be uniform across all local laboratories. |
| FDC Division | | | |
| 7. | FDC/MA/22/000005 Combikit of Aspirin GR tablets 50mg & Promethazine HCL tablets 5mg & Multivitamin-minerals tablets. | M/s Meyer Vitabiotics vide | The firm didn't turn up for presentation. |