

Recommendations of the SEC meeting to examine IND proposals, made in its 19th meeting held on 29.12.2021, 02:00 pm to 06: 00 pm at CDSCO, HQ New Delhi, through Webex (Video conference):

Age nda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	F. No. IND/MA/21/000063 Desidustat Tablets 25 mg and 50 mg	M/s Cadila Healthcare Ltd	The Firm presented their proposal alongwith Phase I, II & III Clinical trial reports before the committee. Based on the clinical trial data presented by the firm, after detailed deliberation, the committee recommended for the grant of permission to manufacture and market Desidustat Tablets 25 mg and 50 mg subject to the following conditions- 1. The firm should submit the Phase IV protocol to CDSCO before launching the product in the market and Phase IV trial should be initiated within three months of approval of the protocol by CDSCO. 2. Revised package insert should be submitted to CDSCO for review. 3. Proposed Package Insert, Label, Carton to be adopted should be approved from CDSCO before marketing of the product as per the requirements of the Rules. 4. The drug should be sold by retail on prescription of Nephrologists/ Internal Medicine specialist. 5. Some of the clinical trial sites should be inspected to verify GCP compliance.