

Recommendations of the SEC (Pulmonary) made in its 09th/25 meeting held on 09.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/24/000066 Olbas Oil 12 ml and 30 ml	M/s NK Healthcare Pvt. Ltd	<p>The firm presented the proposal for grant of permission for Import and Marketing of the drug product Olbas Oil along with justification for local clinical trial waiver, before the committee.</p> <p>After detailed deliberation, the committee opined that the quantities of bio-active ingredients to be quantified in finished product are mentioned as relative quantity. Firm is required to specify the absolute quantity of Bioactive ingredient in finished product.</p> <p>Further, the committee recommended that the firm should submit the followings:</p> <ol style="list-style-type: none"> 1. Justification for same composition/ strength of product for both Cutaneous use and inhalation use. 2. The firm has presented the usage data in terms of the number of vials sold and Adverse Events reported. However, clinical data from well-structured clinical trial study for proposed indications for Cutaneous use and inhalation use is required to be submitted for further consideration.