

Recommendations of the SEC (Analgesic & Rheumatology) made in its 08th/25 meeting held on 17.09.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000273 Paracetamol Injection 1000 mg / 4 ml 1000.000 mg/4 ml	M/s. Troikaa Pharmaceuticals Ltd.	<p>In light of SEC recommendation dated 24.06.2025, firm presented the clarification for observations noted by SEC committee dated 24.06.2025.</p> <p>After detailed deliberation, Committee opined that:</p> <ul style="list-style-type: none"> a) Applied indication can be appropriately addressed with currently available Paracetamol solution for infusion 10 mg/ml (1000 mg/100 ml) formulation. b) There is no superiority/ additional benefit with Paracetamol 1000 mg/4 ml injection over existing Paracetamol solution for infusion 10mg/ml (1000 mg/100 ml) formulation. c) As per PI, if diluted solution is not used within 08 minutes, leading to crystallization which may pose addition risk for usage. d) Applied Paracetamol 1000 mg/4 ml injection shown significantly higher C_{max} and $AUC_{0-t/0-\infty}$ than Paracetamol Intravenous Injection 10 mg/ml (1000 mg/100 ml infusion) and may cause liver toxicity. <p>Hence, after detailed deliberation Committee did not recommend for grant of permission to manufacture and market the Paracetamol 1000 mg/4 ml injection.</p>