

Recommendations of the SEC (Radio-Diagnostic) made in its 01st/25 meeting held on 30.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/22/000072 MultiHance® 0.5 M solution for injection (gadobenate dimeglumine 529 mg/mL)	M/s Imaging Products India Pvt. Ltd	In light of earlier SEC recommendation dated 27-04-2023 and subsequent NOC dated 23.05.2023 issued by this office, the firm presented report (OBS-BII-002 dated 05.02.2024) on Active Surveillance of the safety of MultiHance® 0.5M solution for Injection (Gadobenate dimeglumine 529 mg/ml), before the committee. After detailed deliberation, the committee noted and agreed to the result of the Active Surveillance study.