

**Recommendations of the SEC (Radio-Diagnostic) made in its 01<sup>st</sup> /26 meeting held on 05.02.2026 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	<p>ND/IMP/25/000084</p> <p>Sodium Pertechnetate (99mTc) Injection (Ultra- Technekow Fm, 2.15-43.00 Gbq, Radionuclide Generator) I.P., E.P. 43.000 GBq.</p>	<p>M/S Curium Pharma (India) Private Limited</p>	<p>The firm presented its proposal for grant of permission to import and market the new drug, Sodium Pertechnetate (<sup>99m</sup>Tc) Injection before the Committee.</p> <p>After detailed deliberation, the Committee recommended that proposed drug product should be used only with approved kits. Accordingly, firm should submit the list of approved kits with which the proposed product is intended to be used.</p> <p>The Committee noted that the firm has not presented safety and efficacy data of their proposed product. The consolidated PSUR data submitted and presented by the firm pertained to other approved products. Hence, the Committee recommended that firm should submit PSUR data specific to the product applied for.</p> <p>The Committee further recommended that firm should submit the requisite data to CDSCO for further review by the Committee, including experts from Nuclear Medicine specialty.</p>