Recommendations of the SEC (Renal) made in its 10th/25 meeting held on 14.10.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/25/000113 Calcium-3-methyl-2-oxo butyrate (α-Ketoanalogue to Valine, calcium salt) 86mg/172mg + Calcium-DL-2-hydroxy-4(methylthio)-butyrate (α-hydroxy analogue to methionine calcium salt) 59mg/118mg + Calcium-4-methyl-2-oxo-valerate (α-Ketoanalogue to Leucine, calcium salt) 101mg/202mg + Calcium-2-oxo-3-phenylpropionate (α-Ketoanalogue to phenylalanine, calcium salt) 68mg/136mg + Calcium 3-methyl-2-oxo-valerate (α-Ketoanalogue to Isoleucine, calcium salt) 67mg//134mg + Total Calcium content per tablet 1.25 m mol/ 2.5m mol 0.05gm/0.1gm film coated tablet.	M/s. Stanford Laboratories Pvt. Ltd.	The firm presented their proposal alongwith request for BE & Phase III CT waiver before the committee. After detaileddeliberation, the committee unanimously opined that, in the absence of high-quality evidence demonstrating the clinicalefficacy of ketoanalogue formulations devoid of essential amino acids in themanagement of chronic kidney disease (CKD)Stage 3, stage 4 and stage 5, waiver for a phase III clinicaltrial is not scientifically justifiable. The committee strongly recommends a multicenter,randomized, adequately powered phase IIIclinical trial to assess the safety, efficacy and long-term renal and nutritional outcomes of such formulations in patientswith non-dialysis-dependent CKD. Accordingly, firm should submit Phase III CT protocol to CDSCO for further review by the committee.