

Recommendations of the SEC (Endocrinology & Metabolism) made in its 20th meeting held on 11.12.2024 at CDSCO (HQ), New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|-------|--|---------------------------|--|
| 1. | SND/MA/22/000288 Semaglutide Solution for Injection, Multi-dose Prefilled Pens 2mg/1.5ml (1.34mg/ml) & 4mg/3ml (1.34mg/ml) (Synthetic Origin) | M/s. Natco Pharma Limited | <p>In light of earlier SEC recommendation dated 16.05.2024, the firm presented Bioequivalence study report alongwith the Phase-III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee considered the bioequivalence report and recommended for grant of permission to conduct Phase III clinical trial study as per the protocol presented by the firm with subject to following conditions:</p> <ol style="list-style-type: none"> 1. BMI cut-off should be included in inclusion criteria. 2. Titration of dose should be done based on fasting blood sugar levels at defined intervals. 3. <i>Retinal examination (fundoscopy) should be done at each visit.</i> |