

Recommendations of the SEC (Reproductive) made in its 03rd/25 _{meeting held on 18.03.2025 at CDSCO (HQ), New Delhi:}

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---------------------|--|--|--|
| SND Division | | | |
| 1. | SND/MA/24/000021 Drotaverine Hydrochloride Extended Release Tablets, 120 mg and 160 mg, 240mg | M/s Martin & Harris Laboratories Limited | In light of earlier SEC recommendation dated 21.08.2024, firm presented the BA Study protocol no. C1B03275 dated 19-Jan-2024 along with summary of changes, made w.r.t. earlier formulation before the committee. After detailed deliberation, the Committee recommended for the grant of permission to Conduct BA study as per protocol presented by the firm. |