ABSTRACT

Background: The present research work comprises of the Stability Indicating RP-HPLC analytical method development and validation for selected drugs & pharmaceutical dosage forms belonging to the Antimicrobial class. The antimicrobial drugs are frequently upgraded and newly approved drugs by FDA and CDSCO are available in the markets in the form of new dosage forms as well as combined dosage forms with other drugs. For the newly approved drugs and their drug combinations, the Stability analytical methods are not available in pharmacopoeia and even dissolution methods for the solid dosage forms are also not available for the combined dosage forms. Hence there is a need of newer analytical methods, as well as stability, indicating rapid- RP-HPLC technique and it is optimised for, analysis of drug during different stress conditions as well as in pure from and solid dosage form along with the *in-vitro* dissolution studies carried out for solid dosage forms. **Aim:** The main aim of the present research work to develop and validate spectroscopic & chromatographic analytical methods for the estimation of antimicrobial agents and their combinations in synthetic mixture and assay method for the pharmaceutical dosage forms. **Materials and Methods:** Working Standard drugs- Doravirine, Lamivudine, Tenofovir, Cabotegravir, Rilpivirine, Dolutegravir, Fexinidazole, Maribavir, Molnupiravir, Amoxicillin, Clarithromycin, Vonoprazan, Combined formulations, Chromatographic HPLC system Shimadzu LC-20-AT, UV Spectrophotometer systronics & shimadzu-1800, Hypersil-coloumn ODS-C_{18} (250 mm x 4.6 mm, 5 µm id), Analytical balance, sonicator, Dissolution apparatus Veego Microprocessor. **Results & Discussions:** The Stability Indicating RP-HPLC methods for selected antimicrobial drugs have been developed & validated using ICH recommendations, which demonstrate its accuracy, precision & robustness of the procedures. The ICH parameters Accuracy, Precision, LOD, LOQ, Linearity, Range, Selectivity were successfully performed within the criteria specified by ICH guidelines. The dergadants and pure drugs were successfully identified by the RP-HPLC approach in the stability and forced-degradation investigations under various stress conditions. This approach is used to investigate the *in vitro* dissolution characteristics of drug in solid oral dosage forms.