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Accelerated drug approval, a regulatory overview

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National There are already a number of unmet medical needs along with limited no of drugs available for treatment of life threatening and rapidly spreading diseases like AIDS, HIV, Tuberculosis, Cancer, Viral infections… The current medicines available for treatment are having their own pros and cons, and a search for better medicine is going on. In this scenario, the timeliness with which national regulatory agencies approve new drugs for marketing affects health care professionals and patients significantly. As an unnecessarily long approval process delays access to new medications that is much desperately needed by the patients who are suffering from life threatening diseases and medical conditions which are still lacking proper medicine or aid. Small increase or decrease in timeline of drug approval will have direct affect on their lifeline. Timeline (New Drug Approval) = Lifeline (Patients in-need).Therefore speeding the development and availability of such drugs is a need of time. Food and Drug Administration (USFDA) have provided solution to this problem in form of three distinct approaches those are: *Fast Track, Accelerated Approval and Priority Review*. Each of these approaches implies speed. As per information from official USFDA site implies, compared to normal approval time these approaches together have reduced new drug approval time to a significant extent. Fast track approach emphasizes on following points for its ability to minimize drug approval time: i) Abbreviating the phase which accounts for the most time expend during drug development and approval i.e clinical trials, by providing early and regular consultations between the FDA and the new drug sponsor ii) Fast-track designation means that the product "ordinarily will be eligible for priority review." A "standard" NDA review sets the target date for completing all aspects of the review and FDA's approval decision at ten months starting from the date on which NDA is filed. A "priority" review sets the target date for an FDA decision at six months. iii) Further the fast-track program allows for a "rolling review" which allows FDA to review the NDA as the completed sections are submitted rather than waiting until the entire application arrives for evaluation. NDA review usually does not begin until the drug company has submitted the entire application to the FDA. Accelerated approval approach speed up approval procedure by allowing sponsors to submit clinical trails based on surrogate endpoints. These revitalized FDA drug review approaches have yielded tangible results in bringing safe and effective drugs to patients with serious diseases more quickly. For example, since 1996, 68 drugs for cancer therapies have received approval via these approaches. Shortened review times have also brought promising treatments to patients with HIV/AIDS more quickly. The formalized procedure that come with fast-track designation attempt's to reduce clinical development time by introducing early cooperation, enhanced predictability of FDA decision-making, and efficient agency interventions. Parallely FDA has been vigilant in assuring that reducing the time necessary for drug development has not compromised the safety and effectiveness of drugs for patients with serious diseases.

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Development and validation of a HPTLC method for simultaneous determination of furosemide and spironolactone in its tablet formulation

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The objective of the current study was to develop a simple, precise and accurate High Perfomance Thin Layer Chromatographic [HPTLC] assay method and validated for determination of furosemide and spironolactone in solid pharmaceutical dosage forms. The mobile phase comprising of ethyl acetate: hexane in the volume ratio of [80: 20, v/v] was employed for the elution. Standard solution was prepared in methanol. The standard concentration was 40 µg ml^{-1} of furosemide and 100 µg ml^{-1} of spironolactone. Chromatographic analysis was performed on a HPTLC plates precoated with 0.25 mm layer of chromatographic silica gel mixture [Silica GF254] on aluminum sheets. After development of the chromatographic plate, the detection was carried out using an Ultraviolet scanning densitometer set at a wavelength of 254 nm. The method was validated for specificity, linearity, precision, accuracy, robustness and solution stability. The method was linear in the drug the concentration range from 0.016-0.064 mg ml^{-1} for furosemide and 0.040-0.160 mg ml^{-1} for spironolactone with correlation coefficient 0.9958 and for Spironolactone with correlation coefficient 0.9975. The (relative standard deviation – RSD) values for intraday precision study and interday precision study was < 2.0 % for furosemide and spironolactone. The mean recovery for furosemide was 98.51 – 98.81 % and 98.20 –98.98 % for spironolactone.