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Formulation of Dry Powder Inhaler of Anti-tuberculous Drugs Using Spray Drying Technique and Optimization Using 23 Level Factorial Design Approach

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Abstract:

Background: Targeting anti-tubercular therapeutics to alveolar macrophages using microparticles technology mainly focuses on increasing local concentrations of therapeutics and potentially reducing the frequency of dosing requirements. Rifampicin (RIF), Ofloxacin (OFX) and Ethambutol (ETH) combination show synergism.

Objective: In light of the above facts, the focus of the present study was to develop and characterize novel Dry powder Inhaler formulation incorporating novel drug combination as a pulmonary delivery for the effective eradication of Tuberculosis.

Method: Biodegradable microparticles containing RIF, OFX and ETH were prepared by a spray drying technique using PLGA polymer through the critical process as well as polymer attributes were screened and optimized using 23 factorial design. The identified critical process parameters (CPP's) viz. Inlet temperature, Aspiration rate, and feed rate were selected as independent variables while percentage yield, percentage entrapment efficiency, and particle size were selected as a response. The formulated microparticles were evaluated for particle size, drug-polymer compatibility study, aerodynamic behavior, morphology, particle size distribution, crystallinity, residual solvent content, in-vitro drug release study, and stability study.

Results: By choosing the optimum spray drying conditions maximum yield of 73%, entrapment efficiency of 86% and particle size of 1.4 µm was attained of the optimized batch. Thus the results revealed that spherical microparticles are suitable for inhalation and sustained release for 12 h.

Conclusion: The successful formulation and evaluation of dry powder could be used as an enhanced therapeutic alternative of the standard oral anti-tubercular regimen, rescuing oral dosing, shortening drug regimen and limiting toxicity. This will ultimately improve patient compliance and diminish the prevalence of MDR resistance.

Keywords:

Dry powder inhaler, tuberculosis, PLGA, Spray drying, 23 factorial design, optimization.

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