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Formulation, optimization and evaluation of Atorvastatin calcium-fenofibrate loaded PLGA nanoparticles

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Currently mixed hyperlipidaemia is acting as a leading cause for aggregation of Coronary Heart Disease and Type 2 Diabetes mellitus and worsening the present status. Present work is introducing a new biodegradable nanoparticulate based approach with a view to improving the efficacy and safety of Atorvastatin calcium-Fenofibrate (ATC-FEN) combination with a single formulation for proper management of mixed hyperlipidaemia. Drug-polymer compatibility was checked by FTIR, DSC and X-RD studies which supported the drug polymer compatibility. Nano precipitation method was used for preparation of nanoparticles and the batch contained drug: polymer ratio (1:1), amount of surfactant (200 mg) and aqueous to organic phase ratio (1.5:1) as optimized batch. TEM images for optimized batch exhibited the spherical shape with smooth surface of nanoparticles. XRD results favored the fact that FEN crystallinity reduced in nano particles than pure FEN. *In vitro* release studies showed sustained release after initial burst for both drugs (for ATC 98.99% and FEN 66.78% release in 24 hrs). Correlation coefficient (R²) values were showing first order release for both drugs while diffusional component (n) values exhibited non-fickian anomalous type and fickian type release mechanisms for ATC and FEN respectively. *In vivo* lipid profile studies in rats treated with optimized formulation exhibited significant change in all lipid parameters compared to high fat diet (HFD) fed rats (untreated). Histopathological evaluation of hepatic tissue revealed marked degenerative and fatty changes in HFD fed rats (untreated). Whereas rats treated with optimized batch showed positive micro vascular fatty changes in liver tissue, indicating good efficacy of the formulation. This study thus demonstrates that PLGA based nanoparticles improve therapeutic efficacy and safety of ATC-FEN combination for better management of mixed hyperlipidaemia.

Biography

Ankit Patel is a Post graduate fellow at Indian Institute of Technology (Banaras Hindu University) Varanasi. His current area of research is lipid based nanoparticulate drug delivery system. Before joining as Postgraduate fellow, he had completed Diploma and Bachelor in Pharmacy Studies from Gujarat, India with distinction. He had worked with Alembic Ltd., India in tablet and capsule manufacturing unit as production trainee. He has qualified GPAT-2013 with All India Rank 1. He received financial assistance, from MHRD, Government of India for his post graduation research work. He was felicitated with GPAT Topper Award (Gold Medal) by Indian Pharmacy Graduates Association and received 25,011 INR from Shree Krishna Educational Charitable Trust for his outstanding performance in GPAT-2013.

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