

## Design and development of matrix type hydroxyzine hydrochloride transdermal patches

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Matrix type transdermal drug delivery systems (TDDS) of Hydroxyzine hydrochloride (HHCL) with and without permeation enhancers were prepared by solvent casting method. Mixture of polymers Eudragit RS100, Eudragit RL100, PVP, HPMC E15 LV and ethyl cellulose were employed in the preparation of patches. Dibutylphthalate was used as plasticizer. The prepared patches were evaluated for physicochemical characterization, *in vitro* and *ex vivo* diffusion study. In order to reduce the skin barrier property and to enhance the skin permeation of drug, permeation enhancers transcutool and propylene glycol were incorporated in polymeric films.

The central composite design was applied to optimize the best permeation enhancer. Formulations (HhLS<sub>30t</sub>) with Eudragit RS100, RL100 at 25% transcutool concentration and formulation (HhLS<sub>3-1p</sub>) with Eudragit RS100, RL100 at 15% propylene glycol were found to be the best. Among these two permeation enhancers used, no statistically significant difference ( $p > 0.05$ ) was observed between transcutool (25%) and propylene glycol (15%). All the optimized formulations had shown zero order kinetics and non fickian type of diffusion. No signs of skin-irritation were observed in testing with rabbit.

## Orphan regulations for orphan drug development in India

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Through this paper an attempt has been made to put forward the challenges faced by rare disease drug development and the current scenario of orphan drugs legislations in India. An orphan drug is a pharmaceutical agent that is used to treat a rare medical condition (viz., Huntington's disease, myoclonus disease, Tourette syndrome etc.). Developed countries like US, EU, Japan; Australia has laid down legal framework for combating rare diseases. A path breaking legislation was formulated by the U.S government way back in 1983, known as 'Orphan Drugs Act (ODA)'. The key purpose of ODA was to incentivize R&D initiatives for such drugs to treat millions of population suffering from 'Orphan Diseases'. Though the percentage of patients suffering from 'Rare Diseases' in India is reportedly higher than the world average, unfortunately even today such cases get little help from our government. By considering the importance of ODA, Indian government should also encourage its domestic pharmaceutical industry to get engaged in research to discover drugs for rare diseases by putting an 'Orphan Drugs Act' in place and extending financial support, and regulatory concessions like smaller and shorter clinical trials, without further delay. Thus India could well demonstrate that the concept of Orphan Drugs for Orphan Diseases is really not Orphan in India.

### Biography

I am saikiran reddy pursuing 1<sup>st</sup> M.Pharm in pharmaceutical regulatory affairs from JSS College of Pharmacy, JSS University, Mysore. I actively took part in various seminars and presented papers in national level symposiums.