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Formulation and Characterization of Transdermal Patch of Sildenafil Citrate: *In vitro* and *Ex vivo* Studies

Ashok KUMAR [1], Netra P. NEUPANE [2], Vinesh DAHIYA [3],
Mohd Masih Uzzaman KHAN [4], SS AGRAWAL [5] & Amita VERMA [2] *

[1] *Department of Internal Medicine, University of Kansas Medical Centre, Kansas, 66103, USA*

[2] *Bioorganic and Medicinal Chemistry Research Laboratory, Department of Pharmaceutical Sciences, Sam Higginbottom University of Agriculture, Technology and Sciences, Prayagraj, 211007, India*

[3] *Department of Pharmacognosy, Guru Jambheshawar University Hisar, Haryana, 125001, India*

[4] *Department of Pharmaceutical Chemistry and Pharmacognosy, Unaizah College of Pharmacy, Qassim University, 51911, Saudi Arabia*

[5] *Delhi Pharmaceutical Science and Research University, New Delhi, India*

SUMMARY. **The aim of this work was to develop a suitable matrix-type transdermal drug delivery system (TDDS) of sildenafil citrate. Fifteen different transdermal patches formulations of sildenafil citrate were prepared by using different polymers and blends of different polymers like chitosan, PEG-400 and Isopropyl myristate. Physical studies such as physical appearance, thickness, uniformity of weight, folding endurance, flatness, percentage moisture absorption and drug content uniformity were performed in selective 5 formulations of sildenafil citrate. *In vitro* release studies and skin irritation studies were also performed on 5 selective formulations. The patches containing sildenafil citrate and 1% SPAN 60 released the maximum amount of drug, *i.e.*, 3.062 mg from the formulation. The percentage drug released from the formulation was 12.25%. Skin irritation studies on Wistar rats for 72 h showed no sign of itching and irritation with primary irritation index of 0. Our present study concluded that sildenafil citrate can be formulated into the transdermal matrix type patches to sustain its release characteristics.**

RESUMEN. El objetivo de este trabajo fue desarrollar un sistema de administración transdérmica de fármacos (TDDS) de tipo matriz adecuado de citrato de sildenafilo. Se prepararon quince formulaciones diferentes de parches transdérmicos de citrato de sildenafilo utilizando diferentes polímeros y mezclas de diferentes polímeros como quitosano, PEG-400 y miristato de isopropilo. Se realizaron estudios físicos tales como apariencia física, grosor, uniformidad de peso, resistencia al plegado, planeidad, porcentaje de absorción de humedad y uniformidad del contenido de fármaco en formulaciones selectivas de citrato de sildenafilo. También se realizaron estudios de liberación *in vitro* y estudios de irritación de la piel en 5 formulaciones selectivas. Los parches que contenían citrato de sildenafil y SPAN 60 al 1% liberaron la cantidad máxima de fármaco, es decir, 3,062 mg de la formulación. El porcentaje de fármaco liberado de la formulación fue del 12,25%. Los estudios de irritación de la piel en ratas Wistar durante 72 h no mostraron signos de picazón ni irritación con un índice de irritación primaria de 0. Nuestro presente estudio concluyó que el citrato de sildenafil se puede formular en parches tipo matriz transdérmica para mantener sus características de liberación.

KEY WORDS: characterization, *in-vitro* studies, sildenafil citrate, skin irritation, transdermal drug delivery system (TDDS), transdermal patch.

* Author to whom correspondence should be addressed. *E-mails:* amitaverma.dr@gmail.com, amita.verma@shiats.edu.in

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