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FORMULATION, EVOLUTION AND STABILITY STUDIES OF SUSTAINED RELEASE TABLETS OF MOLSIDOMINE USING HYDROPHILIC MATRIX SYSTEM

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ABSTRACT

Different formulations of Molsidomine, a photosensitive drug, 8 and 16mg sustained release tablets were formulated applying wet granulation method and using hydrophilic polymers (HPMC 100000, HPMC 4000, HPMC 15 and Xanthan Gum). The effect of concentration for these hydrophilic polymers on the dissolution of Molsidomine was studied. Prepared tablets were subjected to physiochemical, in vitro release and stability studies to find out the best formulation. In vitro release studies of tablets were carried out according to the European Pharmacopoeia, 3rd edition (or USP XXIV). Dissolution results showed that an increase of Xanthan Gum and HPMC 100000 concentrations, resulted in reduced drug release. However, the presence of lactose in Xanthan Gum and HPMC 100000 matrix tablets didn't show a different significant result on dissolution rate compared to the other formulation containing dibasic calcium phosphate as a filler. Using Xanthan Gum 70% or a mixture of HPMC15 cp 15%, HPMC-4000 cp and HPMC 100000 30%, were found to be Best in controlling the release for tablet containing 8mg molsidoimine. In addition, a formula of HPMC-15 cp 16.7%, HPMC-4000 cp 16.7% and HPMC 100000 31.75%, were found to be best in controlling the release for tablets containing 16 mg molsidomine according to WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES SJIF Impact Factor 7.632 Volume 10, Issue 7, 2211-2226 Research Article ISSN 2278 – 4357 *Corresponding Author Issa Alsalloum Professor at Al-Hawash Private University-Syria, Former Professor of Industrial Pharmacy and Pharmaceutical Technology at Damascus University, Director of the R&D Department at Biomed Pharma Laboratory. issasalloum48@gmail.com issa.salloum@hpu.edu.sy Article Received on 22 May 2021, Revised on 10 June 2021, Accepted on 30 June 2021, DOI: 10.20959/wjpps20217-19458 www.wjpps.com | Vol 10, Issue 7, 2021. | ISO 9001:2015 Certified Journal | 2212 Issa et al. World Journal of Pharmacy and Pharmaceutical Sciences pharmacopeias requirements. After coating the tablets and studying the effect of light on their stability, no photodegradation was detected after 12 hours with a 50µm thick film layer containing 5% of titanium dioxide or 30µm thick film layer containing 10% or 15% titanium dioxide. Concerning stability studies according to ICH Q1A guidelines, the formulas studied were found to be conformed to compendia specifications. In addition, there was no significant change in dissolution profile in the accelerated stability studies. On the other hand, coated tablets had better stability than the non-coated ones.