

POLYMERIC MATRIX WITH PAPAIN: A CYTOTOXIC AND CUTANEOUS IRRITATION STUDY

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Abstract. Papain is a proteolytic enzyme extracted from the latex of green papaya leaves and fruits. It has been widely used as debridement agent for scars and wound healing agent. However, papain presents low stability, which limits its use to extemporaneous or short shelf life formulations. The objective of this study was to entrap papain into a polymeric matrix in order to obtain a drug delivery system. For this purpose four polymers of medical application were selected and firstly assessed for cytotoxicity by using Neutral Red Method. Cell line of NCTC clone L929 mouse connective tissue cells from ATCC bank was used. Selected polymers were Natural Rubber Bicentrifuged Latex (NRBL), Acrylic Adhesive (AA), monocomponent silicone dispersion (MSD) and bicomponent silicone dispersion (BSD). Non-cytotoxic polymers were submitted to cutaneous irritation test *in vivo*, in order to estimate the irritant potential to human skin, by means the observation and quantification of cutaneous reactions that can occur after just one application of the device. Six rabbits were used for each membrane assessed. Membranes were applied onto rabbits' skin for 24 hours. After this period membranes were removed and the formation of redness and edema was observed 24 and 72 hours after the beginning of the test. Both silicone dispersions used resulted non-cytotoxic, which is an expected result for a biomaterial. However, NRBL and AA polymers showed to be cytotoxic in the same test conditions. The result signifies that probably cytotoxicity of AA polymer was not assessed with the same cell culture. Regarding the cutaneous irritation test MSD and BSD polymers did not cause any cutaneous reaction on animals' skin. It indicates that these materials do not represent an irritant potential to human skin and can be used as biomaterials.

Key words: *papain, polymeric matrix, cytotoxicity, cutaneous irritation test.*