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(54) Title: TOLUIDINE BLUE O DRUG SUBSTANCE AND USE THEREOF FOR IN VIVO STAINING AND CHEMOTHERAPEUTIC TREATMENT OF DYSPLASTIC TISSUES

(57) Abstract: The invention comprises an improved process for preparing TBO drug products includes the steps: (1) synthesising an indamine; (2) converting said indamine into an S-indaminyI thiosulfate; and (3) adding an oxidizing catalyst agent, complexing agent, and an acid to said S-indaminyI thiosulfate to formulate TBO and C-4-methyl regioisomer, and derivatives thereof. The invention further comprises new compositions of matter that are useful for detecting dysplastic tissue, as well as, treating dysplastic tissue, namely, TBO products predominantly comprised of peaks eight, peak six, or a combination thereof. *N,N*-dimethyl-*p*-phenylenediamine as a starting material results in a TBO product composition comprised of peaks eight, seven, six, and five in the approximate ratios 33:5:5:1, respectively. Whereas *N*-dimethyl-*p*-phenylenediamine as a starting material results in a TBO demethylated product composition comprised of peaks six, five, tree and two in the approximate ratio 33:5:5:1, respectively. The invention further comprises an improved PLC method for analyzing the improved TBO drug product, the improvement comprising the addition of an ion-pairing reagent in a first mobile phase and forming a second mobile phase composition comprising 50% alcohol by volume.



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