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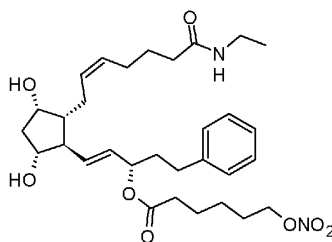
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(54) Title: INDUSTRIAL PROCESS FOR THE PREPARATION OF HEXANOIC ACID, 6-(NITROOXY)-, (1S,2E)-3-[(1R,2R,3S,5R)-2-[(2Z)-7-(ETHYLAMINO)-7-OXO-2-HEPTEN-1-YL]-3,5-DIHYDROXYCYCLOPENTYL]-1-(2-PHENYLETHYL)-2-PROPEN-1-YL ESTER AND HIGH PURE PRODUCT



(I)

(57) Abstract: The present invention relates to a process for preparing hexanoic acid, 6-(nitrooxy)-, (1S,2E)-3-[(1R,2R,3S,5R)-2-[(2Z)-7-(ethylamino)-7-oxo-2-hepten-1-yl]-3,5-dihydroxycyclopentyl]-1-(2-phenylethyl)-2-propen-1-yl ester Compound (I). In accordance with the present invention, a pharmaceutical grade Compound (I) can be efficiently prepared by a one-pot reactions preparation step that includes the esterification of the 15-OH bimatoprost by coupling bimatoprost phenyl-boronate with 6- (nitrooxy)hexanoic acid and the removal of the boronate ester protecting group, followed by an efficient purification step. The invention refers also to high purity Compound (I) substantially free of the impurity 15-(6-chlorohexanoyl) ester of bimatoprost and to ophthalmic pharmaceutical formulations containing the high purity compound.

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