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(54) Title: VARENICLINE STANDARDS AND IMPURITY CONTROLS

(57) Abstract: The subject invention provides a varenicline composition that comprises varenicline, or a pharmaceutically acceptable salt thereof, and an amount of a compound selected from one or more of several mononitro, monoamine mixed aminonitro, diamino or dinitro intermediates, and the concentration of said compound is greater than 0 ppm and not greater than about 500 ppm, not greater than about 100 ppm or not greater than about 10 ppm. Methods for synthesizing and using such varenicline compositions are also provided.

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