

FENFLURAMINE COMPOSITIONS AND METHODS OF PREPARING THE SAME

ABSTRACT

Methods of preparing a fenfluramine active pharmaceutical ingredient are provided. Aspects of the method include (a) hydrolyzing a 2-(3-(trifluoromethyl)phenyl)acetonitrile composition to produce a 2-(3-(trifluoromethyl)phenyl)acetic acid composition; (b) reacting the 2-(3-(trifluoromethyl)phenyl)acetic acid composition with acetic anhydride and a catalyst to produce a 1-(3-(trifluoromethyl)phenyl)propan-2-one composition; and (c) reductively aminating the 1-(3-(trifluoromethyl)phenyl)propan-2-one composition with ethylamine using a borohydride reducing agent to produce a fenfluramine composition. Also provided are compositions and pharmaceutical ingredients prepared according to the subject methods including a pharmaceutically acceptable salt of fenfluramine and having less than 0.2% by weight in total of trifluoromethyl regioisomers.

[Figure 1]