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(57) Abstract:

The present invention relates to a chitosan-coated roflumilast nanoemulsion for intranasal nose-to-brain delivery for the prevention, management, and treatment of Parkinson's disease and related neurodegenerative disorders. The pharmaceutical composition comprises roflumilast or a pharmaceutically acceptable salt thereof, a lipid phase, at least one surfactant, at least one co-surfactant, an aqueous phase, and a chitosan coating. The nanoemulsion possesses nanosized droplets, high drug encapsulation efficiency, enhanced physicochemical stability, and controlled biphasic drug release. The chitosan coating imparts positive surface charge and mucoadhesive properties, thereby increasing nasal residence time, mucosal permeation, and direct transport through olfactory and trigeminal pathways while substantially bypassing the blood-brain barrier and hepatic first-pass metabolism. The formulation enhances brain bioavailability and neuroprotective activity through phosphodiesterase-4 inhibition and modulation of cyclic adenosine monophosphate signaling, resulting in reduced neuroinflammation, oxidative stress, mitochondrial dysfunction, inflammatory cytokine production, and dopaminergic neuronal degeneration.

FORM 2
THE PATENTS ACT 1970
(39 OF 1970)
&
THE PATENTS RULES, 2003
COMPLETE SPECIFICATION
(See Section 10 and Rule 31)

TITLE OF THE INVENTION

CHITOSAN-COATED ROFLUMILAST NANOEMULSION FOR NOSE-TO-BRAIN
DELIVERY IN PARKINSON'S DISEASE

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PREAMBLE TO THE DESCRIPTION

The following specification particularly describes the invention and the manner in which it is to be performed