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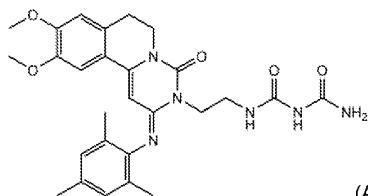
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(54) Title: PARTICULATE COMPOSITION COMPRISING ENSIFETRINE



(A)

(57) Abstract: The invention relates to a particulate composition comprising ensifentrine, wherein the particulate composition further comprises: from greater than 0.00 wt% to 0.60 wt% of 1,3-bis(2-(methylimino)-9, 10-dimethoxy-4-oxo-6,7-dihydro-2H-pyrimido[6,1-a]isoquinolin-3(4H)-yl)ethylurea (BMIQU) relative to the total weight of ensifentrine; and from 0.00 wt% to 0.50 wt% of a biuret impurity of formula (A) relative to the total weight of ensifentrine. A liquid pharmaceutical composition comprising the particulate composition, and a process for producing the particulate composition are also described.

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