(12) PATENT APPLICATION PUBLICATION
(19) INDIA
(22) Date of filing of Application :28/05/2022

(21) Application No.202241030660 A
(43) Publication Date : 01/12/2023

(54) Title of the invention : LC-MS Method for the Enantiomeric Separation of Orphenadrine Citrate in Pharmaceutical Dosage Form

(51) International classification	:G01N0030020000, G01N0030060000, G01N0030880000, B01D0015380000, G01N0030000000
(31) Priority Document No	:NA
(32) Priority Date	:NA
(33) Name of priority country	:NA
(86) International Application No Filing Date	:PCT// :01/01/1900
(87) International Publication No	: NA
(61) Patent of Addition to Application Number Filing Date	:NA :NA
(62) Divisional to Application Number Filing Date	:NA :NA

(71)**Name of Applicant :**
1)JSS College of Pharmacy, Ooty - JSS Academy of Higher Education & Research, Mysuru
Address of Applicant :Rocklands, Post Box No.: 20, Ooty, The Nilgiris, Tamil Nadu, 643 001, India OOTY Tamil Nadu India
(72)**Name of Inventor :**
1)KENTHORAI RAMACHANDRAN, Senthil Kumar
2)SUBRAMANIA NAINAR, Meyyanathan
3)BYRAN, Gowramma
4)BASUVAN, Babu

(57) Abstract :
The present invention discloses LC-MS Method for the Enantiomeric Separation of Orphenadrine Citrate in Pharmaceutical Dosage Form. The chromatographic separation was achieved on Phenomenex® Lux Cellulose 1 (250 mm x 4.6 mm i.d, 5 m particle size) column using mobile phase system containing Acetonitrile: 5 mM Ammonium acetate pH (3.5) adjusted with acetic acid (90:10) at the flow rate of 0.6 mL/min. The method is linear over the range of 30–150 ng /mL for (±) orphenadrine enantiomers with a correlation coefficient (r2 = 0.999). Detection limits and quantification limits of (+) Orphenadrine and (-) Orphenadrine are found to be 10 ng/ml and 30ng/ml respectively. The recovery study of orphenadrine from tablet formulation was found to be 99.96%. Orphenadrine standard solution and mobile phase were found to be stable for at least 48h. The orphenadrine enantiomers were well resolved with mean retention times of about 2.30 and 3.16 min respectively.

No. of Pages : 18 No. of Claims : 3