



ESCITALOPRAM SYSTEM SUITABILITY MIXTURE

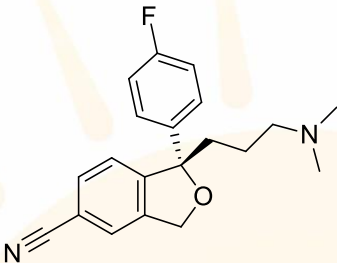
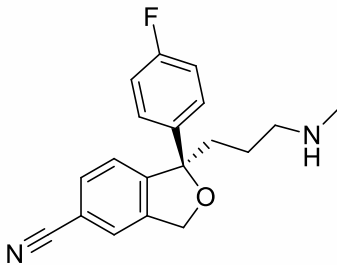
Standard Material Certificate of Analysis

(A mixture containing Escitalopram and Escitalopram EP Impurity D/ RC-D/ Desmethyl Impurity)

- Escitalopram system suitability mixture is established and certified to be used with the European Pharmacopoeia described in Escitalopram Ph. Eur. monograph (01/2017:2758) and USP Escitalopram Oxalate monograph.
- System suitability limits: Resolution between Escitalopram and Escitalopram EP Impurity D/ RC-D/ Desmethyl is (NLT) 1.5
- Escitalopram is S-enantiomer of citalopram, chemical name (1S)-1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydro-2-benzofuran-5-carbonitrile; (+)-(S)-Citalopram; S-(+)-1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydroisobenzofuran-5-carbonitrile, oxalate.
- Escitalopram EP Impurity D is identified as (1RS)-1-(4-fluorophenyl)-1-[3-(methylamino)propyl]-1,3-dihydro-2-benzofuran-5-carbonitrile; Escitalopram Related Compound D; Escitalopram Desmethyl Impurity 1-(3-dimethylaminopropyl)-1-(4-fluorophenyl)-3-hydroxy-1,3-dihydroisobenzofuran-5-carbonitrile; 1-(4-Fluorophenyl)-1-(3-methylamino-propyl)-1,3-dihydro-isobenzofuran-5-carbonitrile.
- Escitalopram EP Impurity D/ RC-D/ Desmethyl is process related impurity & in stability analysis it may lose methyl group and form desmethyl so, it is also considered as degradation impurity
- Column: 4.6 mm x 25 cm, 5 µm Luna C18(2)
(Equivalent columns: Hypersil BDS C-18; ACE C18; Atlantis d C18; Luna C18)



Composition

<u>Escitalopram</u> <i>(S)-1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydro-5-Isobenzofurancarbonitrile</i>	
CAS NO.	128196-01-0
Molecular formula	C ₂₀ H ₂₁ FN ₂ O
Molecular weight	324.39
Chemical Structure	
<u>Escitalopram EP Impurity D</u> <i>(1R)-1-(4-fluorophenyl)-1-[3-(methylamino)propyl]-1,3-dihydro-2-benzofuran-5-carbonitrile</i>	
CAS NO.	62498-67-3
Molecular formula	C ₁₉ H ₁₉ FN ₂ O
Molecular weight	310.4
Chemical Structure	



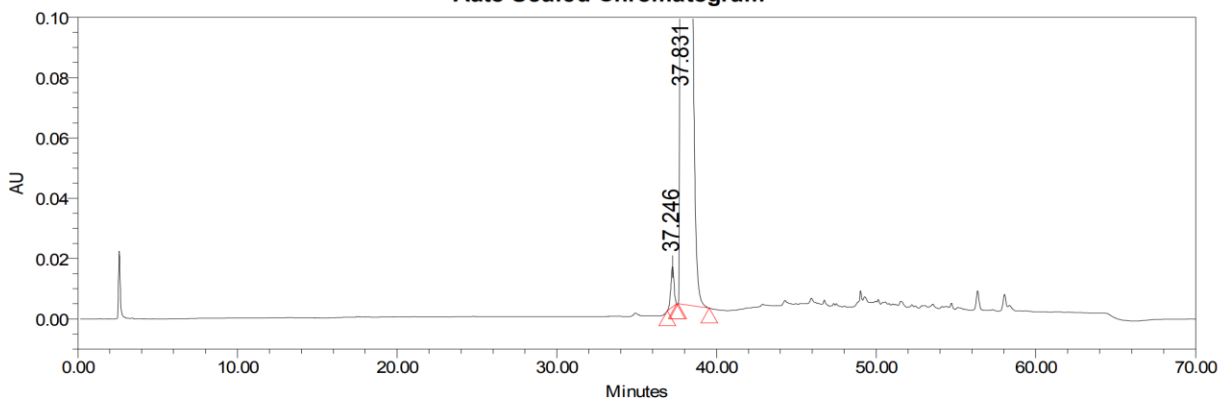
Empower 3
SOFTWARE

MANASA LIFE SCIENCES

SAMPLE INFORMATION

Sample Name:	Escitalopram SST	Acquired By:	System
Sample Type:	Unknown	Sample Set Name	
Vial:	3	Acq. Method Set:	
Injection #:	1	Processing Method	MLS_HPLC
Injection Volume:	20.00 ul	Channel Name:	W2489 ChA
Run Time:	70.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 237nm
Date Acquired:	6/21/2025 2:40:23 AM IST		
Date Processed:	6/23/2025 11:42:41 AM IST		

Auto-Scaled Chromatogram



Peak Results

	Name	Retention Time (min)	Area (μV*sec)	Height (μV)	% Area	RT Ratio
1	Escitalopram Imp-D	37.246	181993	13374	0.80	0.98
2	Escitalopram	37.831	22485793	739578	99.20	1.00

Reported by User: System
Report Method: MANASA LIFE SCIENCE:
Report Method ID: 3482
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