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Research Article

Analytical Method Development and Validation for the Simultaneous Estimation of Olanzapine and Samidorphan in its bulk and Pharmaceutical Dosage forms

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Abstract

A new method was established for simultaneous estimation of Olanzapine and Samidorphan by RP-HPLC method. The chromatographic conditions were successfully developed for these parathion of Olanzapine and Samidorphan by using AgilentC185µm (4.6*250mm) column, flow rate was 1ml/min, mobile phase ratio was Phosphate buffer ph 4.0: ACN (30:70%v/v), detection wavelength was 254nm. The instrument used was WATERS HPLC Auto Sampler, Separation module 2695, PDA Detector 996, Empower-softwareversion-2. The retention times were found to be 3.503mins and 2.577mins. The % purity of Olanzapine and Samidorphan was found to be 100.3 % and 101.1 % respectively. The system suitability parameters for Olanzapine and Samidorphan such as theoretical plates and tailing factor were found to be 1.3, 5824.4 and 1.2, 2936.0 the resolution was found to be 9.4. The analytical method was validated according to ICH guidelines (ICH,Q2(R1)). The linearity study for Olanzapine and Samidorphan was found in concentration range of 20µg-100µg and 20µg-100µg and correlation coefficient(r2) was found to be 0.999 and 0.999, % mean recovery was found to be 102.5 % and 101.0%, % RSD for repeatability was0.6 and 0.5, %RSD for intermediate precision was 0.7 and 0.6 respectively. The precision study was precise, robust, and repeatable. LOD value was 3.1 and 3.02, and LOQ value was 10.1 and 10 respectively. Hence the suggested RP-HPLC method can be used for routine analysis of Olanzapine and Samidorphan in API and Pharmaceutical dosage form.

Keywords: AgilentC18, Olanzapine and Samidorphan, RP-HPLC

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1. Introduction

Olanzapine is a thienobenzodiazepine classified as an atypical or second-generation antipsychotic agent. The second-generation antipsychotics were introduced in the 90s and quickly gained traction due to their impressive efficacy, reduced risk for extrapyramidal side effects and reduced susceptibility to drug-drug interactions. 5 Olanzapine very closely resembles clozapine and only differs by two additional methyl groups and the absence of a chloride moiety. Samidorphan is a novel opioid-system modulator, similar to naltrexone that functions primarily as a μ-opioid receptor antagonist in vivo and is used primarily in combination with antipsychotics to reduce their metabolic dysfunction-associated adverse effects.

2. Methodology

Instrumentation: The instrument used was HPLC Alliance Waters2695, empower software. The stationary phase used was AgilentC18 (4.6x250mm, 5μmDigital weighing balance-Model number BSA224SCW (Ascoset), Sonicator (Enertech)-SE60US, Ph meter Model number AD102U.

Materials and reagents:

Olanzapine and Samidorphan were gift samples provided by Dr. Reddy's laboratory, Hyderabad, Potassium dihydrogen, Acetonitrile, Methanol and Water for HPLC were supplied by Merck India Ltd, Mumbai.

Method development:

A combination of Phosphate buffer: ACN indifferent compositions were tried to reduce the retention time to the minimum. Mobile phase in the ratio of 70:30 was fixed as it gave accurate results and acceptable peak responses.

Chromatographic conditions:

Agilent C185μm (4.6*250mm) column, flow rate was 1ml/min, mobile phase ratio was Phosphate buffer ph 4.0: ACN (30:70%v/v), detection wavelength was 254nm

3. Results and Discussion

Table 1 Accuracy results of Olanzapine

%Concentration (at specification Level)	Area	Amount added(m)	Amount found(m)	% Recovey	Mean Recovery
50%	1426646	5	4.9	101.8%	
100%	2551005	10	9.98	99.9%	102.5%
150%	2139845	15	15.0	100.0%	

Table 2 Accuracy results of Samidorphan

%Concentration (at specification level)	Area	Amount Added(mg)	Amount Found(mg)	%Recovery	Mean Recovery
50%	975578	5	5.0	101.3%	
100%	1718370	10	9.96	99.6%	101.0%
150%	1465857	15	14.9	99.3%	

Table 3 Repeatability results of Olanzapine

Name: Olanzapine

	Name	RT	Area	Height (μV)	USP Plate Count	USP Tailing
1	Olanzapine	2.506	1553631	316525	6346.5	1.3
2	Olanzapine	2.516	1508002	296974	6197.1	1.2
3	Olanzapine	2.519	1545624	307327	6184.0	1.3
4	Olanzapine	2.531	1542374	302327	6176.0	1.2
5	Olanzapine	2.544	1561368	302525	6382.1	1.3
Mean			1542200			
Std. Dev.			20490.0			
% RSD			1.33			

Table 4 Repeatability results Samidorphan

Name: Samidorphan

	Name	RT	Area	Height (μV)	USP Plate Count	USP Tailing
1	Samidor	3.230	2790868	497608	7950.1	1.2
2	Samidor	3.239	2661482	468477	8046.5	1.2
3	Samidor	3.246	2706096	474632	8054.1	1.2
4	Samidor	3.257	2703419	473234	8171.8	1.2
5	Samidor	3.271	2695932	474830	8068.3	1.2
Mean			2711560			
Std. Dev.			47796.3			
% RSD			1.76			

Table 5 Ruggedness results Olanzapine

	Peak name	RT	Area
1	Olanzapine	2.506	1763951
2	Olanzapine	2.516	1794350
3	Olanzapine	2.519	1792044
4	Olanzapine	2.5531	1792044
5	Olanzapine	2.544	1783951
Mean			1786782
Std.dev			10795.03
%RSD			0.60416

Table 6 Ruggedness results Samidorphan

	Peak name	RT	Area
1	Samidorphan	3.230	2575632
2	Samidorphan	3.230	2570930
3	Samidorphan	3.246	2613729
4	Samidorphan	3.227	2613729
5	Samidorphan	3.271	2575632
Mean			2586764
Std.dev			19163.75
%RSD			0.740839

Table 7 System suitability results for Samidorphan (Flow rate)

	Flow Rate (ml/min)	USP Plate count	USP Tailing
1	0.8	3483	1.26
2	1.0	2936	1.3
3	1.2	2832	1.1

Table 8 System suitability results for Olanzapine (Flow rate)

	Flow Rate (ml/min)	USP Plate count	USP Tailing
1	0.8	6645	1.3
2	1.0	5824.4	1.3
3	1.2	6059.0	1.2

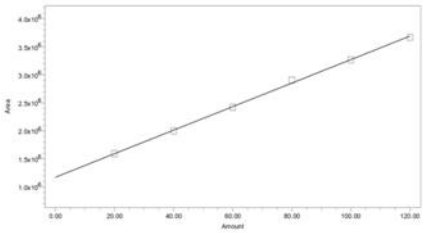

Fig 1 Calibration curve of Samidorphan

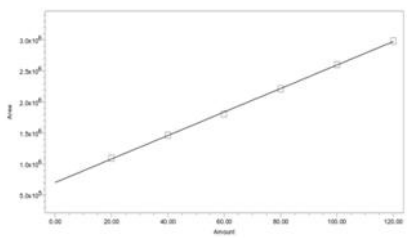

Fig 2 Calibration curve of Olanzapine

4. Conclusion

A new method was established for simultaneous estimation of Olanzapine and Samidorphan by RP-HPLC method. The chromatographic conditions were successfully developed for the separation of Olanzapine and Samidorphan by using Agilent C185µm (4.6*250mm) column, flow rate was 1ml/min, mobile phase ratio was Phosphate buffer pH 4.0: ACN (30:70%v/v), detection wavelength was 254nm.The instrument used was WATERS HPLC Auto Sampler, Separationmodule2695, PDA Detector996, Empower-softwareversion-2. The retention times were found to be 3.503mins and 2.577mins. The % purity of Olanzapine and Samidorphan was found to be 100.3% and 101.1% respectively. The system suitability parameters for Olanzapine and Samidorphan such as theoretical plates and tailing factor were found to be 1.3, 5824.4 and1.2,2936.0 the resolution was found to be 9.4. The analytical method was validated according to ICH guidelines (ICH, Q2(R1)). The linearity study for Olanzapine and Samidorphan was found in concentration range of 20µg-100µg and 20µg-100µg and correlation coefficient(r2) was found to be 0.999 and 0.999, %mean recovery was found to be 102.5% and 101.0%, %RSD for repeatability was 0.6 and 0.5, %RSD for intermediate precision was 0.7 and 0.6 respectively. The precision study was precise, robust, and repeatable. LOD value was 3.1 and 3.02, and LOQ value was 10.1 and10 respectively. Hence the suggested RP-HPLC method can be used for routine analysis of Olanzapine and Samidorphan in API and Pharmaceutical dosage form.

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