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Analytical Method Development and Validation for Haloperidol and Seroquel Combine Pharmaceutical Dosage Forms by RP-HPLC

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ABSTRACT

The proposed HPLC method was found to be simple, specific, precise, accurate, rapid and economical for simultaneous estimation of Haloperidol and Seroquel in tablet dosage form. The developed method was validated in terms of accuracy, precision, linearity, robustness and ruggedness, and results will be validated statistically according to ICH guidelines. The Sample recoveries in all formulations were in good agreement with their respective label claims. From literature review and solubility analysis initial chromatographic conditions. Agilent column (4.6×150mm)5µ, flow rate was 1.0ml/min, mobile phase ratio was (70:30 v/v) ACN: phosphate buffer($KH_2PO_4$and K_2HPO_4) phosphate pH 3 (pH was adjusted with orthophosphoric acid),detection wavelength was 230 nm. The retention times were found to be 2.462 & 3.737 mins. The % purity of Haloperidol and Seroquel was found to be 99.87% and 100.27% respectively. The system suitability parameters for Haloperidol and Seroquel such as theoretical plates and tailing factor were found to be 2733, 1.6 and 3500 and 1.4, the resolution was found to be 4.6. The analytical method was validated according to ICH guidelines (ICH, Q2 (R1)). The linearity study of Haloperidol and Seroquel was found in concentration range of 8µg-40µg and 20µg-100µg and correlation coefficient (r^2) was found to be 0.999 and 0.999, % recovery was found to be 100.1% and 103.1%, %RSD for repeatability was 1.15 and 0.21, % RSD for intermediate precision was 0.3 and 0.18 respectively. The precision study was precision, robustness and repeatabilty.LOD value was 0.574 and 0.34 and LOQ value was 1.7 and 1.04 respectively.

Keywords: HPLC, Haloperidol, Seroquel, ACN: phosphate buffer, Agilent C 18.

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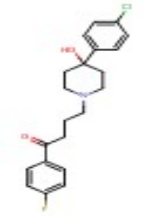
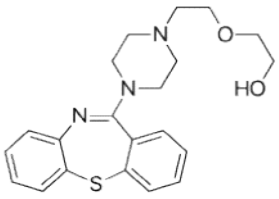
1. Introduction

Haloperidol is used in the treatment of schizophrenia, tics in Tourette syndrome, mania in bipolar disorder, nausea and vomiting, delirium, agitation, acute psychosis, and hallucinations in alcohol with drawal. It may be used by mouth or injection into a muscle or a vein



Haloperidol

Quetiapine, sold under the brand name Seroquel among others, is an atypical antipsychotic medication used for the treatment of schizophrenia, bipolar disorder, and major depressive disorder.



Seroquel

2. Materials and Methods

Instrumentation

HPLC Auto Sampler: Shimadzu Model number SPD20A, Software LC Solutions, Detector: Photo diode array detector, Thermosil C18 Column (4.0×1.25mm, 5µ), Sonicator: Model number SE60US Enertech, U.V double beam spectrophotometer: PG Instrument Model number T60 Software UV Win5, pH meter: ADWA Model number AD102U, Digital Weighing machine:a Model number ER200A .

Chemicals

Haloperidol and Seroquel, KH_2PO_4, Water and Methanol for HPLC, Acetonitrile for HPLC, Ortho phosphoric Acid, K_2HPO_4.

Trial -5 (optimized method):

Chromatographic conditions

Column : Agilent column (4.6×150mm)5µ

Mobile phase ratio: ACN: Phosphate buffer pH 4.0 (70: 30 % v/v)

Detection wavelength : 230 nm

Flow rate : 1.0ml/min

Injection volume : 10µl

Column temperature : Ambient

Auto sampler temperature : Ambient

Run time : 10min

Retention time : 2.462 & 3.737 mins

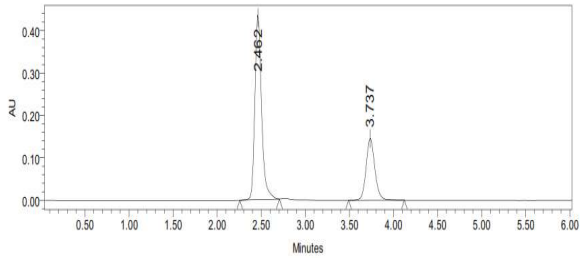


Fig.No.1. Chromatogram showing trial-5 injection

Sample solution preparation:

An equivalent tablet power such that 5 mg of Haloperidol and 2 mg Seroquel hcl tablet powder were accurately weighed and transferred into a 10 ml clean dry volumetric flask, add about 2ml of diluent and sonicate to dissolve it completely and making volume up to the mark with the same solvent(Stock solution). Further pipette 1ml of the above stock solution into a 100ml volumetric flask and was diluted up to the mark with diluent. (Concentration is 50 ppm for Haloperidol and 20 ppm for Seroquel)

Standard solution preparation

5 mg Haloperidol and 2 mg Seroquel hcl working standard was accurately weighed and transferred into a 10ml clean dry volumetric flask and add about 2ml of diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent (Stock solution).Further pipette out 1ml of the above stock solution into a 10ml volumetric flask and was diluted up to the mark with diluent. (Concentration is 50 ppm for Haloperidol and 20 ppm for Seroquel)

Method Validation

- Linearity
- Accuracy
- Precision
- Intermediate Precision
- Limit of Detection
- Limit of Quantification
- Robustness
- System suitability testing

3. Results and Discussion

Table 1 Linearity results of Haloperidol

S.No	Linearity Level	Concentration	Area
1	I	8ppm	471603
2	II	16ppm	626230
3	III	24ppm	794999
4	IV	32ppm	946124

5	V	40ppm	1102139
Correlation Coefficient			0.999

Table 2 Linearity results of Seroquel

S.No	Linearity Level	Concentration	Area
1	I	20ppm	56472
2	II	40ppm	73841
3	III	60ppm	92655
4	IV	80ppm	111541
5	V	100ppm	130567
Correlation Coefficient			0.999

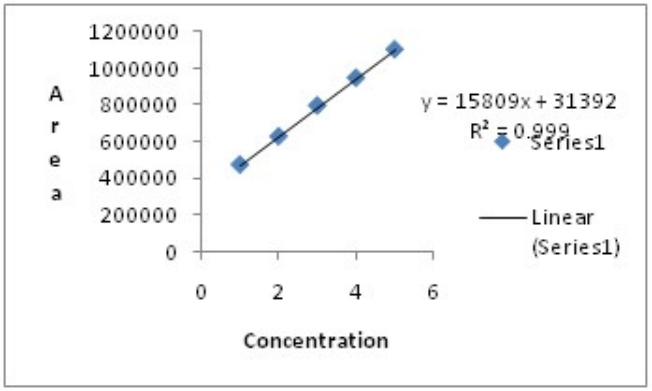


Fig. 2 Calibration curve of Haloperidol

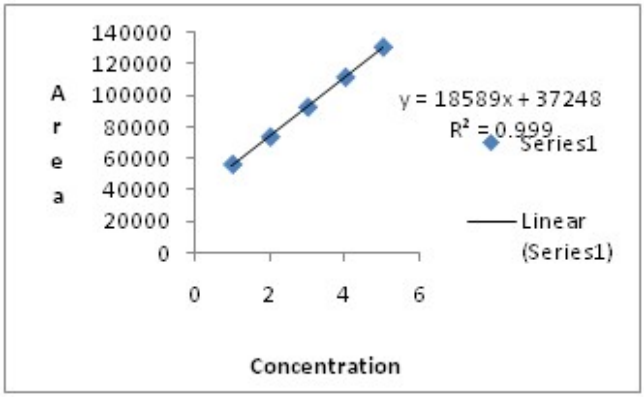


Fig 3 Calibration curve of Seroquel

Table.No.3. Showing accuracy results for Haloperidol

%Concentration (at specification level)	Average area	Amount added (mg)	Amount found (mg)	% Recovery	Mean recovery
50%	1659739	5	5.02	100.1%	100.19%
100%	3542243	10	9.96	99.60%	
150%	5265371	15	15.1	101.30%	

Table.No.4. Showing accuracy results for Seroquel

%Concentration (at specification level)	Average area	Amount added (mg)	Amount found (mg)	% Recovery	Mean recovery
50%	542367	5	5.0	101.1%	102.30%
100%	1015445	10	10.5	105.5%	
150%	1792465	15	15.0	100.5%	

Table.No 5. Showing% RSD results for Haloperidol

	Peak name	RT	Area
1	Haloperidol	2.506	2367917
2	Haloperidol	2.516	2324161
3	Haloperidol	2.519	2390163
4	Haloperidol	2.531	2323428
5	Haloperidol	2.544	2329454
Mean			2347025
Std.dev			27150.26
%RSD			1.156795

Table.No.6. Showing %RSD results for Seroquel

	Peak name	RT	Area
1	Seroquel	3.230	925541
2	Seroquel	3.239	923214
3	Seroquel	3.246	923881
4	Seroquel	3.257	920840
5	Seroquel	3.271	926447
Mean			923984.6
Std.dev			1948.274
%RSD			0.210856

Table.No.7. Showing results for intermediate precision of Haloperidol

	Peak name	RT	Area
1	Haloperidol	2.506	4663690
2	Haloperidol	2.516	4609383
3	Haloperidol	2.519	4642290
4	Haloperidol	2.531	4653384
5	Haloperidol	2.544	4635880
Mean			4640925
Std.dev			18415.67
%RSD			0.39681

Table.No.8. Showing results for intermediate precision of Seroquel

	Peak name	RT	Area
1	Seroquel	3.230	859395
2	Seroquel	3.239	856248
3	Seroquel	3.246	854757
4	Seroquel	3.257	858139
5	Seroquel	3.271	857066
Mean			857121
Std.dev			1584.995
%RSD			0.184921

Table.No.9. Showing system suitability results for Haloperidol

S. No	**Flow rate (ml/min)**	**System suitability results**	
		USP Plate Count	**USP Tailing**
1	0.8	4227.9	1.4
2	1.0	3873.2	1.4
3	1.2	3288.7	1.3

Table.No.10. Showing system suitability results for Seroquel

S. No	**Flow rate (ml/min)**	**System suitability results**	
		USP Plate Count	**USP Tailing**
1	0.8	5688.6	1.3
2	1.0	5095.5	1.3
3	1.2	4449.8	1.3

Table.No.11. Showing system suitability results for Haloperidol

S.No	**Changein Organic Composition in the Mobile Phase**	**System suitability results**	
		USP Plate count	**USP Tailing**
1	10% Less	5688.6	1
2	Actual	5095.5	2
3	10% More	4449.8	3

Table.No.12. Showing system suitability results for Seroquel

S. No	Change in organic composition in the mobile phase	System suitability results	
		USP Plate Count	USP Tailing
1	10% Less	5688.6	2
2	Actual	5095.5	4
3	10% More	4449.8	2

4. Conclusion

The proposed method is simple, rapid, accurate, precise and specific. Its chromatographic run time of 10 min allows the analysis of a large number of samples in short period of time. Therefore, it is suitable for the routine analysis of Haloperidol and Seroquel in pharmaceutical dosage form.

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