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Analytical Method Development and Validation for Simultaneous Estimation of Carbidopa and Olanzapine in Pharmaceutical Dosage Forms by RP-HPLC

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ABSTRACT

High performance liquid chromatography is at present one of the most sophisticated tool of the analysis. The estimation of Carbidopa and Olanzapine was done by RP-HPLC. The Phosphate buffer was p^H 4.5 and the mobile phase was optimized with consists of Phosphate buffer: Methanol P^H 4.5 (20:80 v/v). Kromosil C_{18} Column (250mm x 4.6mm)5µg or equivalent chemically bonded to porous silica particles was used as stationary phase. The detection was carried out using UV detector at 254nm. The solutions were chromatographed at a constant flow rate of 1ml min^{-1}. The linearity range of Carbidopa and Olanzapine were found to be from 100-500 µg/ml of Carbidopa and 1-5µg/ml of Olanzapine . Linear regression coefficient was not more than 0.999.The values of % RSD are less than 2% indicating accuracy and precision of the method. The percentage recovery varies from 98-102% of Carbidopa and Olanzapine. LOD and LOQ were found to be within limit.The results obtained on the validation parameters met ICH and USP requirements .it inferred the method found to be simple, accurate, precise and linear. The method was found to be having suitable application in routine laboratory analysis with high degree of accuracy and precision.

Keywords: Kromosil $C_{18,}$ Carbidopa and Olanzapine, RP-HPLC

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1. Introduction

Carbidopa (Lodosyn) is a drug given to people with Parkinson's disease in order to inhibit peripheral metabolism of levodopa. This property is significant in that it allows a greater proportion of peripheral levodopa to cross the blood–brain barrier for central nervous system effect.

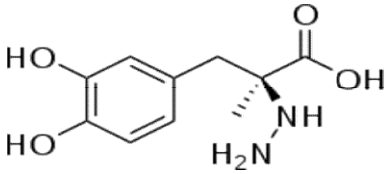


Fig 1: Chemical structure of Carbidopa

Olanzapine, sold under the trade name Zyprexa among others, is an atypical antipsychotic primarily used to treat schizophrenia and bipolar disorder for schizophrenia, it can be used for both new onset disease and long-term maintenance. It is taken by mouth or by injection into a muscle.

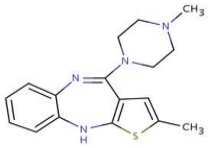


Fig 2: Chemical structure of Olanzapine

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: ADWAModel number AD102U, Digital Weighing machine:a Model number ER200A .

Chemicals:

Carbidopa and Olanzapine, KH_2PO_4, Water and Methanol for HPLC, Acetonitrile for HPLC, Ortho phosphoric Acid, K_2HPO_4.

Optimized Chromatographic conditions:

Parameters	**Description**
Flow rate	: 1ml min^{-1}
Column	: Kromosil C_{18} Column (250mm x 4.6mm)5µg.
Mobile Phase	: Phosphate buffer:Methanol P^H 4.5(20:80 v/v)
Buffer	: Potassium dihydrogen orthophosphate PH 4.5 adjusted with Orthophosphoric acid
Detector	: PDA
Column temperature	: Ambient
Type of elution	: Isocratic
Wavelength	: 254 nm
Injection volume	: 20µl
Run time	: 10min

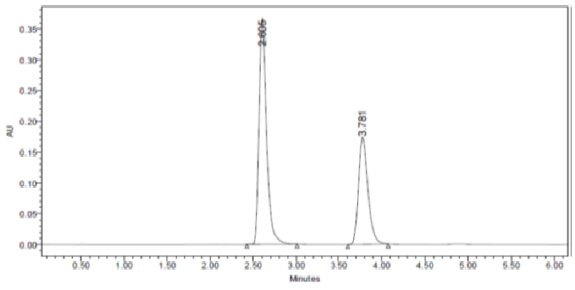


Fig 3: Optimized Chromatogram

Standard Solution Preparation:

Accurately weigh and transfer 10 mg of Carbidopa and Olanzapine 10mg of working standard into a 10mL& 100ml clean dry volumetric flask add about 7mL of Diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution). Further pipette 3ml& 0.3ml of the above stock solutions into a 10ml volumetric flask and dilute up to the mark with diluent.

Sample Solution Preparation:

Accurately weigh 10 tablets crush in mortor and pestle and transfer equivalent to 10 mg of Carbidopa and Olanzapine (marketed formulation) sample into a 10mL clean dry volumetric flask add about 7mL of Diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent.

Method Validation

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

3. Results and Discussion

Table1: Results of system suitability parameters for Carbidopa and Olanzapine

S.No	Name	Retention time(min)	Area (µV sec)	Height (µV)	USP resolution	USP tailing	USP plate count
1	Carbidopa	2.5	124505	213642	6 0	1.2	4673.4
2	Olanzapine	3.9	1308495	154566		1.3	6090.3

Table 2: Results of method precision for Carbidopa

Injection	Area
Injection-1	1302729
Injection-2	1302947
Injection-3	1303236
Injection-4	1303977
Injection-5	1309759
Average	1304529.8
Standard Deviation	2961.1
%RSD	0.2

Table 3: Results of method precession for Olanzapine

Injection	Area
Injection-1	123149
Injection-2	123766
Injection-3	124271
Injection-4	124691
Injection-5	124956
Average	124162.7
Standard Deviation	725.6
%RSD	0.6

Table 4: Results of Intermediate precision for Carbidopa

Injection	Area
Injection-1	1300148
Injection-2	1304520
Injection-3	1305937
Injection-4	1306476
Injection-5	130871
Average	1305070.2
Standard Deviation	3061.8
%RSD	0.2

Table 5: Results of Intermediate precision for Olanzapine

Injection	Area
Injection-1	122487
Injection-2	122626
Injection-3	122632
Injection-4	122702
Injection-5	122962
Average	122681.8
Standard Deviation	174.8
%RSD	0.1

Table 6: Accuracy (recovery) data for Carbidopa

%Concentration (at specification Level)	Area	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	656659.5	5.0	5.036	100.7%	99.84%
100%	1304258	10.0	10.003	100.0%	
150%	1854608	14.4	14.224	98.780%	

Table 7: Accuracy (recovery) data for Olanzapine

%Concentration (at specification Level)	Area	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	65800	5.3	5.34	100.8%	100.51%

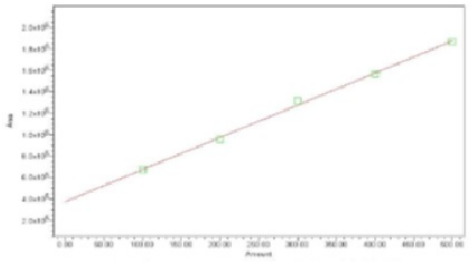
100%	124353	10	10.10	100.01%	
150%	177940	14.2	14.45	99.68%	

Table 8: Area of different concentration of Carbidopa

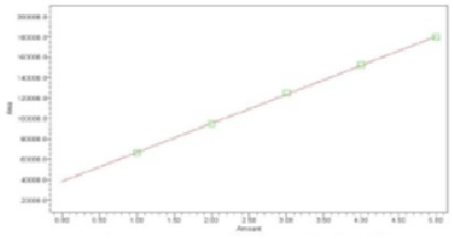
S.No.	Linearity Level	Concentration	Area
1	I	100ppm	668934
2	II	200ppm	956781
3	III	300ppm	1313873
4	IV	400ppm	1563458
5	V	500ppm	1867084
Correlation Coefficient			0.999

Table 9: Area of different concentration of Olanzapine

S.No	Linearity Level	Concentration	Area
1	I	1ppm	66510
2	II	2ppm	94701
3	III	3ppm	124802
4	IV	4ppm	152731
5	V	5ppm	179732
Correlation Coefficient			0.999



Calibration graph for Carbidopa



Calibration graph for Olanzapine

Fig 4: Calibration graphs

Table 11: Analytical performance parameters of Carbidopa and Olanzapine

Parameters	Carbidopa	Olanzapine
Slope (m)	66574	12529
Intercept (c)	53592	50245
Correlation coefficient (R^2)	0.999	0.999

Table 11: Results of LOD

Drug name	Baseline noise(µV)	Signal obtained (µV)	S/N ratio
Carbidopa	52	152	2.9
Olanzapine	52	156	3

Table 12: Results of LOQ

Drug name	Baseline noise(µV)	Signal obtained (µV)	S/N ratio
Carbidopa	52	522	10.03
Olanzapine	52	524	10.1

Table 13: Flow Rate (ml/min) data for Carbidopa

S. No	Flow Rate (ml/min)	System Suitability Results	
		USP Plate Count	USP Tailing
1	0.6	5339.9	1.4
2	0.8	4673.4	1.3
3	1.0	5216.0	1.4

Table 14: Flow rate (ml/min) data for Olanzapine

S. No	Flow Rate	System Suitability Results

	(ml/min)	USP Plate Count	USP Tailing
1	0.8	7063.3	1.3
2	1.0	6090.3	1.2
3	1.2	6998.0	1.3

Table 15: Change in Organic Composition in the Mobile Phase for Carbidopa

S.No	Change in Organic Composition in the Mobile Phase	System Suitability Results	
		USP Plate Count	USP Tailing
1	10% less	4508.4	1.3
2	*Actual	4673.4	1.4
3	10% more	4318.1	1.3

Table 16: Change in Organic Composition in the Mobile Phase for Olanzapine

S.No	Change in Organic Composition in the Mobile Phase	System Suitability Results	
		USP Plate Count	USP Tailing
1	10% less	6387.7	1.2
2	*Actual	6090.3	1.2
3	10% more	6232.5	1.2

4. Conclusion

The developed method is simple, precise and rapid, making it suitable for estimation of Carbidopa and Olanzapine in bulk and tablet dosage form.

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