



Coetaneous Determination of Coartem Drug Products by Chromatography Technique

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(Received: 05 December 2025

Revised: 15 January 2026

Accepted: 10 February 2026)

KEYWORDS

acetonitrile,
Artemether,
isocratic,
Lumefantrin
e; phosphate
buffer;HPLC

ABSTRACT:

This abstract illustrate an precise, isocratic RP-HPLC strategy have been created by thecreator for the concurrent estimation of coartem in unadulterated andadvertised details by utilizing Inertsil C16 column (250×4.6 mm, 5μ) improved mobile phasecontaining phosphate buffer(pH 5.5) and acetonitrile in the extent of 45:55 %v/v andDiscoverywavelength at 218nm. The retention times were 2.207min and 3.733min forcoartem respectively. The linearity range was found to be 10-30μg/ml for artemether and 20-60μg/ml for lumefantrine individually. The developed method wasValidated for specificity, system suitability, precision, linearity, accuracy, Limit of Detection,Limit of Quantification, robustness, and Stability and the examine results acquired for all theapproval parameters by this proposed strategy were in reasonable concurrence with ICHstandards. Thus, the developed RP-HPLC method represents another good alternative for thealready existing HPLC methods especially those using certain types of detectors which aren't present in most of the laboratories.

Objectives: The current chromatographic division be performed on Shimadzu LC20-AT Liquid chromatography outfitted with SPD-20A noticeable quality UV-unmistakable detector and Spinchrom programming and reversed-phase column [Inertsil ODS 3V C18(250x4.6mm,5μ) as the stationary phase. Thermo Electron Corporation twofold shaft UV-noticeable spectrophotometer (Vision ace programming), Ultrasonic cleaner, Shimadzu scientific equalization AY-220 and Vaccum smaller scale filtration unit with 0.45μ layer channel was utilized in the present investigation. Elico pH meter (Hyderabad, India) LI 120 model be intended for pH estimations. All dilutions were performed in standard class-A, volumetric glassare..

Methods: The created RP-HPLC strategy was approved as per ICHguidelines utilizing the accompanying specifications.

Results

In outline, another basic, exact, precise, isocratic RP-HPLC strategy have been created by the creator for the concurrent estimation of Coartem in unadulterated and advertised details by utilizing improved mobile phase containing poly phosphate buffer(pH 5.5) and Ethane nitrile in the extent of 45:55 %v/v and discovery wavelength at 216nm. In the present measure the versatile stage arrangement was simple and the solvents utilized were of minimal effort making the technique increasingly affordable. The examine results acquired for all the approval parameters by this proposed strategy were in reasonable concurrence with ICH standards and consequently, it is



presumed this created RP-HPLC technique can be advantageously utilized in eventual fate of these medications and it additionally can be embraced as elective strategy in future for pharmacokinetic contemplates and bio analytical tests of these two medications in joined measurement plans.

1. Introduction

Artemether, (**Fig.7.01**) is an antimalarial specialist used to treat intense uncomplicated malaria. The system of activity includes collaboration of the peroxide-containing drug with heme, a hemoglobin debasement side-effect, got from proteolysis of hemoglobin.

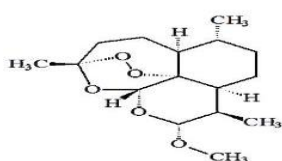


Fig.7.01: Chemical structure of Artemether

Lumefantrine, (**Fig.7.02**) is an antimalarial specialist used to treat intense uncomplicated jungle fever. Accessible information recommended that lumefantrine restrains the improvement of β -hematin by complexing with hemin, hinders nucleic acid and protein combination

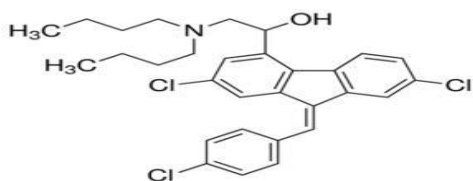


Fig.7.02: Chemical structure of artemether

A combination of these two drugs is accessible in the neighborhood drug store in the brand name of Combither oral Tablets [Artemether 20 mg and lumefantrine 120 mg] showed for the treatment of intense uncomplicated jungle fever brought about by plasmodium falciparum, incorporating intestinal sickness procured in chloroquine-safe areas. Not very many HPLC strategies were accounted for the assurance of coartem in combination structures [68-73]. Basing on this understanding it made fundamental to build up another RP-HPLC technique designed for habitual investigation of the above-said drugs in consolidated

details, and during this agreement endeavors were made by the creator to create basic, exact, precise RP-HPLC strategy intended for the concurrent test of the titled drugs.

2. Objectives

Liquid chromatography outfitted with SPD-20A noticeable quality UV-unmistakable detector and Spinchrom programming and reversed-phase column [Inertsil ODS 3V C18(250x4.6mm,5 μ) as the stationary phase. Thermo Electron Corporation twofold shaft UV-noticeable spectrophotometer (Vision ace programming), Ultrasonic cleaner, Shimadzu scientific equalization AY-220 and Vaccum smaller scale filtration unit with 0.45 μ layer channel was utilized in the present investigation. Elico pH meter (Hyderabad, India) LI 120 model be intended for pH estimations. All dilutions were performed in standard class-A, volumetric glassware.

Chemicals and Reagents: Pharmaceutically marked unadulterated example of coartem were gotten from Lincoln pharma, Private Limited, as talented examples and business medication coartem in the trade name ARH-L oral Tablets [Artemether 20mg and lumefantrine 120mg] were obtained from the neighborhood drug store. Milli-Q water, Ethanenitrile (HPLC Grade), poly phosphoric acid

Preparation of Mobile Phase: The mobile phase utilized in the present measure comprises of blended phosphate buffer (pH: 5.5) and Ethane nitrile in the proportion of 55:45 %v/v]. The mobile phase was refined through 0.55- μ m layer channel and degassed before use.

Buffer Preparation: Weigh precisely about 4.08gms of monobasic potassium phosphate (30mM) and 3.48gms of dibasic potassium and phosphate ions (20mM) and break up in 1000ml of HPLC Grade water at that point modify the pH: 6.8 with poly phosphoric acid and separated through a 0.45 μ layer channel.

Diluent Preparation: Mobile phase is frayed as diluent in the current examine.



Preparation of stock & working standard solutions:

Standard stock arrangements of the present considered drugs were set up by weighing precisely 10mg of artemether and 20mg of lumefantrine were moved into a spotless and dry 100ml volumetric flask. To this flask, around 70 ml of diluent was included and sonicated for five minutes. Afterward, the volume of the flask was made up to the imprint with a similar diluent [Concentrations 100µg/ml for artemether and 200µg/ml, for lumefantrine].

From the above-arranged stock arrangement pipette out appropriate aliquots into a perfect and dry 10ml volumetric flask, the diluent be indicated the imprint to obtain a last convergence of 10 - 30µg/ml for artemether and 10 - 30µg/ml, for lumefantrine separately.

Arrangement of sample solution: Ten oral tablets of ARH-L [Artemether 20mg and lumefantrine 120mg] obtained from the neighborhood dispensary were powdered to a fine powder. At that point test arrangement was set up by gauging and moving comparably 100mg of the fine powder of definition blend into a 100ml spotless and dry volumetric jar containing

70ml of diluent and sonicated to break down it totally and the volume made sufficient with a similar solvent. From the above-arranged stock arrangement pipette out aliquots of the above arrangement and moved into a spotless and distinctive dry 10ml volumetric carafes, the diluent was indicated the imprint 10ml to acquire a last convergence of 10-30µg/ml for coartem, separately.

20µL volumes of the standard and test arrangements be infused multiple times and the peak territories be documented. The mean and %RSD was determined from the peak zones.

3. Methods

System Suitability: System appropriateness specifications like the quantity of hypothetical plates, HETP and peak tailing were resolved for both the drugs with the projected technique and the outcomes were organized in **Table.7.01**. All the framework reasonableness parameters for created strategy for coartem were inside the acknowledgment criteria.

Table.7.01. System appropriateness of coartem

Parameters	Artemether	Lumefantrine
No. of theoretical plates	3330	5076
Tailing factor	1.36	1.219
Area	2022.473	5681.631
Retention Time	2.207	3.733

2. Specificity:

i. Blank and Placebo Interference: Particularity of the proposed strategy is set up via infusing blank and placebo utilizing the above chromatographic conditions. The chromatograms of blank and placebo arrangement demonstrated no peaks at the maintenance time of the artemether and lumefantrine peak uncovering that the diluent and placebo arrangement utilized in test readiness doesn't meddle in the estimation of Coartem in tablets.

3. Linearity & Detector Response: The linearity be completed by plotting and computing straight relapse investigation for the standard bends of Coartem [Figs.7.04 and 7.05] individually. Two standard bends were acquired in the fixation scope of 10-30µg/ml for artemether and 20-60µg/ml for lumefantrine individually [Table.7.02]. The incline and capture an incentive for the alignment bend was $y = 65.02x + 861.206$ ($r^2 = 0.9952$) for artemether and $y = 176.7x + 2370.2$ ($r^2 = 0.9956$) for lumefantrine individually. From the information acquired it is uncovered that a great relationship subsists amid response aspect and centralization of referred drugs inside the focus extend showed as above separately.

The LOD esteems for artemether and lumefantrine were seen as 0.0428µg/mL and 0.0940µg/mL, separately and the LOQ esteems for artemether and lumefantrine be



seen as 0.1429 µg/mL and 0.3138 µg/mL individually uncovering great affectability of the proposed strategy [Table.7.03

Recovery Level	Artemether			
	Amount Added		Amount Found	%Recovery
	Standard	Test		
50%	0	5	14.99	99.98
100%	0	5	25.03	100.02
150%	0	5	34.97	99.96
Mean Recovery *& %RSD	99.98% with %RSD-0.0304%			
Recovery Level	Lumefantrine			
	Amount Added		Amount Found	%Recovery
	Standard	Test		
50%	0	5	14.98	99.97
100%	0	5	24.97	99.97
150%	0	5	34.94	99.96
Mean Recovery *& %RSD	99.96% with %RSD-0.00504%			

*Average of three determinations

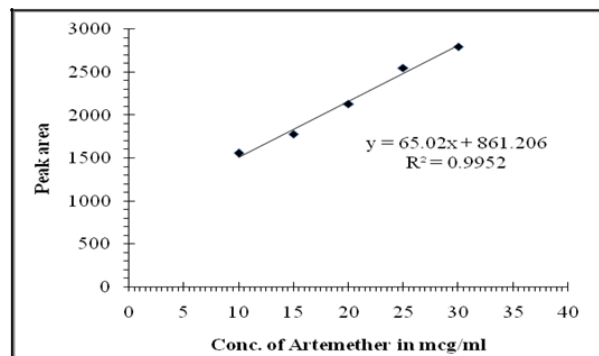


Fig.7.04. Calibration curve of Artemether

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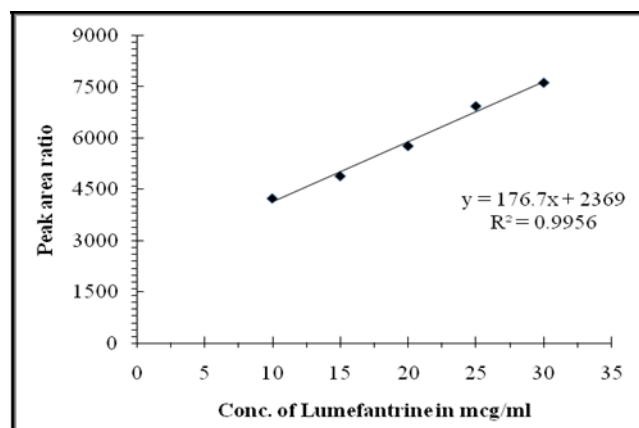


Fig.7.05. Calibration curve of Artemether

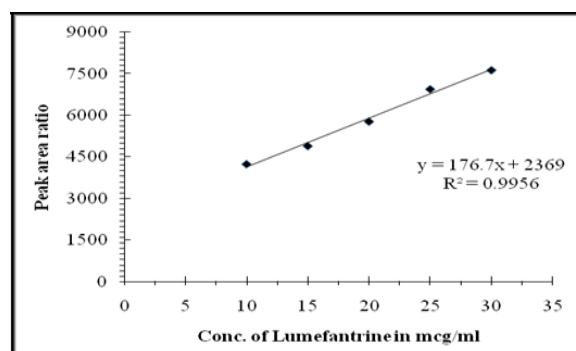


Table.7.02: Results of linearity of Coartem

Artemether		Lumefantrine	
µg/mL	Peak Area Ratio	µg/mL	Peak Area Ratio



10	1554.875	10	4245.29
15	1779.9	15	4900.04
20	2129.471	20	5782.059
25	2547.47	25	6951.37
30	2796.682	30	7637.418
Slope, b	65.02	Slope, b	176.7
Intercept, a	861.206	Intercept, a	2370.2
Correlation, r^2	0.9952	Correlation, r^2	0.9956

Table.7.03: LOD & LOQ values of Coartem

	Artemether	Lumefantrine
LOD($\mu\text{g/mL}$)	0.0428	0.142
LOQ($\mu\text{g/mL}$)	0.094	0.313

4.Precision:The exactness of the created technique was assessed via doing intra-day investigation by infusing six reproduce infusions of 100% test centralization of the cited drugs and the outcomes be communicated considering standard deviation and %RSD.. From the outcomes (Table.7.04) [%RSD of 0.377 and 1.77 for artemether and 0.299&1.198 for lumefantrine] it was uncovered that the created technique was seen as exact, individually

Table.7.04. Results of precision of ofartemether and lumefantrine

	Artemether		Lumefantrine	
	Rt	Peak Area	t	Peak Area
Sample 1	2.213	2051.034	3.74	5660.339
Sample 2	2.19	2018.034	3.71	5659.607
Sample 3	2.21	2069.94	3.733	5787.091
Sample 4	2.203	2079.924	3.727	5820.721
Sample 5	2.21	2076.366	3.74	5721.721
Sample 6	2.203	2129.41	3.733	5782.059
%Mean*	2.204	2070.785	3.73	5738.59
SD*	0.008	36.67	0.0111	68.95
%RSD*	0.377	1.77	0.299	1.198

*Average of six determinations

5.Accurateness:The truthfulness of the technique be resolved at three fixation levels(50,100 and 150%) via recuperation tries, were completed in triplicate arrangements on composite mix gathered from 10 tablets of Coartem, dissected according to the proposed strategy. The rate recuperations ran from 99.96-100.02% for artemether and 99.96-99.97% for lumefantrine individually. From the information announced in Table.7.05, uncovered that the created RP-HPLC strategy was seen as exact for Coartem examine.

Sample No.	Peak Area	
	Artemether 20mg	Lumefantrine 120mg
1	99.98	99.99



2	99.95	99.98
3	99.89	99.97
AVG*	99.94	99.98
SD*	0.04	0.01
%RSD*	0.04	0.01

Table.7.05: Outcomes of accuracy of Coartem

6. Robustness Studies: The vigor investigation of the created measure technique for **Coartem** were set up in the referenced fluctuation conditions (± 2 units change in stream rate and discovery wavelength). Measure estimation of the test planning arrangement was not influenced and it was as per that of real. Framework reasonableness parameters were additionally discovered palatable; subsequently, the scientific strategy would be closed as hearty **Table.7.06**.

7. Solution stability study: The solidness learns at 100% test convergence of the revealed drugs in mobile phase be completed for 24hrs at 35°C. From the above examinations, the analytes were consistent in the versatile stage for 24hrs, indicating the steadfastness of assessment in the projected approach, **Table.7.07**.

Chromatographic parameters	Changed value	Retention time		Tailing factor	
		TM	LF T	A TM	LF T
Flow Rate (± 0.2 ml/min)	0.8 mL/Min	.93	4.907	1.44	1.308
	1.2 mL/Min	.78	2.98	1.368	1.185

Wavelength (± 2.0 nm)	216nm	.223	3.71	1.36	1.219
	220nm	.203	3.207	1.409	1.219

Table.7.07. Stability testimonials of Coartem

8. Examination of marketed formulation:

Analysis of promoted tablets {Combither oraltabls [Artemether 20 mg and lumefantrine 120mg]} was done utilizing the above thought improved HPLC stipulations. % RSD acquired by means of the projected strategy intended for artemether and lumefantrine be seen as 99.94 and 99.98%, individually, **Table.7.08**

Table.7.08. Results for analysis in formulations of Coartem

Medicines	% Appraisal at 0 hr	% Appraisal at 24 hr	% Deviation
Artemether	99.4	99.94	0.99
Lumefantrine	99.91	99.98	0.99

*Average of six determinations

4. Results

HPLC technique advancement: In the improvement of the technique for the chose drugs, various trial preliminaries were made by changing the columns, mobile phase piece, stream rate, temperature, and recognition wavelength.

At first, ponderers were made by choosing a suitable column. For this reason, the creator utilized X-land C16 (250x4.6) mm, 5 μ , Inspire C16 (250x4.6) mm, 5 μ , and Inertsil ODS 3V C16 (250x4.6) mm, 5 μ columns. Out of these the HPLC column, Inertsil ODS 3V C16 (250x4.6) mm, 5 μ was chosen for the present



investigation as it gave the peaks with better gaussian shape for the three drugs.

To advance the shape and width of the peaks for the mentioned column a reasonable mobile phase was inspected utilizing mobile phase blends of various extremities. Different combinations of mobile phases were screened and at long last, the mobile phase comprising of Phosphate buffer changed in accordance with pH 5.5 and acetonitrile in the proportion of 40:60 %v/v was favored as it gave symmetric peaks of coartem separately. The best affectability and selectivity were gotten by online wavelength exchanging at 218nm, which permitted the examination of these two drugs in a solitary run as the isosbestic purpose of coartem were seen as 216nm.

Further, the stream rates somewhere in the range of 0.5 and 1.5ml/min are considered. A stream pace of 1.0 ml/min gave an ideal sign to clamor proportion with a sensible partition time of coartem individually.

In any case, at long last the Inertsil C16 column (250×4.6 mm, 5μ) with a stream pace of 1.0mL/min of mobile phase and UV discovery at a wavelength of 218nm and encompassing column temperature through mobile phase of phosphate buffer changed in accordance with pH 4.5 and acetonitrile in the proportion of 40:60 %v/v brought about brilliant elution of the two drugs by way of low maintenance and run times. A similar buffer was utilized as a diluent for standard and test arrangements. By means of the developed provisions, the chromatogram of the referred to drugs [coartem] were settled with maintenance times (2.207min and 3.733min for coartem individually) and hypothetical plates and great goals separately

Discussion

In outline, another basic, exact, precise, isocratic RP-HPLC strategy have been created by the creator for the concurrent estimation of Coartem in unadulterated and advertised details by utilizing improved mobile phase containing poly phosphate buffer(pH 5.5) and Ethane nitrile in the extent of 45:55 %v/v and discovery wavelength at 216nm. In the present measure the versatile stage arrangement was simple and the solvents utilized were of minimal effort making the technique increasingly affordable. The

examine results acquired for all the approval parameters by this proposed strategy were in reasonable concurrence with ICH standards and consequently, it is presumed this created RP-HPLC technique can be advantageously utilized in eventual fate of these medications and it additionally can be embraced as elective strategy in future for pharmacokinetic contemplates and bio analytical tests of these two medications in joined measurement plans.

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