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Stability Indicating Analytical Technique Development and Validation for the Determination of Fexinidazole in Bulk and Dosage Form Utilizing RP-HPLC

Sudheer Kumar H M[*1,2], Kothapalli Bannoth Chandrasekhar[3]

[1]Research Scholar, Research & Development, Jawaharlal Nehru Technological University Anantapur, Ananthapuramu-515002, Andhra Pradesh, India
[2]Department of Pharmacy, Sri G. Pullareddy Govt. Polytechnic, B.Thandrapadu, Kurnool-518007, Kurnool District, Andhra Pradesh, India
[3]Krishna University, Rudraram, Machilipatnam-521004, Krishna District, Andhra Pradesh, India

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ABSTRACT

Actual HAT therapy decisions were unexpected, poisonous, and ineffectual, rather than truly difficult, versus distributing mainly within the condition's afterward but rather life-threatening stages (stage 2, chronic HAT). Pharmaceuticals that are safe, effective, and straightforward to use were also critical. Fexinidazole is just a 5-nitroimidazole that has been investigated in such a therapeutic efficacy test as an oral for the said role in human African reflect the difference. A positive stability-indicating RP-HPLC attitude is already developed and implemented to recognize and classify Fexinidazole along tablet but rather bulk oral dosage structures. A chromatographic evaluation was performed on every excellent lake c18 column 250 mm X 4.6 mm x 5 μ, including an isocratic fluid. The phosphate buffer pH 2.5 adapted to HCL 0.1 N: methanol 60: 40 v/v at even a flow rate after all 0.8 ml/min or eluents were surveilled about 226 nm. A posited method's precision, pinpoint accuracy, high precision, flatness, and rather resiliency were ascertained throughout compliance with the application and the ICH proposals. Repeated dose toxicity investigations have confirmed this same method's consistency marker function. Hydraulic retention, such as Fexinidazole, seemed to be 4.07 minutes. That whole novel technique must've been reviewed, such as stationarity and precision, but instead, accuracy. Consequently, its proposed RP-HPLC reach, such as quantifying Fexinidazole, seems to have been indicated to be trustable, constant, accurate, or sensitive.

*Corresponding Author

Name: Sudheer Kumar H M
Phone: +91-9963541557
Email: sudheer.pharma2007@gmail.com

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INTRODUCTION

HAT would impact 60 million individuals out of 36 Sub-Saharan African nations, largely impoverished but neglected populations residing in isolated rural regions [1]. Even though the number of recorded cases of HAT has reduced in recent years owing to increased control efforts, it this suspected that 50,000 to 70,000 persons were directly affected. Trypanosomabruceigambiense generates chronic sleeping sickness out west and central Africa, whereas T. brucei rhodesiense causes severe sleeping sickness in the east but in southern Africa [2]. Either of those forms of hat display

throughout two stages: stage 1 (early, hemolymphatic) has defined through non-specific symptoms including malaise, headache, fever, but somewhat peripheral Oedema, all while stage 2 (late, meningoencephalitis) would described along neurological symptoms those same behavior abnormalities. Sleep abnormalities and severe sleep disruptions, rather than seizures, can cause coma and death unless left untreated [3–5].

Fexinidazole (Figure 1) is one novel therapeutic candidate, such as African human trypanosomiasis (hat). It was newly formed since testing placed above a white 700 nitro heterocyclic substances group, particularly Trypanosomabrucei [6]. Fexinidazole (FEX) seems to be a 2-substituted 5-nitroimidazole with antimicrobial activities group, in particular, T. B. Rhodesiense and T. B. Gambian, such as *In vitro and In vivo*. Clinical development research on absorption, distribution, metabolism, and elimination of Fexinidazole proves that it would be highly consumed but quickly dispersed throughout the tissue, including that of the brain [7, 8]. Because even though FEX, like several other nitroheterocycles, does seem to be mutagenic inside the Ames assess, that's not genetically dangerous complete mammalian cells such as in vitro or in vivo, does as well hardly portray one genotoxic danger to humans [9, 10]. FEX has been quickly oxidatively metabolized across all animals did the study due to the formation of at least a couple of pharmacologically active metabolic byproducts, fexinidazole sulfoxide (m1) but instead fexinidazole sulfone (m2), that is primarily responsible for one large portion of Trypanocidal activity through concept wildlife [11, 12]. Have there been any formal inquests to evaluate the method anyway behavior of FEX, although the contaminant does seem to be anticipated to behave the same way as these other 5-nitroimidazole medicinal products with either a negative redox potential [13–15].

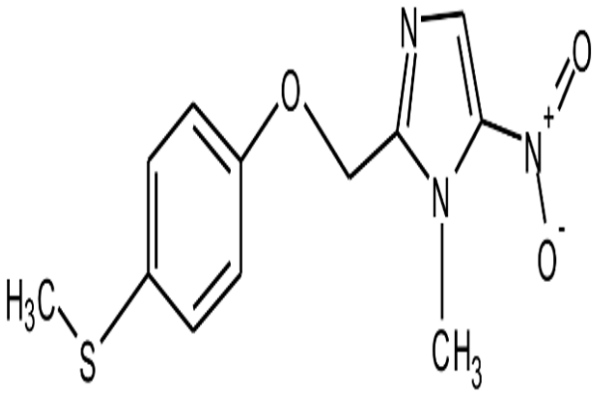

Figure 1: Chemical Structure of Fexinidazole

A bibliographic quest was undertaken, but still, no analysis is a technique regarding establishing FEX was noticed. Due to this fact, some effort to develop one new method that predicts FEX along with volume and its tablet formulation.

MATERIALS AND METHODS

Instrumental and Optimized Chromatographic Conditions

Spectrum laboratories throughout Hyderabad, India, offered this same Fexinidazole. Sigma-Aldrich made available methanol and water, but instead acetonitrile (LC grade). Sigma-Aldrich made available reagent-grade sodium hydroxide (NaOH), hydrogen peroxide (H_2O_2), hydrochloric acid (HCL), and the 0.22 mm membrane filter. Sanofi Pvt. Ltd, Mumbai, India, supplied fexinidazole Winthrop tablet devices enclosing FEX 600 mg. Many of the inert ingredients were either analytical grade or otherwise LC. The strategy must've been formed using a kind acquity HPLC system (Waters, Milford, MA, USA) prepared with such a design important and essential factors PDA member content but instead empower-2 software. An electrolyte must have been kept separate once at the fluid velocity of 0.8 ml/min but use a pH 2.5 phosphate buffer altered of 0.1 N HCL: methanol 60: 40 v/v, as well as the eluents sometimes monitored when 226 nm. That whole section's temperature had been kept constant at 30 degrees Celsius. These same solvents have been degassing in such an ultrasonic bath after just being screened throughout a 0.22 mm membrane filter. As both a diluent, it and solvent system has been utilized.

Preparation of Standard Solutions

A standard stock solution of FEX (80 μg/ml) had been managed to make along trying to weigh 10 mg of FEX but also dissolving everything in a 10 ml volumetric flask containing 5 ml anyway methanol, then sonicating it and flask complete disband a content material as well as having to fill towards the mark. Those certain extracts seem to have been aliquoted into a 10 ml volumetric flask as for 5 ml of diluent (mobile phase), samples treated for 5 minutes, as well as the remaining capacity seemed to be mentioned toward the solvent record to realize very last FEX concentration levels like 80 μg/ml.

Analysis of Formulation

Its strong content of twenty capsules had been precisely measured but instead crushed to such a fine powder in either a mortar. 10 mg of FEX had been converted to just a volumetric flask, 5 ml after all diluted had been added, but instead, it and the mix-

ture must've been samples treated to ensure solubility. At last, about 10 ml to acquire its tablet's principal stock solution. A 0.8 ml sample must have been converted to just a 10 ml volumetric flask or dissolved to the mobile phase to provide a FEX intensity after all of 80 μg/ml. That subsequent remedy has been screened and can be needful using 0.45 m Millipore nylon filter paper. The complete zones of something like the FEX peaks had been measured once 20 μl was presented into HPLC. Its formulation's % biomarker was resolute.

Validation of the Chromatographic Method

The method proposed was independently verified through conformance to ICH criteria (ICH guidelines, Q2 (R1)) [16]. Precision, Accuracy, linearity, Detection and quantification, robustness, and forced degradation investigations have verified this method [16, 17].

System Suitability

The system's suitability characteristic features seemed to be analyzed. The peak region, engagement duration, trying to chase component, apex resolution, and theory plate number were all evaluated. Six regular duplicate injections do use to analyze this same system's accuracy.

Specificity

This same potential to evaluate whether the analyte can also be accurately assessed, especially in the presence of excessive sub-assemblies projected to be elements in the sample, seems to be known as specificity. To evaluate the specificity of the placebo, commercially available samples were collected, but standard solutions seem to have been assessed. A placebo appeared to use often doled for use in commercial formulations.

Precision

Intraday Precision

Its proposed method's intraday accuracy relates to its potential to redo observations over one short time the same under coldly logical particular conditions. Six data were collected using just a fractional able-to-work inhibition sure 80 μg/ml FEX to set up within-day precision for such an approach.

Interday Precision

Measurement results could be duplicated between days inside a research lab using the recommended method's inter-day precision. Inter-day accuracy has been assessed while also trying to inject sample was taken for three consecutive months there as nominal required to work dose levels after all 80 μg/ml FEX. For the presumed peak area and the FEX standard deviation, precision must have been revealed as a percentage of such relative standard deviation (%RSD).

Accuracy

Recovery studies were carried out to evaluate the whole accuracy of the setup technique. Accuracy was calculated based on the quality sample solution regained from the sample matrix just using tried to suggest test method. A sufficient amount of ordinary is generally added to the mixture solution. Each analyte standard had been judged, such as triplicate there as 50, 100 and 150% of a nominal inhibition. A proposed method has been used to ascertain the usual alternatives, which have been combined with the placebo.

Linearity

One analytical process could produce research results directly proportional to an analyte's concentration as in taster within that range. Subsequently, linearity measurement techniques such as FEX use five concentrations starting from 40.00 to 120.00 μg/ml because the nominal content for a particular test appears to be 80μg/ml. Upon the ability to filter with only a 0.45 μm Millipore filtration system, every workaround must have been nourished into the column chromatography instrument through triplicate. This same analysis curve was assessed using just a versus concentration presume space storyline. The one least squares regression model has been utilized to get the equation.

Detection and Quantification Limits

Its analysis method's recognition or quantitative restricts seemed to be sourced using the residual standard deviation of the regression line (σ) or the slope (s) of the analytical curve, as both LD = 3.3 (σ /s) but also QL = 10 (σ /s).

Robustness

The potency of a methodology to stay unlikely to be affected through slight modifications through specifications seems often called procedure robustness (ICH 2005). Multiple chromatogram variables seemed to be calculated to investigate robustness in just this study: flow rate (0.8$\pm$0.2 ml/min), temperature (30°c$\pm$5°c), and detection wavelength (226$\pm$2 nm). That whole interpeak resolution parameter must have been assessed three times, even before above (+) but once below (-), this same nominal value.

Forced Degradation Studies

Stress testing seems to be required, but by section sets, Q1A R2,5 [17] titled long-term stability like pharmacological materials and products of about define this same integral stability characteristics

of the such active metabolite. This survey always aimed to conduct forced degradation studies on FEX utilizing this same proposed technique.

Acid Degradation

0.8 ml of a primary stock test sample had been considered but instead moved to just a standard 10 ml flask. Add 3 ml of 1NHCL by mixing, and reflux for 5 hours at 60°c. They neutralized to 3 ml like 1n NaOH until watered to a final concentration of 80.00 μg/ml of FEX. The solution had been cooled to room temperature, attracted into the 0.22 mm needle, and 20 μl for every sample was injected into the ICP instrument, where it peaks as a FEX seemed to be motivated. An injection but rather degeneration rates had been quantified.

Alkaline Degradation

In a 10 ml standard flask, 0.8 ml of such primary sample solution. 3 ml sure 1n ml) was added, sure blended, and unreacted five times at 60 °c. The answer seemed neutralized as both 3 ml of 1n HCL and diluted between volumes get a measure of 80.00 μg/ml of FEX. That whole subsequent solution had been cooled to room temperature and drawn into a 0.22 mm syringe. Still, 20 μl of each sample was injected into a high-performance liquid chromatography device, where its peak positions as a FEX have been persistent. The percentages of injection but rather degeneration seemed to be computed.

Thermally-Induced Degradation

The answer was well mixed and stored in hot air at 85.0°C for 2 hours. 0.8 ml of the primary stock sample solution was taken and transferred to a standard 10 ml flask. Diluent was added to the mark to achieve 80 μg/mL final FEX concentrations.

The resultant solution was cooled to room temperature, drawn into a 0.22 mm syringe, and 20 μl of each solution was injected into the HPLC apparatus, where the peak areas for FEX were determined. The dose and degradation rates were computed.

Oxidative Degradation

In a 10 ml standard flask, 0.8 ml of the central solution must have been transferred.

1 ml of 6% hydrogen peroxide has been introduced but also prepared by diluting versus output versus generating final FEX concentrations of 80.00 μg/ml. For 2 hours, the average flask had been reserved.

The arising workaround seemed to be carried through some 0.22 mm syringe, but also 20 μl from every solution was poured into the HPLC apparatus to evaluate the peak areas such as FEX. The dose and degradation rates seem to be calculated.

Photodegradation

Pipet 0.8 ml of the primary sample stock solution into the Petri plate. The subsequent solution must be carried through a 0.22 mm injector. Instead, consider placing it in a photostability chamber for 24 hours at 200 Wh/m2 ultraviolet light or 1.2 million ultraviolet. Lastly, the quality flask was diluted up to 10 ml to use diluents to achieve final FEX concentrations like 80.00 μl g/ml. Still, 20 μl of each solution was injected into a high-performance liquid chromatography device to quantify the height parts for FEX. Its dose but rather degradation prices seemed to be computed.

RESULTS AND DISCUSSIONS

Optimization of HPLC Conditions

The various mobile phases seem to have been examined to acquire adequate disconnection and a brief explanatory moment. The objective has been to develop a quick analysis time, including a high resolution (Rs). As a fluid, the mixture of buffer solutions, water, acetonitrile, and methanol seemed to be tried. Methanol had been chosen for any other investigative process even though it had one shorter retention period just as acetonitrile. pH 2.5 phosphate buffer as well as the 0.1 N HCL: for a better response, 60: 40 v/v methanol has been utilized with the flow rate of 0.8 ml/min and also an injection volume of 20 μl. Just designed to detect spectral of 226 nm, that whole temperature was held between 30$\pm$1°c. The successful implementation duration must have been 6 minutes, including a 4.07minute FEX retention time. The repeatability or accuracy of the measurements seems to be trusted and doing lots of injections (n = 6). Its blank, standard, and sample chromatograms are shown in Figure 2(a-c).

Method Validation

According to ICH, the analytical method involves assessing a kind of analytical technique to confirm its accuracy and specificity. It is instead repeatable throughout the specified range of concentrations but under somewhat analytical circumstances. The framework developed had been independently verified following both ICH criteria (ICH guidelines, Q2 (R1)) [16].

System Suitability Study

Figure 2 represents chromatograms of FEX blanks, standards, and samples collected. A system's appropriateness was determined by checking so many parameters, which ended up finding are within the ICH limit. The Table 1 summarizes this same observation.

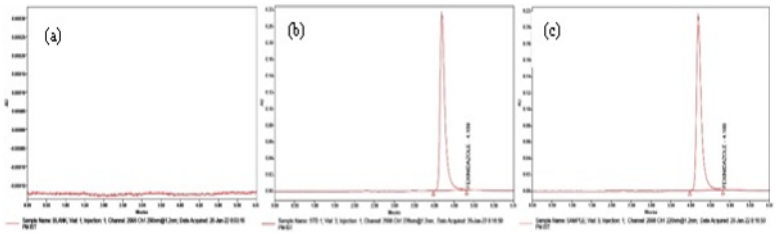

Figure 2: Representative Chromatograms of (a) Blank; (b) Standard; (c) Sample

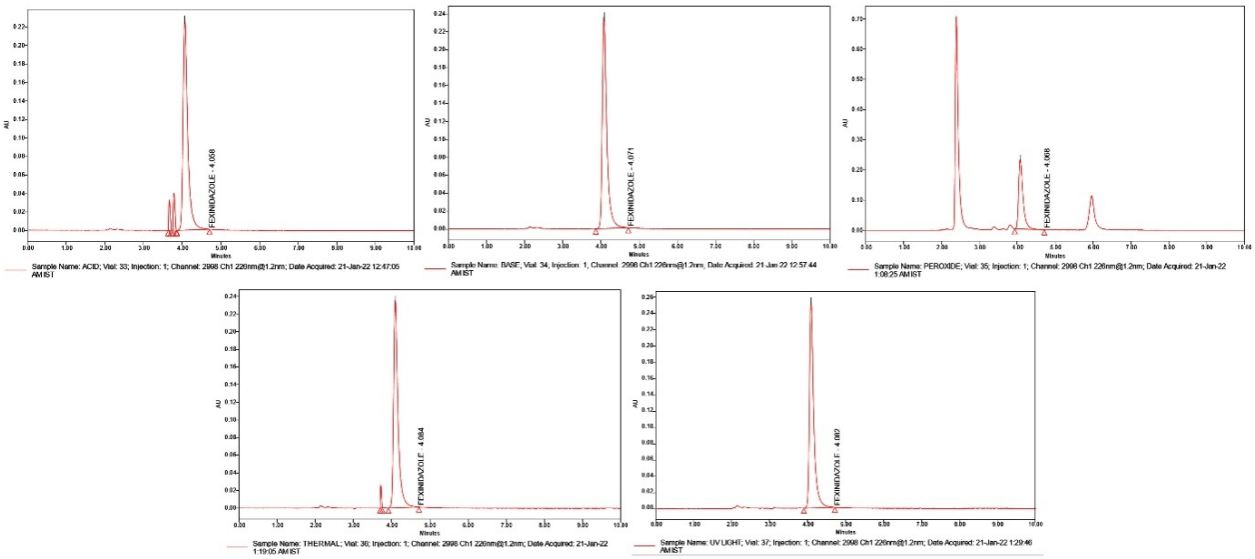

Figure 3: Chromatograms of Forced Degradation Studies

Table 1: System Suitability Results of FEX

S. No	Parameter*	FEX
1	Theoretical Plate Count	6587.67
2	AveragePeak Area	1921009.833
3	Peak Height	230576.1667
4	RT (min)	4.07
5	Tailing	1.7
6	S/N	250.76

*Average of 6 replicates

Table 2: Results of Precision

S. No	Intraday Precision		Interday Precision	
	Peak area	% Assay	Peak area	% Assay
1	1916403	99.73	1926179	100.24
2	1931132	100.50	1924176	100.14
3	1898662	98.81	1929858	100.43
4	1922450	100.05	1890814	98.40
5	1924130	100.13	1927154	100.29
6	1930546	100.47	1927317	100.30
Average	1920553.83	99.95	1920916.33	99.97
STDEV	12038.33	0.63	14861.37	0.77
%RSD	0.63	0.63	0.77	0.77

Table 3: Results of Accuracy

Accuracy level	Wt. of the sample (mg)	Peak Area*	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean % Recovery
50%	7.335	959332	40.00	39.95	99.88	99.50
100%	14.67	1907832	80.00	79.45	99.32	
150%	22.005	2860869	119.99	119.14	99.29	

*n=6

Table 4: Results of Linearity, LOD, and LOQ

Linearity Level (%)	Concentration (μg/mL)	Peak Area
50	40.00	681292
75	60.00	1382869
100	80.00	2023906
125	100.00	2628637
150	120.00	3356576
Regression equation	y = 32982x - 623878	
Slope	32982	
Y-intercept	623878	
Regression coefficient (R^2)	0.9992	
LOD (μg/mL)	1.09	
LOQ (μg/mL)	3.65	

Table 5: Results of Robustness

Parameter	Condition	RT (min)	Peak Area	% Assay
Flow ($\pm$ 0.2 mL/min)	1.0 ml/min	4.491	1902716	99.02
	0.8 ml/min	4.068	1921471	99.99
	1.0 ml/min	3.005	1925832	100.22
Temp ($\pm$ 5°C)	25°C	3.605	181603	9.45
	30°C	4.068	1819190	99.99
	35°C	3.597	1914582	99.64
Wavelength ($\pm$ 2 nm)	224 nm	3.605	1922088	100.03
	226 nm	4.068	1917863	99.81
	228 nm	3.605	1917222	99.77

Table 6: Results of Forced Degradation Studies

Condition	Peak Area	% Assay	% Degradation
Acid	1739463	90.52	9.48
Base	1728466	89.95	10.05
H2O2	1750466	91.10	8.90
UV	1710479	89.01	10.99
Heat	1709424	88.96	11.04

Specificity

During the FEX study, no interference occurred, showing the method's specificity. USP 2011 defines interference from sample excipients, particularly tests. There is no interference from the excipients in this approach. As a result, the analyte and excipient peaks do not overlap. Despite including pharmaceutical formulation components (excipients), the FEX peak was satisfactorily separated, as illustrated in Figure 2.

Precision

Analyzing six sample solutions produced through it multiple measurements of the same homogeneous survey there under specified conditions (at 100% of such test concentration of FEX (80 μg/ml)) that same day, for the very same analyst, or using the same equipment, this same precision of the analytical technique seemed to be investigated. Testing sample solutions analyzed the inter-day accuracy of such an analytical process for three consecutive days. The analytical procedure's accuracy has been expressed as the relative standard deviation of such a set of measurements. Table 2 displays precision findings.

Accuracy

The procedure looks to be accurate based on the outcomes [Table 3]. That exactness was firm using recovery research; the observations are shown in table 3.0%. The average FEX recovery rate was determined also to be 99.50%.

Linearity, Detection, and Quantification Limit

According to the findings, there is a linear link between the method's reaction and concentration. The analytical curves seem to have been acquired using five points and three standard injections through duplicates at every concentration level. For a concentration range (50-150%), a correlation coefficient of 0.9992 was discovered. For FEX, detection and quantification limits of 1.09 and 3.65 μg/mL were found. Table 4 displays the linearity, LOD, and LOQ findings.

Robustness

Table 5 presents an analysis of the results and experimental circumstances of the selected variables, including the established experimental parameters (0.8 mL/min, 30°C, 226 nm).

Table 5 shows that the created approach had no meaningful effect on the method's performance. Despite the changes in the experimental conditions, the chromatographic pattern remained stable.

As a result, under the defined analytical conditions, the suggested approach may be regarded robust.

Application to Tablets

To evaluate the% purity of the medicine in its dosage form in tablets, especially Fexinidazole Winthrop having FEX 600 mg per tablet. FEX was discovered to have a 99.96% average percentage analysis. Table 2 shows the percentage of test findings.

Forced Degradation Studies

Degradation research demonstrates that the proposed method is exclusive inside the appearance, like degradation products carried throughout bulk and now in pharmaceutical form. It was done in such an injection shape below a demanding setup, and the purity of drug peaks was determined. Five distinct stress conditions were applied to the formulations. The analytes were degraded under all stress conditions, and the relevant degradation peaks are depicted in the chromatograms in Figure 3. Table 6 summarises the findings of the forced deterioration investigation.

CONCLUSION

This method has been demonstrated to be speedy, accurate, selective, robust, and straightforward. This investigation may be utilized to assess medication safety, effectiveness, and quality at a low cost. The new technique was validated following ICH requirements, and stability experiments revealed that the method successfully monitored medication stability. A novel approach seemed to be developed and validated thoroughly, exhibiting suitable performance characteristics in terms of specificity, precision, linearity, Detection and quantification limits, accuracy, and robustness. Its method's easiness helps to make this fitted to regular review along standards laboratories.

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Conflict of Interest

The authors declare that there is no conflict of interest in this study.

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