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Research Article

Quality by Design (QbD) Method for Concurrent Evaluation of Azelnidipine and Telmisartan Using UPLC and Stability Indicating Studies

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ABSTRACT

Chromatographic techniques to estimate concentrations of Telmisartan and Azelnidipine tablet dosage forms following ICH guidelines. QbD is used in the development of UPLC method. By using design expert software chromatographic settings were optimized. There was (4.6 X 250 mm, 5 μ m) Inertsil ODS column, mobile phase ratio (70: 30) buffer: acetonitrile, pH 3 of phosphate buffer. Flow rate is one ml/min, wavelength: 225 nanometers, Injection volume: 10-micron litres, Run time: 8 minutes. Telmisartan & Azelnidipine, the corresponding percentage relative standard deviation of precision is 0.7 and 0.1. Telmisartan and Azelnidipine accuracy means recovery of 99.59 & 100.01 respectively and linearity correlation coefficients of 0.999 of telmisartan and azelnidipine their LOQ and LOD were determined to be 10 and 3 respectively. Degradation studies of acid, base, peroxide, thermal and photo are 7.71, 7.74, 7.69, 7.81, and 7.87, respectively. Azelnidipine and Telmisartan levels were measured using an approved UPLC-QbD technique. Using ICH guidelines, this method evaluated the system's suitability, durability, linearity, sensitivity, specificity, accuracy, and precision.

INTRODUCTION

According to the Quality by Design theory, instead of evaluating analysis based on results, quality should be incorporated into the process. HPLC uses complex mobile phase systems, systems with a high retention period and limited sensitivity, or systems with more than two solvents. Therefore, a

QbD strategy has been used to build a new UPLC method. Using the (QbD) Quality by Design technique, the development stage should consider analytical process quality into consideration¹. A QbD is a methodical approach that focuses on products and process expertise, quality risk management, and process control, all backed by reliable research. A QbD is a methodical method

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of developing a technique that prioritizes quality risk management, product and process expertise, and process control supported by trustworthy research².

The experimental target profile (ATP), as well as key method characteristics (CMA) crucial method attributes, that is, peak area, retention time, symmetric factor, tailing factor, plate count, and resolution between adjacent peaks, are included in the design (DOE)³. Even though many methods based on the QbD principle have been published, there are no definite guidelines for creating QbD-based analytical procedures. Analytical approaches utilized QbD to accomplish various objectives, such as technique creation, optimization robustness studies, etc⁴. Recently, concept of QbD has grown in importance when creating analytical methods using the design of the experiments (DOE). Therefore, a novel UPLC method utilizing a QbD methodology has been developed to estimate Telmisartan and Azelnidipine in tablet dose forms⁵. Telmisartan lowers blood pressure (hypertension). Heart attacks, strokes, and kidney issues are all reduced by lowering blood pressure. The drugs known as angiotensin receptor blockers include Telmisartan (ARBs). It operates by widening blood arteries to facilitate easier blood flow⁶ Telmisartan has a molecular mass of 514.6 and the chemical formula C₃₃H₃₀N₄O₂. Its melting point ranges from 261°C to 263°C. In the pH range of 3 to 9, water is largely insoluble, and strong acids are weakly soluble (except for hydrochloric acid). They are used to treat hypertension alone or in combination with other antihypertensive.

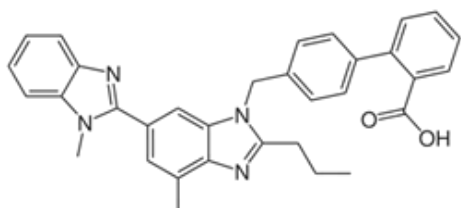


FIGURE: 01 Structure of Telmisartan

The class of drugs known as anti-hypertensive medicines includes Azelnidipine. Azelnidipine blocks Ca²⁺ from entering the vascular walls of voltage-dependent smooth muscle channels. Channel Ca²⁺ can be divided into numerous sub-channels of L, T, N, P, Q, and R. Calcium channel L-type promotes the contraction of smooth muscle, which results in high blood pressure. Smooth muscle walls of the vascular smooth muscle relax and lower blood pressure when calcium channels are closed, preventing the smooth muscle from contracting. azetidin-3-yl 3-[1-(di phenyl methyl)] is the molecular name for Azelnidipine. 2 methyl-5-propan-2-yl amino -1,4-dihydro-4-nitrophenyl-3,5-dicarboxylate of pyridine. Its chemical composition is C₃₃H₃₄N₄O₆ and its molecular weight of it 582.657. It melts at 193°C to 195°C⁸.

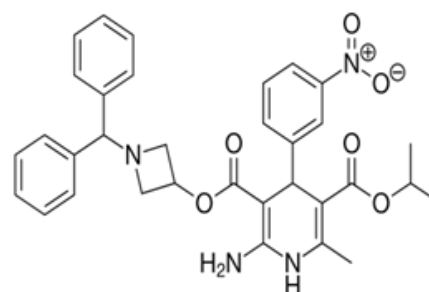


FIGURE: 02 Structure of Azelnidipine

MATERIALS AND METHODS

Software named empower and separation module 2695 is used to merge the data. For sample preparation, tools such as the weighing machine, pH meter, UV Spectrometer, and the Borosil pipettes, burettes, and beakers were employed. Chromatographic condition: Water HPLC was 25 degrees Celsius, autosampler, and a PDA detector. Separation approach: pH 3.0 buffer or phosphate buffer, Inertsil ODS column (4.6*250mm, 5"), Isocratic method 30% ACN, 70% buffer, and a flow rate of one millilitre per minute make up the mobile phase. The utilized wavelength is 225

nanometers. The injection volume is 10-micron litres— 8 minutes total run time.

RESULTS AND DISCUSSION:

Mobile Phase Optimization: Among the early stages of mobile phases studied were Methanol: Phosphate Buffer, Methanol: Ortho Phosphoric Acid Buffer, methanol to acetonitrile of different ratios. Phosphate buffer : acetonitrile (70:30 v/v) is added to mobile phase by maintaing pH 3. Ultraviolet range for Telmisartan 10gram/ml & Azelnidipine 10gram/ml in diluents (components in the mobile phase) was obtained through scanning at 200 to 400-nanometer region. 225 nanometre UV spectrum wavelength was picked.

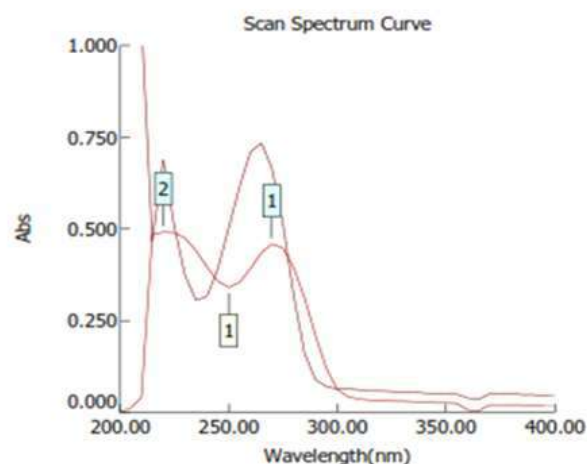


FIGURE: 03 UV Graph

Phosphate buffer preparation: Take 3.4 grams of potassium dihydrogen phosphate and 1000 millilitres of HPLC water. 0.1M NaOH was added to get the pH until 3. After being sonicated for 10 minutes, through membrane filter 0.45 solution was purified.

Mobile phase preparation: Acetonitrile and phosphate buffer in ratio 30% and 70% are combined and kept in vacuum filtered through 0.45inch then filter and kept in 10 minutes in an ultrasonic water bath.

TABLE: 01 Build Information

File Version	13.0.9.0		
Type of Study	Surface response	Subtype	Randomized
Design type	Box-Behnken	Runs	15.00
Model of Design	Quadratic	Blocks	No
Time build (mili sec)	202		

TABLE: 02 Factors

No. of Factors	Name of the factor	Units	Type	Subtype	Min	Max	Coded Low	Coded High	Mean	Std. Dev
A	Mobile Phase Ratio		Numeric	Continuous	-10.00	10.00	-1 ↔ -10.00	+1 ↔ 10.00	0.0000	7.56
B	Flow rate	ml/min	Numeric	Continuous	-0.1000	0.1000	-1 ↔ -0.10	+1 ↔ 0.10	0.0000	0.0756
C	Buffer pH		Numeric	Continuous	-1.0000	1.0000	-1 ↔ -1.00	+1 ↔ 1.00	0.0000	0.7559

TABLE: 03 Responses of drugs

Response of drugs	Name of the parameter	Unit	Observed result	Minimum	Maximum	Mean Deviation	Standard Deviation	Ratio
R1	Retention time of Telmisartan	Min	15.00	0.8	1.8	1.39	0.3091	2.25
R2	Tailing factor of Azelnidipine		15.00	0.9	1.5	1.13	0.1633	1.67

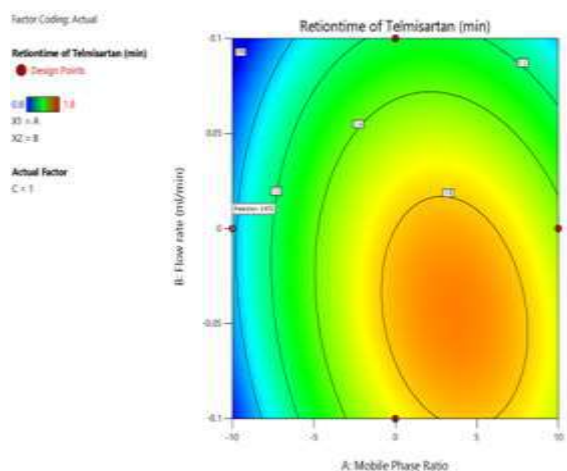


FIGURE: 04 Retention time of Telmisartan

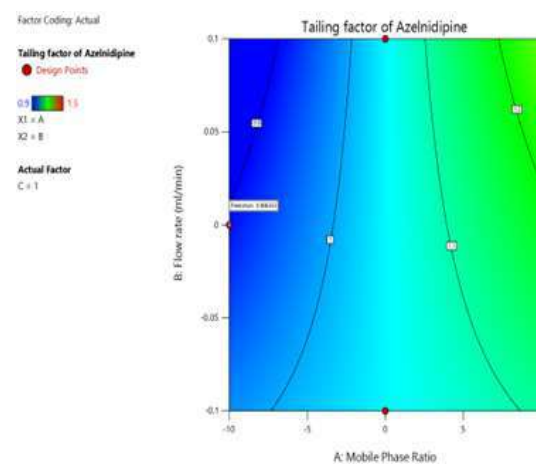


FIGURE: 05 Tailing factor of Azelnidipine

TABLE: 04 Azelnidipine tailing factor responses

Source	Squared sum	Df	Average Square	F-value	p-value	
Model	0.2425	6	0.0404	2.47	0.1179	not significant
Mobile Phase Ratio	0.0013	1	0.0013	0.0764	0.7892	
Flow rate	0.0450	1	0.0450	2.75	0.1357	
C-Buffer pH	0.0612	1	0.0612	3.75	0.0890	
Mobile Phase Ratio, Flow rate	0.0225	1	0.0225	1.38	0.2746	
Mobile Phase Ratio, Buffer pH	0.0900	1	0.0900	5.50	0.0470	
Flow rate, Buffer pH	0.0225	1	0.0225	1.38	0.2746	
Residual	0.1308	8	0.0164			
Lack of Fit	0.1308	6	0.0218			
Error	0.0000	2	0			
Correlation Total	0.3733	14				

TABLE: 05 Telmisartan and Azelnidipine Area summarized

Injection	Telmisartan Area summarized	Azelnidipine Area summarized
1	191345	107339
2	191232	107232
3	191671	107131
4	191999	107399
5	192898	107018
6	194679	107089
Avg	192304.0	107201.3
Stand. Deviation	1308.1	148.4
% Relative standard deviation	0.7	0.1

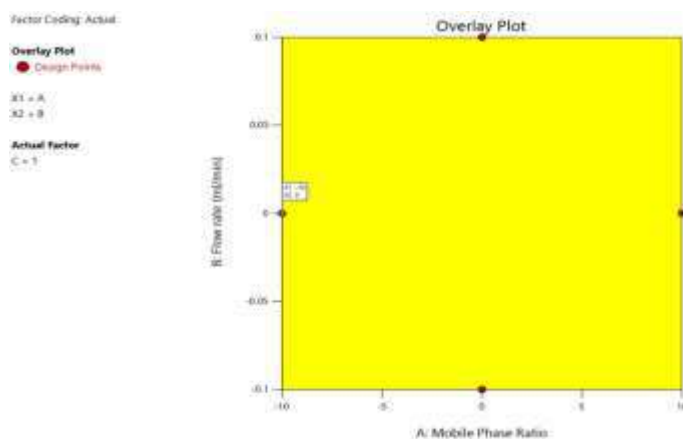


FIGURE: 06 Overlay Plot

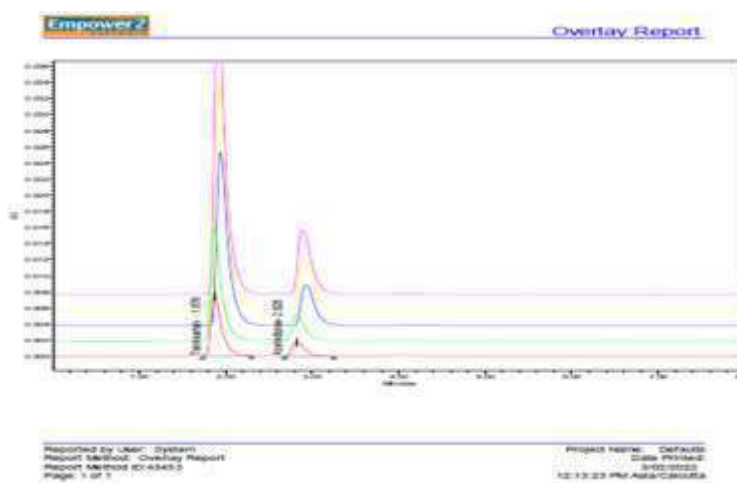


FIGURE: 07 Overlay report

Preparing a Standard Solution: Working standards, properly weigh and add to 10ml volumetric flask, add azelnidipine and telmisartan taken in quantities of 8 mg and 40 mg. 7.0 mL of the diluent should be dissolved ultrasonically, and

the same solvent should be added. (stock response). From stock solution 0.75ml is taken in to 10ml volumetric flask the desirable concentration will be diluted with the required amount of liquid.

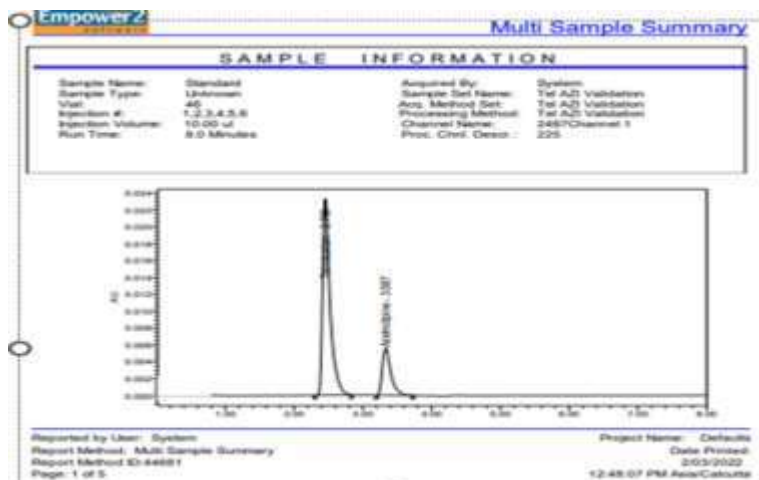


FIGURE: 08 Standard Chromatogram

Preparation of the Sample Solution: Add approximately 7 ml of diluent, the necessary weights of azelnidipine 8mg and telmisartan 40mg tablet powder is taken in volumetric flask (10ml). Mix the solution and then add stock solution to

reach the desired strength. From the stock solutions above, 0.75 ml, should be taken in 10ml volumetric flask. The necessary therefore concentration will be diluted with the required amount of Liquid.

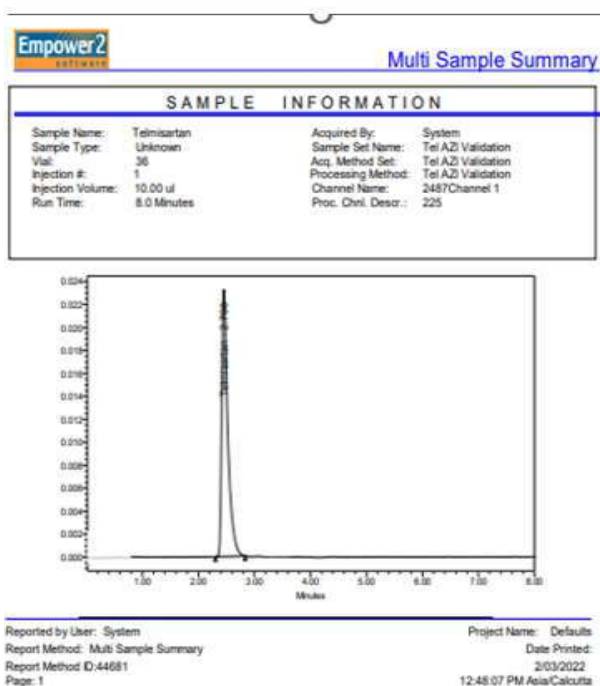


FIGURE: 09 Telmisartan Chromatogram

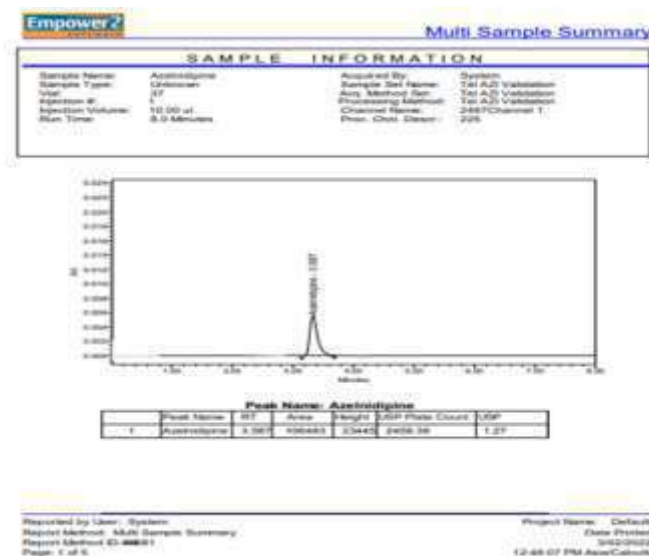


FIGURE: 10 Azelnidipine Chromatogram

PRECISION: Stock solution preparation: Use exact weights to measure and transfer Azelnidipine 8 mg. and Telmisartan 40 mg into a

dry, clean, 10-milliliter volumetric flask as working standards. Add additional of the same solvent to achieve the desired volume. Add 7mL

of the diluent and ultrasonically dissolve it. (Stock remedy) One of the stocks mentioned above, solutions, 0.75 ml, into a volumetric flask that can hold 10 ml of liquid. The desired concentration

will then be diluted with the required amount oLiquid. A maximum of 2% RSD should be present in the results of the region of six standard injections.

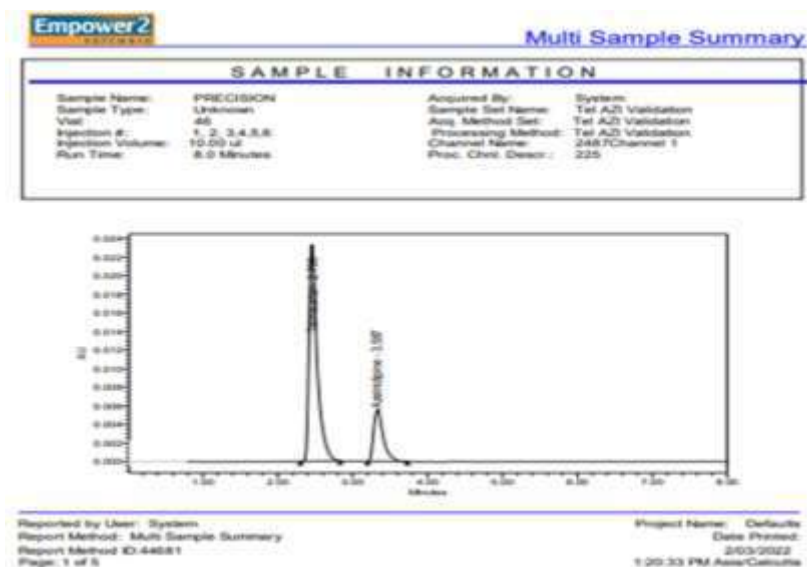


FIGURE: 11 Precision Chromatogram of Telmisartan and Azelnidipine

TABLE: 06 Precision results Telmisartan and Azelnidipine

Injection	Precision area Telmisartan	Precision area Azelnidipine
1	192345	104533
2	192432	104232
3	192971	104531
4	192899	104399
5	192898	104018
6	192333	104689
Ave	192646.3	104400.3
Stand Deviation	305.8	241.9
Percentage Relative Standard Deviation	0.2	0.2

INTERMEDIATE PRECISION/RUGGEDNESS: Precision was used for several days to assess the method's intermediate accuracy (ruggedness).

Preparation of stock solution: Combine 8 milligrams of Azelnidipine & and 40 milligrams of Telmisartan in a 10-milliliter volumetric flask, using accurate weights as working standards. To get the appropriate volume add 7 millilitres of the diluent and ultrasonically dissolve it, after which you can add more of the same solvent. (Stock

reaction). One of the above stocks, solutions, 0.75 ml, should take in 10 ml volumetric flask. Dilute with necessary volume of liquid will be used to get the desired concentration. An RSD of no more than 2% should be present in the region of results from six standard injections.

ACCURACY: Preparation of Standard stock : Take 8mg Azelnidipine & 40mg Telmisartan in 10ml volumetric flask. Reach the necessary volume and add 7 mL diluent and dissolve it. One of the stocks above solutions, 0.75 ml, should be

pipette into a volumetric flask that can hold 10 ml of liquid. The required amount of liquid will next be diluted to the desired level.

Make a 50% solution (Regarding the desired Assay concentration):As working standards, precisely weigh 4mg of Azelnidipine and 20 mg of Telmisartan in 10ml volumetric flask.

Approximately take seven millilitres of the solvent once the diluent dissolves to get the volume to the desired value. (Stock reaction). From the above stock solutions, 0.75 ml, should be pipette into a volumetric flask that can hold 10 ml of liquid. The required amount of liquid will next be diluted to the desired concentration.

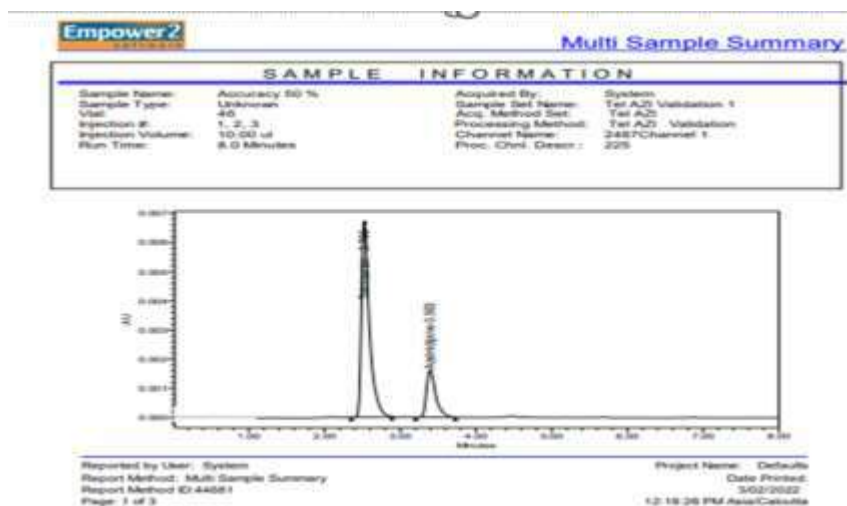


FIGURE: 12 Accuracy 50% chromatogram of Telmisartan and Azelnidipine

In order to make a 100 % solution (Regarding the desired assay concentration)

Working standard, in 10ml volumetric flask, combine Azelnidipine 8 mg and Telmisartan 40mg. Weigh the mixture carefully. To increase the volume up to level, add 7 mL of the diluent,

sonicate it until it is fully dissolved, and then repeat the process. (Stock reaction). From the stock above solutions, 0.75 ml pipette and transfer in 10 ml volumetric flask. The required liquid should be diluted to the appropriate concentration after that.

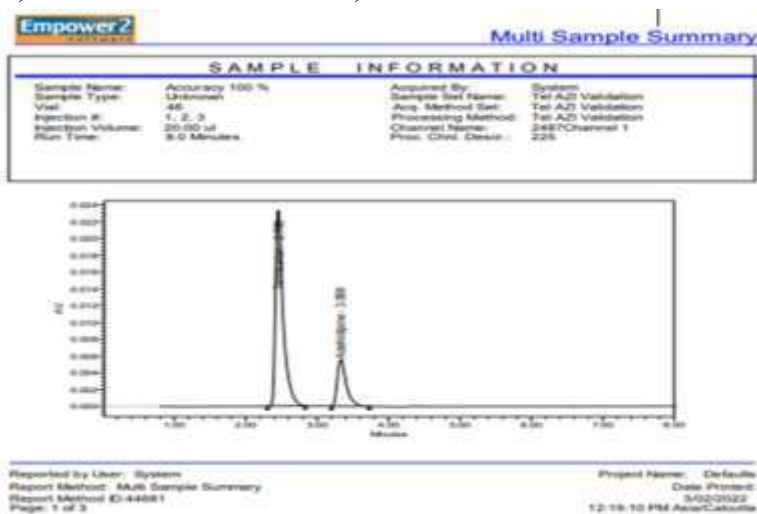


FIGURE: 13 Accuracy 100% chromatogram of Telmisartan and Azelnidipine

In order to make a 150 % solution (Regarding the desired assay concentration): Working standard of 12 mg of Azelnidipine and 60 mg of Telmisartan that has been precisely weighed. Once

the diluent has been thoroughly dissolved, add about 7 mL of it. In volumetric flask (10ml), 1.5ml of stock solution is added and dilute to desired concentration.

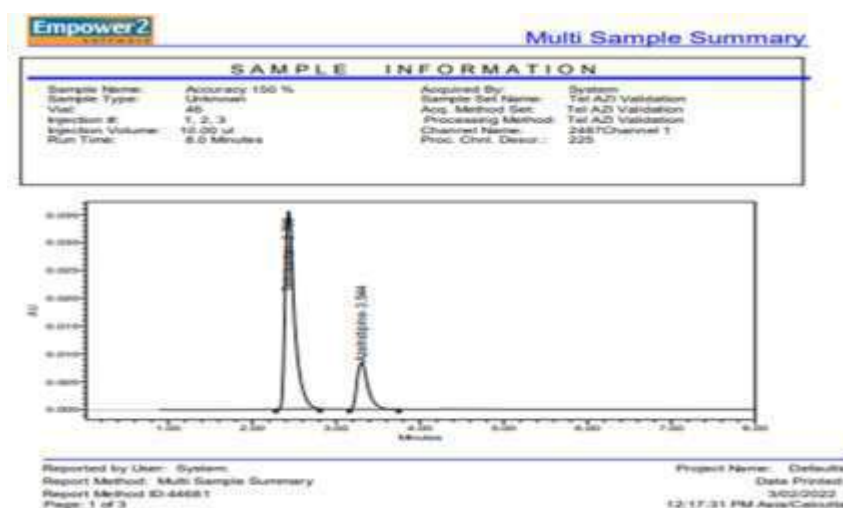


FIGURE: 14 Accuracy 150% chromatogram of Telmisartan and Azelnidipine

TABLE: 07 Telmisartan accuracy results

% Conc (specific Level)	Area	Add Amount (mg)	Found Amount (mg)	Percentage Recovery	Mean Recovery
50%	95505	10	9.97	99.67	99.59
100%	191399	20	19.97	99.87	
150%	285309	30	29.77	99.25	

TABLE: 08 Azelnidipine accuracy results

% Conc (specific Level)	Area	Add Amount (mg)	Found Amount (mg)	Percentage Recovery	Mean Recovery
50 percent	53846	4.05	4.06	100.23	100.01
100percent	107344	8.1	8.09	99.90	
150percent	159676	12.04	12.04	99.89	

LINEARITY: Stock solution preparation: As working standards, take 40 mg of Telmisartan and Azelnidipine 8 mg in 10 volumetric flask. Add 7ml of diluent to achieve desired vol. (Stock reaction)

Preparation of Level – I: To dilute the stock solution, add 0.25 ml to 10 ml in a volumetric flask..

Preparation of Level – II: In 10 ml volumetric flask add 0.5 ml of the stock solution was added.

Preparation of Level – III: By adding 0.75 ml into a volumetric flask with ten million litres of diluent, the stock solution indicated above was diluted to the right concentration.

Preparation of Level – IV: The stock solutions were diluted to the required concentration by addition of 1ml to the volumetric flask (10 ml).

Preparation of Level – V: Put 1.25 milliliters of the stock solution into a 10-milliliter volumetric flask, then use diluents to adjust the concentration.

Procedure: After injecting, measure the peak area after inserting it into the chromatographic device at each level, and plot the concentration versus peak area and the correlation coefficient. (X-axis represents concentration, Y-axis represents peak area)

SYSTEM SUITABILITY: In a standard solution, the peaks brought on by Telmisartan and Azelnidipine should not have a tailing factor of more than 2.0. The resolution in a standard solution peaks for Telmisartan and Azelnidipine should be at least 2.

Calculation:

$$\% \text{ Assay} = \frac{AT}{AS} * \frac{WS}{DS} * \frac{DT}{WT} * \frac{Avg \ weight}{Label \ Claim} * \frac{P}{100} * 100$$

Where: AT stands for average sample preparation area counts.

AS is an acronym for average preparation area counts.

Working standard weight is WS (as measured in milligrams).

P is the percentage standard purity.

TABLE: 09 Linearity results of Telmisartan

Telmisartan	
Conc (microgram/ml)	Area
100	65787
200	131783
300	194311
400	256245
500	317748

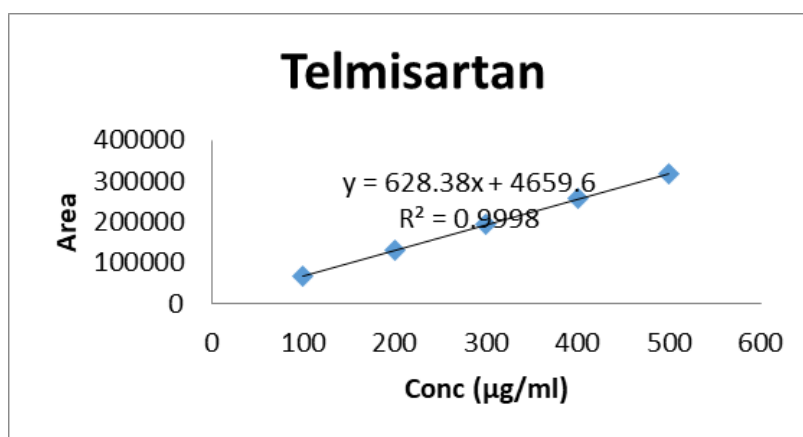


FIGURE: 15 Linearity of Telmisartan

ASSAY RESULTS:(Telmisartan)

$$\frac{191907}{191265} * \frac{20}{10} * \frac{1.5}{10} * \frac{100}{254} * \frac{10}{1.5} * \frac{254.3}{20} * \frac{99.8}{100} * 100 = 100.25\%$$

Label Claim = mg/ml. Working standard weight is WS (as measured in milligrams).

P is the percentage of working standard purity.

CALCULATION: (For Azelnidipine)

$$\% \text{ Assay} = \frac{AT}{AS} * \frac{WS}{DS} * \frac{DT}{WT} * \frac{Average \ weight}{Label \ Claim} * \frac{P}{100} * 100$$

Where; AT is average area counts.

AS is an acronym for average preparation area counts.

TABLE: 10 Linearity results of Azelnidipine

Azelnidipine	
Conc(µg/ml)	Area
20	32441
40	67728
60	100630
80	134448
100	172463

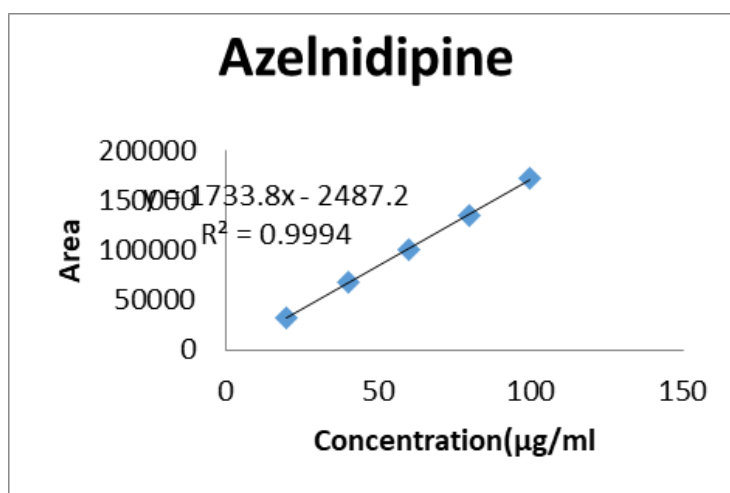


FIGURE: 16 Linearity of Azelnidipine

Results for System Suitability:

1. The standard injection's tailing factor was 1.11.
2. The standard injection yields 2381.56 theoretical plates.
3. The standard injection yields a resolution of 4.42.

sonicated and added to around 7 mL of diluent after being precisely measured and poured in a dry, clean, 10-milliliter volumetric flask. The volume is increased to sufficient level, add more liquid while using the same solvent. 0.75 ml of stock solutions in 10ml volumetric flask increasing the concentration as appropriate. S/N The LOD solution must have a ratio value of 3.

ASSAY RESULTS: (For Azelnidipine)

$$\frac{106240}{107234} * \frac{8.19}{10} * \frac{1.5}{10} * \frac{10}{254} * \frac{10}{1.5} * \frac{254.3}{8.1} * \frac{99.8}{100} * 100 = 98.99\%$$

The correlation coefficient must be at least 0.999 in order to be accepted.

DETECTION LIMIT: LOD:

Prep of 300µg/ml sol: To completely dissolve the 40 mg of Telmisartan working standard, it must be

LIMIT OF DETECTION: (Azelnidipine)

Preparation for 60 microgram/ml solution: Add 7 mL of diluent and 8 mg of Azelnidipine working standard accurately measuring and transfer in volumetric flask (10ml). Continue adding liquid the solvent until the required volume is obtained. Adjust the concentration as appropriate and transfer 0.75 ml of the stock solutions in volumetric flask (10ml) S/N the LOD solution must have a ratio of three.

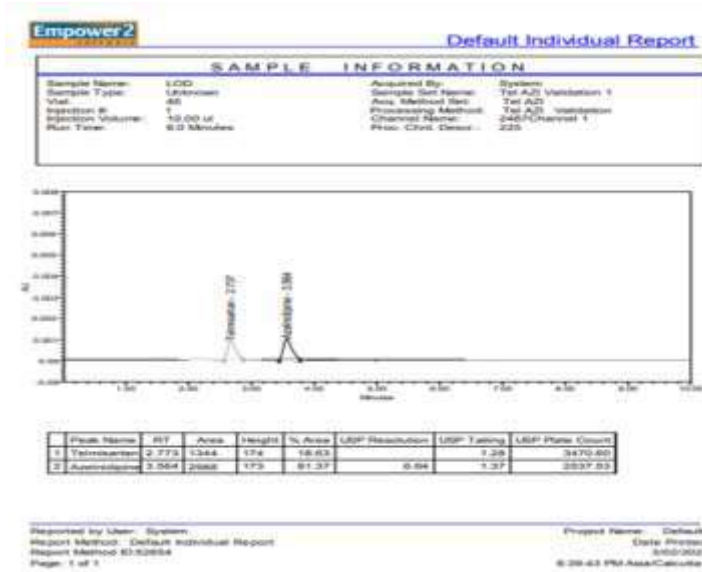


FIGURE: 18 LOD of Telmisartan and Azelnidipine

LIMIT OF QUANTIFICATION:
(Telmisartan)

Preparation of 300 g/ml sol: To completely dissolve 40 mg of Telmisartan working standard, it must be sonicated and added to around 7 mL of diluent after being accurately measured and transfer in 10ml volumetric flask capacity. Volume can be adjusted to the required level. Take 0.75 ml of stock solution in 10ml volumetric flask, add diluents to adjust the concentration (stock reaction). S/N ratio value for LOQ must be 10.

(LOQ) LIMIT OF QUANTIFICATION:
(Azelnidipine)

60 µg/ml solution preparation: In 10 ml volumetric flask, 8 mg of Azelnidipine working standard should be properly measured, and sonicated to completely dissolve the diluent. Continue adding liquid using the same solvent until the required volume is obtained. (Stock reaction)

Preparation for 5.64 µg/ml solution: Fill a 10ml volumetric flask with 0.94 ml of the stock solution. After that dilute with enough liquid to get the required concentration. For the LOQ solution, the S/N Ratio needs to be 10.

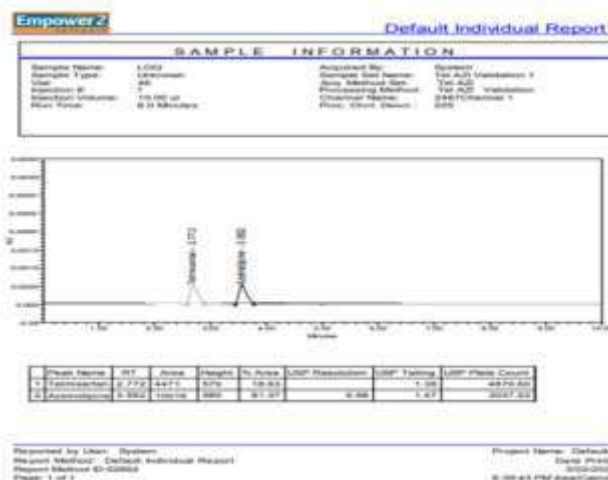


FIGURE: 19 LOQ of Telmisartan and Azelnidipine



ROBUSTNESS: A. Flow rate ranged between 0.9 and 1.1 ml/minutes. Response in addition to the process flow rate, a variety of flow rates were used for the preparation and analysis of 300 ppm of Telmisartan and 60 ppm of Azelnidipine. The fact that the approach still yields accurate results when the flow rate varies by 10% is thus demonstrated

B. Organic composition in the Mobile phase was $\pm 10\%$. Both mobile phase composition and modified mobile phase composition were used in this method to produce and analyse 300ppm Telmisartan and 60 ppm Azelnidipine. According to aforementioned data, the variation is 10 percent.

TABLE: 11 Telmisartan system suitability results

Serial. no	Flow Rate (millilitre/ minutes)	Results of System Suitability	
		USP Plate Count	USP Tailing
1	0.9	3828.18	1.21
2	1	3417.62	1.14
3	1.1	3328.18	1.11

TABLE: 12 Azelnidipine system suitability results

Serial. no	Flow Rate (ml/ minutes)	Results of System Suitability		
		USP Plate Count	USP Tailing	USP Resolution
1	0.9	3213.92	1.23	4.96
2	1	2381.56	1.11	4.42
3	1.1	3415.92	1.21	4.96

TABLE: 13 Telmisartan system suitability results

Serial. no	Change in Organic Composition in the Mobile Phase	System Suitability Results	
		USP Plate Count	USP Tailing
1	10 percentage less	3726.18	1.21
2	Actual	3417.62	1.14
3	10 percentage more	3343.64	1.34

TABLE: 14 Azelnidipine system suitability results

Serial. no	Change in Organic Composition in Mobile Phase	System Suitability Results		
		USP Plate Count	USP Tailing	USP Resolution
1	10% less	3175.92	1.31	4.96
2	*Actual	2381.56	1.11	4.42
3	10% more	34445.92	1.23	4.96

DEGRADATION STUDIES:

According to ICH "stability testing of novel pharmaceutical substances, Stress testing needs to be done to determine component's innate stability characteristics. This research aimed to test if Telmisartan and Azelnidipine would degrade under stress using the provided methods.

Preparation of stock: Use exact weights to weigh and transfer Azelnidipine 8 mg and Telmisartan 40

mg into a 10 ml volumetric flask as working standards. Addition of 7 mL of the diluent, ultrasonically dissolve it to get the right volume, and then add more of stock solution.

Degradation of acid condition: 3ml of 0.1N HCl & 0.75 ml the previously described combination should be added with a pipette in 10 ml volumetric flask and neutralized with 10ml of 0.1 N NaOH .



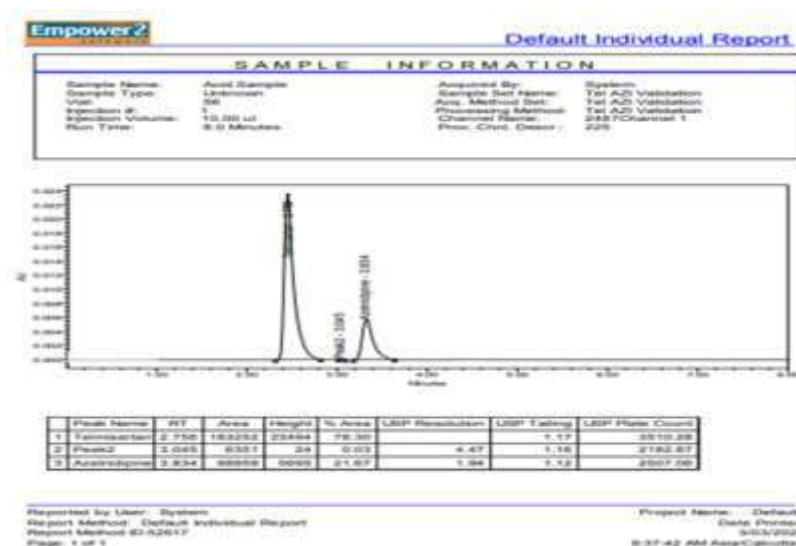


FIGURE: 20 Acid Degradation of Telmisartan and Azelnidipine

Degradation of alkaline condition: In a 10 ml volumetric flask, add 3 ml of 0.1N NaOH to 0.75 ml of stock solution. Pour the filtered sol in vials by using syringe filters with 0.44-micron pore size.

Telmisartan, Azelnidipine are taken in Petri plate for 3 hours at 110⁰ C. The sample is diluted using diluents, and then subjected to UPLC analysis.

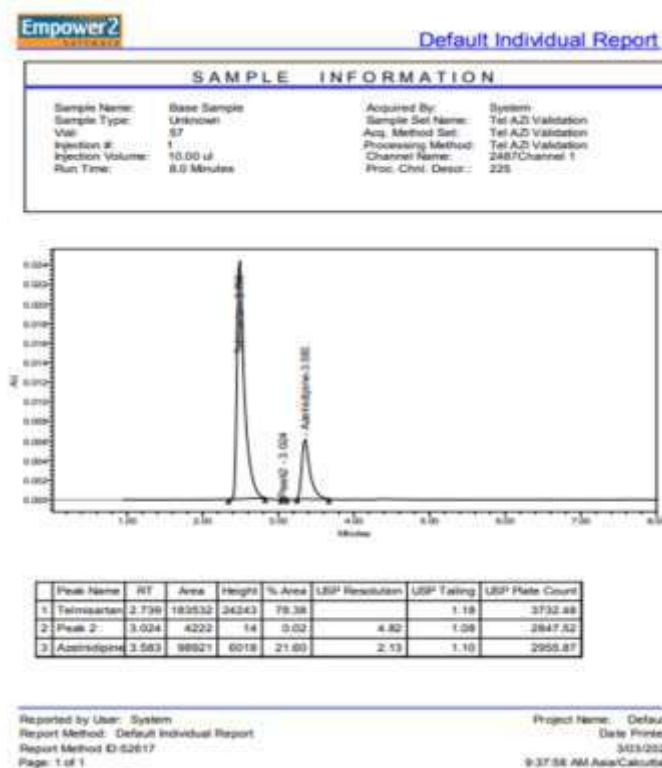


FIGURE: 21 Base Degradation of Telmisartan and Azelnidipine

Oxidative degradation: To the volumetric flask (10 ml), 0.75 ml of the stock solution and 1 ml of 30% H₂O₂ are added. After that, the vol flask kept

at room temp for 15 minutes. filtrated solution after passing it through 0.45-micron syringe filters.

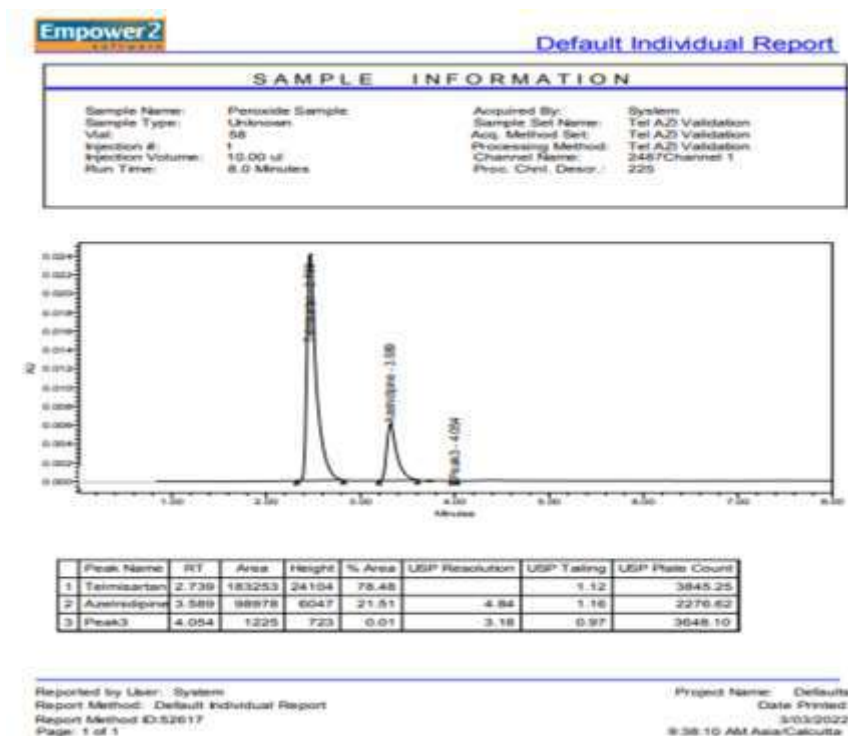


FIGURE: 22 Peroxide Degradation of Telmisartan and Azelnidipine

TABLE: 15 Showing the Results of % Degradation of Telmisartan&Azelnidipine

Sample Name	Telmisartan		Azelnidipine	
	Area	% Degraded	Area	% Degraded
Standard	191642		107223	
Acid degradation	183252	4.38	98959	7.71
Base degradation	183532	4.23	98921	7.74
Peroxide degradation	183253	4.38	98978	7.69
Thermal degradation	187552	2.13	98851	7.81
Photo degradation	186452	2.71	98789	7.87

DISCUSSION:

To estimate Telmisartan and Azelnidipine simultaneously an attempt has been made by using QbD and the obtained results in the above tables and figures indicates to optimize that chromatographic conditions and extend the method to estimate these drugs in UPLC. Optimized chromatographic conditions were finalized by QbD as phosphate buffer and acetonitrile mobile phase ratio 70:30 v/v and pH is maintained at 3. Inertsil ODS column (4.6*250mm, 5") at a wavelength of 225nm was selected which gives good separation with

acceptable values. After finalizing the chromatographic conditions, sample and standard solutions prepared and transfer in UPLC, and values were noted. According to ICH precision values are 0.7 and 0.1, accuracy % recovery range should be between 98% to 102 % the value of accuracy was found to be 99.59 and 100.01%. LOD and LOQ should be less than 3 and 10 respectively, LOD was found to be 2.737 and 3.564 and LOQ was found to be 2.772 and 3.562 for Telmisartan and Azelnidipine respectively. Acid, base, Peroxide, Thermal, and Photo were performed and percentage degradation was found to be 7.71,7.74,7.69, 7.81and 7.87 where there the

degradation is much less and shows the stability of the compounds.

CONCLUSION:

(QbD) is frequently used to develop new pharmaceutical products. It reduces risks and product unpredictability. We measured the levels of Azelnidipine and Telmisartan using UPLC-QbD method. In accordance with ICH standards, this method evaluated the suitability, sensitivity, specificity, accuracy, linearity, precision, and robustness of the system. Thus, the UPLC-QbD-based approach was used for routine tablet dosage form analysis and quality monitoring.

ABBREVIATIONS:

- QbD: Quality by Design
- UPLC: Ultra Performance Liquid Chromatography
- Min: Minutes
- %: Percentage
- ICH: International Conference Harmonization
- ml: Milliliters
- °C : Degree Celsius
- Ppm: Parts Per Minutes
- % RSD: Percentage Relative Standard Deviation
- LOD: Limit of Detection
- LOQ: Limit of Quantification
- µg/ml: micro gram per milliliter
- conc: concentration
- gms: grams
- mg: milligrams
- NaOH: sodium hydroxide
- HPLC: High Performance Liquid Chromatography
- UV: Ultra Violet Spectroscopy
- Nm: nanometer
- DoE: Design of Experiments

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