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Research Article

VALIDATED STABILITY INDICATING HPLC METHOD FOR ESTIMATION OF NARATRIPTAN

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ABSTRACT

This work states validated stability indicating HPLC method for estimation of naratriptan hydrochloride. Chromatographic Analysis was performed using LC-GC Qualisil Gold, C18 (250 X 4.6 mm i.d., 5 µ). Isocratic mode of separation was followed. The linearity range of Naratriptan Hydrochloride was 3-18 µg/ml. The value of correlation coefficient was 0.9990. The % RSD values in the Precision studies were < 2%. This confirmed that the method was sufficiently precise. The accuracy of the method was validated by recovery studies and was found to significant and under specification limits, with % recovery 98.56-101.03. The assay result was found to be 100.68%. The method also passes the specifications for robustness parameters. Limit of detection of naratriptan hydrochloride was found to be 0.0173 µg/ml and Limit of quantification of naratriptan hydrochloride was found to be 0.0572 µg/ml and also other ICH guidelines are validated.

Keywords: Naratriptan, RP-HPC, ICH Guidelines

INTRODUCTION

Naratriptan is chemically referred to as ethane sulfonamide N-methyl-2-3-(1-methylpiperidine-4-yl)-1H-indol-5-yl]. It is a triptan drug used to treat migraine headaches and is a selective agonist of the subtype 5-hydroxytryptamine 1 receptor. It is well absorbed (74%) having high protein binding and is metabolized by a wide range of cytochrome P_{450} iso-enzymes into a number of inactive metabolites and has a 5-8 hour half-life. Among Several methods used for the estimation of Naratriptan HCl spectrophotometry, liquid chromatography – electro spray mass spectrometry, ultra-performance liquid chromatography, micellar electro kinetic capillary chromatography and differential pulse voltammetry, reverse phase high performance widely used to validate ICH guidelines. The purpose of this investigation was to develop a simple, sensitive, selective and reproducible analytical method for the quantitative estimation of drug[1-4].

MATERIALS AND METHODS

Sun Pharmaceuticals Industries Ltd, Ahmednagar, Maharashtra, India has kindly provided Naratriptan hydrochloride API as a donation sample. Dichloromethane, toluene, methanol and triethylamine have been bought from S.D. Mumbai, India, Fine-Chem Limited. Purchased from the local market Naratriptan hydrochloride tablets produced by Sun Pharma Medication Private Ltd. containing NRT-HCl

Chromatographic conditions

The mobile phase consisted of methanol, water (0.2% tri ethyl amine buffer) in the ratio of 25:75 (adjusted to pH 3 with orthophosphoric acid) and contents of the mobile phase were filtered before use through a 0.45 µ membrane filter and degassed for 15 minutes. The mobile phase was pumped from the solvent reservoir to the column at a flow rate of 1.0 ml/min and the injection volume was 20 µl. The eluents were monitored at 223 nm. The optimization trials were shown in Table 1. The optimized conditions were shown in the Table 2 and Figure 1.

Calibration of standards

Different amounts of inventory alternatives for Naratriptan Hydrochloride were correctly transmitted into 10 ml volumetric flasks and diluted to mark the output variety of 3-18 µg / ml. Six solutions have been prepared and the final volume with mobile phase has been created up to the mark. By plotting the peak area against the drug concentration, the calibration curve was obtained.

Method validation of Naratriptan Hydrochloride

Specificity and selectivity, linearity, LOD, LOQ, accuracy, precision, and robustness of the validation method were performed.[8-12]

Specificity and selectivity

Specificity is a method's capacity to distinguish between the intended analyte(s) and other sample elements. HPLC method selectivity is shown by separating analytes from other potential components such as impurities, degradants, or excipients. Figures 2 and 3 showed the outcomes.

Linearity

Naratriptan hydrochloride has been checked for linearity of calibration curves (peak area Vs concentration) in pure solution

over concentration ranges of about 3-18 µg / ml. There was less than 15 minutes of eluting moment. The regression lines associated with normal drug levels using regression analysis, the calibration curves were linear in the studied range and regression equations were obtained.

$Y = 208317.019x + 301417.467$, $r^2 = 0.9990$ for Naratriptan Hydrochloride.

The mean ± standard deviation (SD) was calculated for the standard curve slope, intercept and correlation coefficient (n = 3). The information is shown in Tables 3, 4 and Figure 4 below.

Precision

Repeatability
The method's precision was assessed by calculating the percentage RSD of peak areas of six standard concentration replicate injections. Naratriptan hydrochloride's average RSD was found to be 0.33%. Table 5 showed the outcomes.

Reproducibility
The RSD of peak areas of eight replicate injections of standard concentrations was calculated. The average RSD of Naratriptan Hydrochloride was found to be 0.30%. The results are shown in Table 6.

Intermediate precision (Intra and Inter-day)
The accuracy demonstrated on separate days of analytical results variability within the same laboratory. The RSD of peak regions of three replicate injections was calculated for three distinct normal levels. Naratriptan hydrochloride's average RSD was discovered to be 0.50 percent for intra-day research. For Inter-day studies the average RSD of Naratriptan Hydrochloride was found to be 0.38%. These results are shown Table 7.

Accuracy

Recovery tests determined the method's accuracy. The drug's reference requirements were added to the formulation at a rate of 80%, 100%, 120%. The recovery studies were conducted three times and the recovery percentage and relative standard deviation of recovery were calculated and shown in Table 8.

% Recovery = (Amount found/Amount added) X 100.

Assay of Naratriptan Hydrochloride

Weighed exactly 10 mg of pure drug Naratriptan Hydrochloride and transferred to a volumetric flask of 10 ml. The quantity was methanol (1000 µg / ml) up to the mark. 1 ml was transmitted to a volumetric flask of 10 ml and the volume was passed to the portable stage mark (100 µg / ml). From the solution above, 0.5 ml was drawn into a volumetric flask of 10 ml and the volume was added to the mark. Under chromatographic circumstances above, the solution was injected, and the maximum region was measured. Triplicate was made of the assay procedure and the weight of the drug used for assay was calculated. The proportion of drug detection, mean and standard deviation was calculated and shown in Table 9 and Figure 5.

Limit of Detection (LOD) and Limit of Quantitation (LOQ)

The Limit of Detection (LOD) and Limit of Quantitation (LOQ) for the procedure were performed on samples containing very low concentrations of analytes under the ICH guidelines. By applying the mathematical formula method, LOD was expressed by establishing the minimum level at which the analyte can be reliably detected. LOQ was considered as the lowest concentration of analyte in standards that can be reproducibly measured with acceptable precision. The LOD and LOQ values for Naratriptan Hydrochloride were shown in the Table 10.

Robustness

The optimum HPLC requirements set for this technique were mildly altered as a means of evaluating the robustness of the technique for samples of Naratriptan hydrochloride dissolved in the drug matrix. The minor changes include flow rate (± 0.1 ml / min), change in mobile phase composition (± 2 ml) and wavelength detection (± 3 nm). The data is shown in Table 11.

System suitability

To evaluate the technique that can produce the outcome of acceptable accuracy and precision, it is described as trials. Following completion of the method development and validation, the system suitability was performed. Five replicate drugs analyze at concentrations of 10 µg / ml of Naratriptan hydrochloride evaluated the suitability of the system and parameters such as plate number (n), tailing.

Forced degradation studies of Naratriptan Hydrochloride

Studies of degradation were conducted in accordance with ICH rules. The aim of this research was to find out the degradation products, which in turn assist in establishing the pathways of degradation and the drug molecule's inherent stability. Degradation experiments were conducted using acidic, alkaline, oxidative, picture and thermal condition to verify the selectivity of the suggested technique.

Procedure for forced degradation studies

To determine, whether the analytical method and assay were stability indicating or not, Naratriptan Hydrochloride API was stressed under various conditions to conduct forced degradation studies. Intentional degradation was attempted to stress conditions of acidic (0.1N HCl, 1N HCl, 1N HCl heated at 60^0C), alkali (0.1N NaOH, 1N NaOH, 1N NaOH heated at 60^0C), oxidative (0.3% H_2O_2, 3% H_2O_2 and 10% H_2O_2), photo (sunlight) and thermal treatment (heated at 105^0C) to evaluate the ability of the proposed method to separate Naratriptan Hydrochloride from its degradation products.

If under the above conditions reasonable degradation has been seen, the test can be stopped at this point. However, the drug should be subjected to greater strengths and longer length in the event of no degradation under the above circumstances. If complete degradation after initial conditions has been observed, the strength of acid / alkali / oxidative resistance may be reduced to with decrease in the reaction temperature.

Acid degradation

Accurately 25 mg of the Naratriptan Hydrochloride pure drug was weighed transferred into 25 ml clean dry volumetric flask. The volume was made up to the mark with 1N HCl and maintained at 60^0C (1000 µg/ml). Periodically (0, 1, 3, 6 hours) 1 ml was taken in to 10 ml volumetric flask and made up to the mark with mobile phase (100 µg/ml). From the above solution 1 ml was taken into 10 ml volumetric flask, add 5 ml of mobile phase and adjust the pH to between 3-4 by adding 1N NaOH, dilute with mobile phase up to the mark (10 µg/ml). The solution was injected under above chromatographic conditions and peak area was measured. The represented data were shown in Table 13.

Alkaline degradation

It is weighed precisely 25 mg of the pure drug Naratriptan Hydrochloride, transferred to 25 ml of clean dry volumetric flask. The volume was built up to the 1N NaOH mark and kept at 600C (1000 µg / ml). In a 10 ml volumetric flask, 1 ml was taken periodically (0, 3, 6, 9 hours) and made up to the mobile phase mark (100 µg / ml). From the above solution 1 ml was taken into 10 ml volumetric flask, add 5 ml of mobile phase and adjust the pH to between 3-4 by adding 1N HCl, dilute with mobile phase up to the mark (10 µg/ml). The solution was injected under above chromatographic conditions and peak area was measured. The represented data were shown in Table 14.

Oxidative degradation

It is weighed precisely 25 mg of the pure drug Naratriptan Hydrochloride, transferred to 25 ml of clean dry volumetric flask. The volume was made up to the mark with 10% H_2O_2 (1000 µg / ml) and the flask was kept aside at room temperature. Periodically (0, 1, 24, 48, 72, 120 hours) 1 ml was taken in 10 ml volumetric flask and made up to the mark with mobile phase (100 µg / ml). 1 ml was taken from the above solution in a volumetric flask of 10 ml and made up to the mobile phase mark (10 µg / ml). Under chromatographic circumstances above, the solution was injected, and the maximum region was measured. Table 15 shows the information represented.

Photo degradation

Accurately weighed 25 mg of the pure drug Naratriptan Hydrochloride transferred to 25 ml of clean dry volumetric flask. The volume with HPLC water (1000 µg / ml) was made up to the mark. The flask was exposed for 6 hours to sunlight. Periodically (0, 1, 3, 6 hours) 1 ml in 10 ml volumetric flask was drawn and made up to the portable stage mark (100 µg / ml). 1 ml was taken from the above solution in a volumetric flask of 10 ml and made up to the mobile phase mark (10 µg / ml). Under chromatographic circumstances above, the solution was injected, and the maximum region was measured. Table 16 and numbers showed the information represented.

Thermal degradation of solid sample at 105^0C

Accurately 300 mg of the Naratriptan Hydrochloride pure drug was weighed, kept in a petri dish and maintained at a temperature of 105^0C in a controlled temperature oven. Periodically (0, 1, 3, 6 hours) 10 mg of sample was weighed, transferred into a 10 ml volumetric flask and made up to the mark with HPLC water (1000 µg/ml). From the above solution 1 ml was taken in 10 ml volumetric flask and made up to the mark with mobile phase (100 µg/ml). Again 1 ml was withdrawn from the above solution and transferred to a 10 ml volumetric flask and made up to the mark with mobile phase (10 µg/ml). The solution was injected under above chromatographic conditions and peak area was measured. The represented data were shown in Table 17.

Results for Development and Validation of RP-HPLC method for the determination of Naratriptan Hydrochloride

Method development and optimization of Naratriptan Hydrochloride

Selection of Wavelength

Wavelength for detection was chosen using a double beam UV-VIS spectrophotometer (Lab India) to obtain absorption spectrum of Naratriptan hydrochloride in water. It demonstrates that the methanol content of Naratriptan hydrochloride is λ_{max} at 223 nm. The same wavelength was used in HPLC method development; where the impurities can also be detected.

Selection of Mobile Phase

Several solvent systems were tried to get good optimized conditions for Naratriptan Hydrochloride.[13-16]

Table 1: Optimization of mobile phase for the determination of Naratriptan Hydrochloride

S. No.	Mobile phase Composition (1.0 ml/min flow rate)	Retention time (R_t) in minutes	Asymmetry	Theoretical plates
1	Methanol: water 50:50	10.680	1.59	502
2	Methanol: water 45:55	12.107	1.02	748
3	Methanol: water (0.2% TEA, pH adjusted to 3.0 with OPA) 50:50	3.313	1.47	6212
4	Methanol: water (0.2% TEA, pH adjusted to 3.0 with OPA) 40:60	4.000	1.35	5394
5	Methanol: water (0.2% TEA, pH adjusted to 3.0 with OPA) 35:65	4.780	1.22	4904
6	Methanol: water (0.2% TEA, pH adjusted to 3.0 with OPA) 30:70	6.240	1.15	5123
7	**Methanol: water (0.2% TEA, pH adjusted to 3.0 with OPA) 25:75**	**9.740**	**1.25**	**8414**

Optimization trials of Naratriptan Hydrochloride

Table 2: Optimized Chromatographic conditions of Naratriptan Hydrochloride

S. No.	Parameter	Optimized Condition
1	Mobile Phase composition	Methanol and water (0.2% TEA, pH 3 with OPA) in the ratio of 25:75
2	Stationary phase	LC-GC Qualisil Gold, C_{18} (250 X 4.6 mm i.d., 5 µ)
3	Flow Rate	1 ml/min
4	Run time	15 min
5	Column temperature	Ambient
6	Volume of injection	20 µl
7	Detection wavelength	223 nm
8	Retention time of the drug	9.740 min

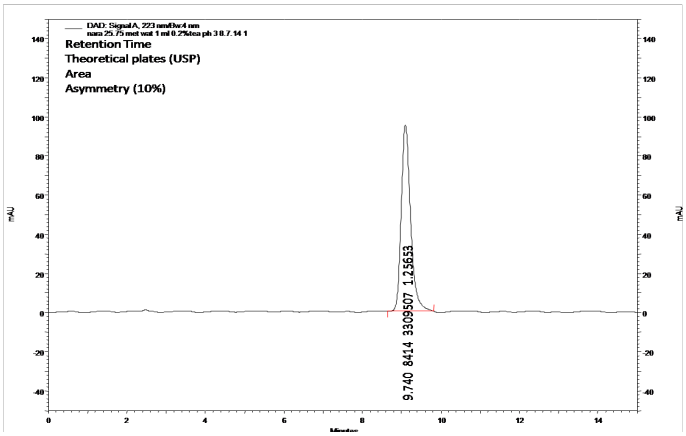

Figure 1: Optimized chromatogram of Naratriptan Hydrochloride

Validation of Naratriptan Hydrochloride

Specificity

Specificity is a method's capacity to discriminate in the sample between the intended analyte(s) and other elements. The HPLC method's specificity is demonstrated by separating the analytes from other potential components such as impurities, degradants or excipients.

Volume of 20 µl of working placebo sample solution was injected into the chromatograph and the chromatogram was recorded and presented below. No peaks were found at retention time of 9.753 minutes and decrease in the peak area was observed. As no peaks were found at retention time of 9.753 minutes, the proposed method was specific for the detection of Naratriptan Hydrochloride.

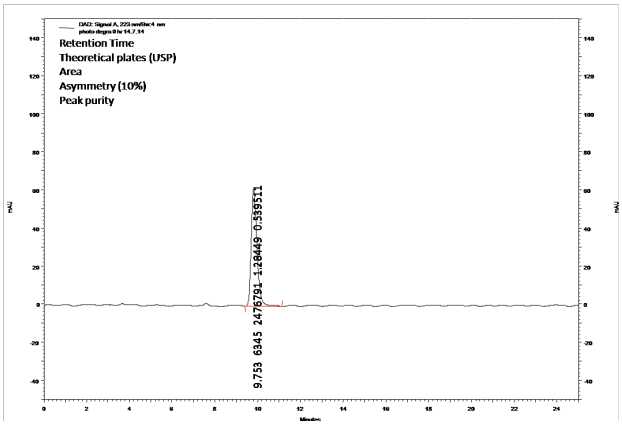

Figure 2: Chromatogram of Naratriptan Hydrochloride (control)

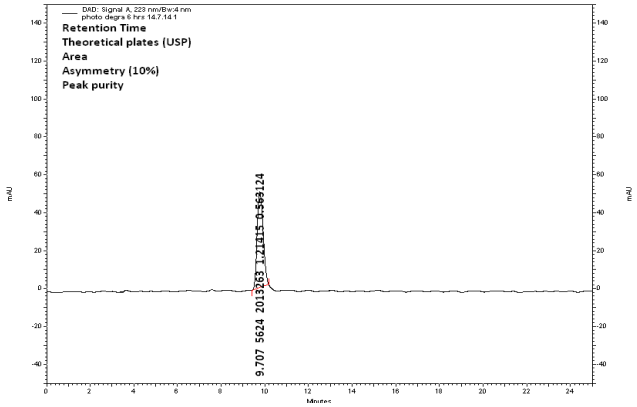

Figure 3: Chromatogram of degraded sample

Linearity

Table 3: Calibration of Naratriptan Hydrochloride

S. No.	Concentration (µg/ml)	Peak area Mean ± SD (n = 3)	% RSD
1	3	921359 ± 1428	0.15
2	6	1529405 ± 7452	0.48
3	9	2228963 ± 11820	0.53
4	12	2806768 ± 6521	0.23
5	15	3369709 ±14863	0.44
6	18	4076273 ± 37075	0.90

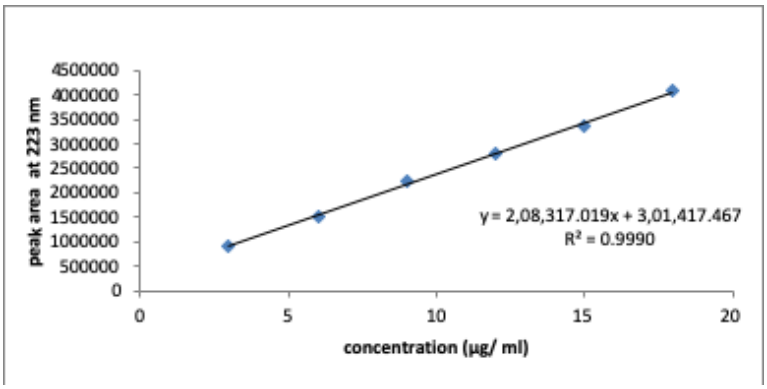

Figure 4: Calibration curve of Naratriptan Hydrochloride

Table 4: Linearity Report of Naratriptan hydrochloride

S. No.	Parameter	Values for Naratriptan Hydrochloride
1	Linearity range	3- 18 µg/ml
2	Regression equation	y = 208317.019 x + 301417.467
3	Correlation	0.9990
4	coefficient	301417.467
5	Intercept	208317.019
	Slope	

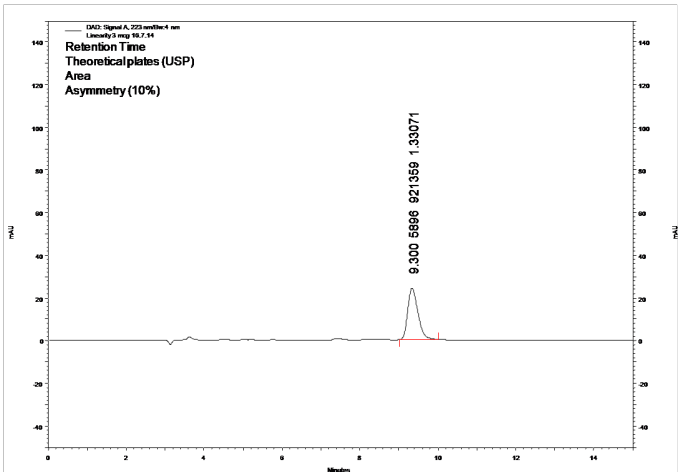

Figure 5: Linearity of Naratriptan HCl

Precision

i.System Precision (Repeatability)

Table 5: System precision of Naratriptan Hydrochloride

Injection No	Concentration (µg/ml)	Peak area at 223 nm	R_t (min)
1	5	1350131	9.207
2	5	1343764	9.465
3	5	1341723	9.203
4	5	1351921	9.258
5	5	1350248	9.315
6	5	1352063	9.224
Mean ± SD		1348308.33 ± 4432	9.278 ± 0.10
% RSD		0.33	1.08

ii.Method Precision (Reproducibility)

Table 6: Method Precision of Naratriptan Hydrochloride

Injection No	Concentration (µg/ml)	Peak area at 223 nm	R_t (min)
1	5	1352197	9.526
2	5	1351921	9.465
3	5	1341723	9.203
4	5	1343764	9.258
5	5	1350248	9.315
6	5	1352063	9.224
7	5	1350131	9.207
8	5	1349743	9.638
Mean ± SD		1348973.75 ± 3998	9.354 ± 0.16
% RSD		0.30	1.71

iii.Intermediate precision

Table 7: Intra and Inter-day Precision of Naratriptan Hydrochloride

S. No.	Conc. (µg/mL)	Intra-day Precision		Inter-day Precision	
		Peak area Mean ± SD (n = 3)	% RSD	Peak area Mean ± SD (n = 3)	% RSD
1	3	921359 ± 1374	0.14	908014 ± 1624	0.17
2	9	2228963 ± 21556	0.96	2231462 ± 11319	0.50
3	18	4076273 ± 16749	0.41	4328276 ± 20295	0.46

Accuracy

Table 8: Recovery studies of Naratriptan Hydrochloride

S. No.	Pre-analysed sample conc (µg/ml)	Recover y level	Amount added (µg/ml)	Amount of drug found (µg/ml), (n = 3) mean ± SD	% recovery	% RSD
1	5	80%	4	3.963 ± 0.021	99.07	0.53
		100%	5	4.928 ± 0.035	98.56	0.71
		120%	6	6.062 ± 0.024	101.03	0.40

Assay

Table 9: Assay of Naratriptan Hydrochloride

S. No.	Active pharmaceutical ingredient (API)	Concentration (µg/ml)	Amount found (µg),(n = 3) Mean ± SD	% Assay	% RSD
1	Naratriptan Hydrochloride	5	5.034 ± 0.013	100.68	0.26

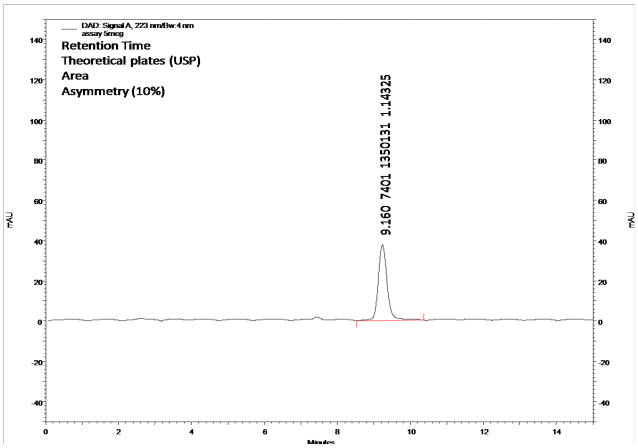

Figure 5: Assay chromatogram of Naratriptan Hydrochloride

Limit of detection (LOD) and Limit of Quantitation (LOQ)

Table 10: LOD and LOQ report of Naratriptan Hydrochloride

S.No	Drug	LOD	LOQ
1	Naratriptan Hydrochloride	0.0173 µg/mL	0.572 mL

Robustness

Table 11: Robustness studies of Naratriptan Hydrochloride

Parameter	Conditions	R_t (min)	Area (n = 3)	% Assay	Remarks
Optimized	MeOH : water (0.2% TEA, p^H 3) in ratio of 25: 75, 1 ml/min, λ_{max}: 223 nm	9.740	3309507 ± 13042	100	-------
Flow rate	0.9 mL/min	10.020	3567637 ± 2761	107.79	Not Robust
	1.1 mL/min	9.187	3212488 ± 7913	97.06	Not Robust
Mobile phase	M:W (23:77)	10.020	3361907 ± 11327	101.58	Robust
	M:W (27:73)	9.120	3369842 ± 5575	101.82	Robust
Wavelength	220 nm	9.740	3346187 ± 5548	101.10	Robust
	226 nm	9.740	3259678 ± 9150	98.49	Robust

System suitability

Table 12: System suitability parameters of Naratriptan hydrochloride

S. No.	Parameter	Values obtained	Acceptance criteria
1	Retention time	9.740	
2	Theoretical plates	8414	> 2000
4	Peak Asymmetry	1.25	≤ 1.5

Table 13: Acid degradation of Naratriptan Hydrochloride in 1N HCl at 60^0C

S. No.	Time (hours)	Peak area	% degradation
1	0	2221907	0
2	3	2052827	7.60
3	6	1833616	17.47

Table 14: Alkaline degradation of Naratriptan Hydrochloride in 1N NaOH at 60^0C

S. No.	Time (hours)	Peak area	% degradation
1	0	2440842	0
2	3	2323538	4.80
3	6	2177712	10.78
4	9	1964207	19.52

Table 15: Oxidative degradation of Naratriptan Hydrochloride in 10% H_2O_2 at room temperature

S. No.	Time (hours)	Peak area	% degradation
1	0	2448003	0
2	24	2412693	1.44
3	48	2365725	3.36
4	120 (5 days)	2174707	11.16

Table 16: Photo degradation of Naratriptan Hydrochloride

S. No.	Time (hours)	Peak area	% degradation
1	0	247679	0
2	3	2254568	8.97
3	6	2013263	18.71

Table 17: Thermal degradation (at 105^0C) of Naratriptan Hydrochloride

S. No.	Time (hours)	Peak area	% degradation
1	0	3406020	0
2	3	3141807	7.75
3	6	2769379	18.69

DISCUSSION

The method was validated for all validation parameters as per ICH guidelines. The linearity range of Naratriptan Hydrochloride was 3-18 µg/ml. The value of correlation coefficient was 0.9990. The % RSD values in the Precision studies were < 2%. This confirmed that the method was sufficiently precise. The accuracy of the method was validated by recovery studies and was found to significant and under specification limits, with % recovery 98.56-101.03 (within acceptable range 98-102%). The assay result was found to be 100.68% (i.e. within 95-105%). The method also passes the specifications for robustness parameters. LOD of Naratriptan Hydrochloride was found to be 0.0173 µg/ml and LOQ of Naratriptan Hydrochloride was found to be 0.0572 µg/ml.

Forced degradation HPLC method has been developed for the estimation of Naratriptan Hydrochloride API with mobile phase system of methanol: water (0.2% TEA, pH 3 with OPA) in the ratio of 25: 75 v/v. The flow rate of 1ml/min was used on C_{18} column (250 x 4.6 mm, 5 µm particle size). The retention time of Naratriptan Hydrochloride was observed at 9.740 min and peak asymmetry of 1.25 and found to be linear, precise, accurate, specific and robust. Hence the method can be used routinely for the estimation of Naratriptan Hydrochloride API. The results of stress testing of the API, undertaken according to ICH guidelines, revealed that degradation was observed under acidic, alkaline, oxidizing, photolytic and thermal conditions. The drug was highly sensitive to light followed by liable to thermal, acid, alkaline and oxidative degradation. Naratriptan Hydrochloride is the essential therapeutic agent in the treatment of migraine. Among the analytical methods available in estimation and quantification, HPLC method emerges reliable in vast areas of interest that incited the author to undertake method development and validation as per ICH guidelines.

The method was validated for all validation parameters as per ICH guidelines. The linearity range for Naratriptan Hydrochloride was 3-18 µg/ml, with $r^2 = 0.9990$. The % RSD for intra- and inter-day precision was < 2%. The assay has been performed. The accuracy of the method was validated by recovery studies and was found to significant and under specification limits, with % recovery 98.56-101.03% (within acceptable range 98-102%). The method was also passing the specifications for robustness parameters.

A stability study on Naratriptan Hydrochloride was carried out and an efficient HPLC method for the quantification of Naratriptan Hydrochloride. The results of stress testing of the API, undertaken according to ICH guidelines, revealed that degradation was observed under acidic, alkaline, oxidizing, photolytic and thermal conditions. The drug was highly sensitive to light followed by liable to thermal, acid, alkaline and oxidative degradation.

Naratriptan Hydrochloride is having λ_{max} of 223 nm in methanol. As the molecule is having less chromophoric groups, the degradants formed may not have chromophores at the selected wavelength. Hence the degradants may not have been seen at the selected wavelength.

CONCLUSION

In present study the API namely Naratriptan Hydrochloride (Selective 5-HT_1 receptor subtype agonist) the essential therapeutic agent is given in treatment of migraine. Among the analytical techniques available in the estimation and quantification, HPLC method is an emerging technique reliable in vast areas of research that incited the author to undertake method development and validation as per ICH guidelines for the same.

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