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Analytical method for the Determination of Dissolution and Assay for Itopride HCl SR 60 % w/w pellets

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Abstract

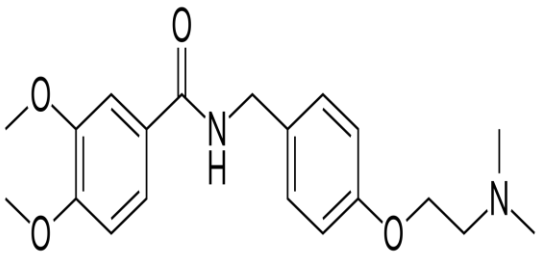
ITOPRIDE HCL chemical Name according to IUPAC is N-[[4-(2-Dimethylaminoethoxy) pheny l]methyl]-3,4-dimethoxybenzamide hydrochloride and it's molecular formula, molar mass are C_{20} H_{26} N_2O_4, 358.438 gram /mol [1] . Solubility of Itopride hydrochloride in water is around 78 milligrams per millilitre (mg/mL) at 25°C and other solvents DMSO and ethanol, aqueous buffer [2] . Itopride Hydrochloride acts as gastro prokinetic agent[3] i.e. increasing the flow of food material from the mouth to stomach i.e. used for treating gastrointestinal indications such as heartburn, vomiting, nausea, bloating and stomach senses swollen due to build-up of gas[4] , non-ulcer dyspepsia (indigestion). Itopride hydrochloride acts on the brain's chemoreceptor trigger zone and prevent the vomiting. In-house U.V spectroscopic method was proposed for the analysis of dissolution and assay of ITOPRIDE HCL SR 60 % W/W PELLETS ,Apparatus USP-II (Paddle), Dissolution medium water, volume 900ml, RPM-100RPM, temperature; 37.0±0.5°C, and time intervals are 1st , 4th , 8th and 12th hours. The determination was accomplished by U.V Photo Spectrometer at λ (max) 258nm.Proposed method was validated according to ICH guidelines [5] and results are within the limits and satisfactory.

Keywords: ITOPRIDE HCL SR 60 % W/W PELLETS, API, USP-II, pH, RPM, U.V Spectrophoto meter, ICH, Validation.

Introduction:

Itopride Hydrochloride acts as gastroprokinetic agent i.e. increasing the flow of food material from the mouth to stomach i.e. used for treating gastrointestinal indications such as heartburn, vomiting, nausea, bloating and stomach senses swollen due to build-up of gas[3] , non-ulcer dyspepsia (indigestion). Itopride hydrochloride acts on the brain's chemoreceptor trigger zone and prevent the vomiting.

Structure of Itopride



IUPACname of the Itopride is N-[[4-(2-Dimethylaminoethoxy) phenyl]methyl]-3,4-dimethoxybenzamide and it's molecular formula , molar mass are C_{20} H_{26} N_2O_4, 358.438 gram /mol

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[1]. Solubility of Itopride hydrochloride in water is around 78 milligrams per millilitre (mg/mL) at 25°C and other solvents DMSO and ethanol , aqueous buffer or Isotonic saline is given below[2].

	In DMSO	In ethanol	In aqueous buffers or isotonic saline
	78mg/mL (197.52 mM) at 25°C	38mg/mL(96.22 mM)at 25°C	at 38 mg/mL (96.22 mM) at 25°C

Absorbance maximum (λ maximum) of the ITOPRIDE HHYDROCHLORIDE was found to be 258 nm.

Analytical method development related articles were reported by Venkata Basaveswra Rao etal [6-8] "Estimation of Diclofenac Sodium pellets (Extended release) in commercial dosage forms using a simple and convenient spectrophotometric method, Estimation of venlafaxine in commercial dosage forms using simple and convenient spectrophotometric method, Dissolution test for Omeprazole Pellets 8.5 %(High dissolution): Optimization and Statistical analysis, G.kurmaiah etal reported the "Review on u.v spectroscopic method development and validation" [9] , Srinivas etal reported the "Development and validation of dissolution test for Tamsulosin Hydrochloride Pellets", Determination of Flubiprofen pellets 57% using drug release method by U.V, Dissolution profile of phenylephrine hydrochloride pellets,[11-13],from this data, a simple analytical method for the determination of Dissolution profile and assay of ITOPRIDE HYDROCHLORIDE pellets dosage forms was proposed. Chemicals, instruments and Methodology as follows.

Chemical used: ITOPRIDE HYDROCHLORIDE working standard is procured form M/s Metrochem API Pvt.Ltd. Methanol AR grade procured from Sigma Aldrich, HCL LR grade procured from Vizag Chemicals,

Glass ware & Instruments: Volumetric flask -100 ml, pipette-10 ml, measuring cylinder 100 ml-All are A Grade, Dissolution Tester 8 bowls USP-II make Electro lab, U.V Spectro photo meter make Shimadzu software LC solutions 2010

Methodology:

Dissolution parameters:

(Itopride HCl):

Apparatus : USP Apparatus type-II (Paddle)

Medium : 900 ml water

R.P.M : 100

Temperature: 37.5±0.5°C

Time intervals for Drug release:

Release rate pattern: Drug should release after

Ist hour : 10- 35 %

IVth hour : 40- 70%

VIIIth hour : 65- 90%

XII th hour : NLT75%

Preparation of solutions:

Standard Preparation: Weigh accurately 100mg of ITOPRIDE HCl working standard into a 100 ml volumetric flask, dissolve in 0.1N HCl and dilute to Volume with the same and mix. Transfer 1 ml of this solution into a 100 ml volumetric flask and dilute to volume with 0.1N HCl.

Test **preparation**:

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Put the pellets equivalent to about 100mg of ITOPRIDE HCl in six dissolution vessels containing 900ml of medium (water) that has been equilibrated to 37.5±0.5°C. Tap the pellets gently to make them settle to the bottom and start the apparatus immediately.

After completion of respective time interval , pipette out & filter 10 ml of solution from each bowl and dilute 5 ml to 50 ml in a volumetric flask with 0.1 N HCl.

Read the absorbance of standard and sample at 258 nm using 0.1N HCl as blank and calculate the results

Calculations:%Drugreleased

$$\frac{AT}{AS} \times \frac{WS}{100} \times \frac{1}{100} \times \frac{900}{WT} \times \frac{50}{5} \times \frac{100}{Assay} \times P =$$

AT = Absorbance of test solution, AS = Absorbance of standard solution

WS= Weight of working standard WT= Weight of test sample

P = Potency of working standard.

Assay of ITOPRIDE HCl by U.V Spectro photo meter:

Solutions preparations:

Standard preparation:

Weight accurately 100 mg of ITOPRIDE HCl working standard into a 100 ml volumetric flask dissolve in 20 ml of methanol and dilute to volume with methanol and mix. Transfer 1 ml of this solution into a 100 ml volumetric flask and dilute to volume with methanol.

Sample preparation:

Take 4.0 grams of Pellets in to a mortar and grind the pellets to a uniform fine powder. Weigh accurately quantity equivalent to 100 mg of ITOPRIDE HCl in to a 100 ml volumetric flask, add 20 ml of methanol, dissolve and dilute to volume with methanol and mix. Filter the preparation. Transfer 1 ml of this solution into a 100 ml volumetric flask and dilute to volume with methanol.

Procedure: Measure the absorbance of the both the standard and sample preparation in suitable U.V- Visible Spectrophotometer at 258 nm using methanol as blank.

Calculation: Calculate the % of ITOPRIDE HCl Present in the pellets in the pellets using the following formula

$$\frac{AT}{AS} \times \frac{WS}{WT} \times P$$

AT = Absorbance of test solution, AS = Absorbance of standard solution

WS= Weight of working standard WT= Weight of test sample

P = Potency of working standard.

Method Validation: The proposed method was validated according to ICH(Q2) guideline.

Results and discussion

Analytical Method validation parameters are as follows

Accuracy,Precision,Linearity,LOD(limitofdetection),LOQ(limitofquantification),Specificity,Range,Robustness.

Accuracy: Accuracy is defined as the closeness of the test results to the true value.

The accuracy of the method was determined by spiking the drug-release samples with known quantity of the active substance and subjecting them to quantitative determinations.

The results are given in the following tables and demonstrate the accuracy of the method

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Accuracy for ITOPRIDE HYDROCHLORIDE at 20% of Specified Table-1

Sample	Concentration		
	Spiking Concentration	Recovered Concentration	Recovery (%)
1	0.02014	0.02013	99.50%
2	0.02014	0.02014	100.00%
3	0.02014	0.02012	99.90%
4	0.02014	0.02012	99.90%
5	0.02014	0.02013	99.50%
6	0.02014	0.02014	100.00%
		Mean	99.80%

Accuracy for ITOPRIDE HYDROCHLORIDE at 45% of Specified Limit: Table-2

Sample	Concentration		
	Spiking Concentration	Recovered Concentration	Recovery (%)
1	0.04526	0.04526	100.00%
2	0.04526	0.04524	99.95%
3	0.04526	0.04526	100.00%
4	0.04526	0.04523	99.93%
5	0.04526	0.04524	99.95%
6	0.04526	0.04526	100.00%
		Mean	99.98%

Accuracy for ITOPRIDE HYDROCHLORIDE at 70% of Specified Limit: Table-3

Sample	Concentration		
	Spiking Concentration	Recovered Concentration	Recovery (%)
1	0.07036	0.07034	99.97%
2	0.07036	0.07036	100.00%
3	0.07036	0.07031	99.92%
4	0.07036	0.07033	99.95%
5	0.07036	0.07036	100.00%
6	0.07036	0.07030	99.91%
		Mean	99.96%

Accuracy ITOPRIDE HYDROCHLORIDE at95% of Specified LimitTable-4

Sample	Concentration		
	Spiking Concentration	Recovered Concentration	Recovery (%)
1	0.09516	0.09513	99.96%
2	0.09516	0.09515	99.98%
3	0.09516	0.09516	100.00%
4	0.09516	0.09516	100.00%
5	0.09516	0.09511	99.94%
6	0.09516	0.09513	99.96%
		Mean	99.97%

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Sample	Concentration		
	Spiking Concentration	Recovered Concentration	Recovery (%)
1	0.12056	0.12050	99.95%
2	0.12056	0.12058	99.93%
3	0.12056	0.12054	99.98%
4	0.12056	0.12055	99.99%
5	0.12056	0.12052	99.96%
6	0.12056	0.12058	99.85%
		Mean	99.94%

Accuracy for ITOPRIDE HYDROCHLORIDE at 120% of Specified LimitTable-5

Precision: Precision is a measure of Reproducibility or of Repeatability of the analytical method and is usually expressed the relative standard deviation. Suitable tests have been carried out to ensure the Precession of the method.

Precession of method: This is determined by using the analytical method to a sample, sufficient number of times (Six) to get analytically valid results .Sample to be Weighed Six different times at required Concentration and to be analytical for method.

Observation: Relative standard deviation of method results to be calculated from the observation using the formula.

Sl. No	Std weight in mg	Std Absorbance	Sample weight in mg	Sample Absorbance	%of Drug release	RSD %
1			166.6	0.599	96.56	
2			166.8	0.601	96.76	
3			166.9	0.603	97.03	
4			166.7	0.602	96.98	
5			166.5	0.598	96.46	
6	100.3	0.555	166.6	0.599	96.56	0.24

Calculation:

Standard Deviation SD =

$[\sum(X-X_1)^2/(n-1)]^{1/2}$

Relative standard deviation RSD=[SD/Mean]*100

Characteristics Acceptance Criteria: RSD of absorbance Response Less than 2.00%

Water-900 ml-12hr. Table-6

Linearity and Range:

The linearity of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample.

A linear relationship should be evaluated across the range of the analytical procedure. It may be demonstrated directly on the active substance (by dilution of a standard stock solution) and/or on separate weighing of synthetic mixtures of the

% Of Standard Concentrations	Concentration (mg/ml)	Absorbance
60	0.06056	0.332
75	0.07568	0.451
100	0.10080	0.555
120	0.12092	0.669
135	0.13504	0.747
	Corrlelation coefficient	0.9999
	Slope	5.5647
	y-Intercept	0.0045

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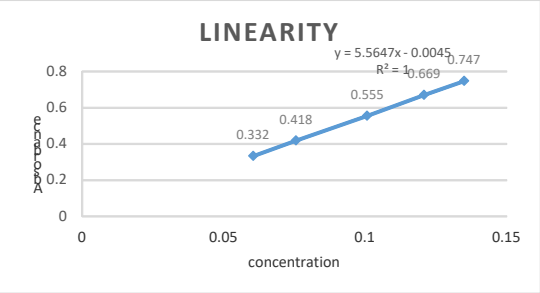
product components, using the proposed procedure. Table.7

Linearity and Range Table-8



Range

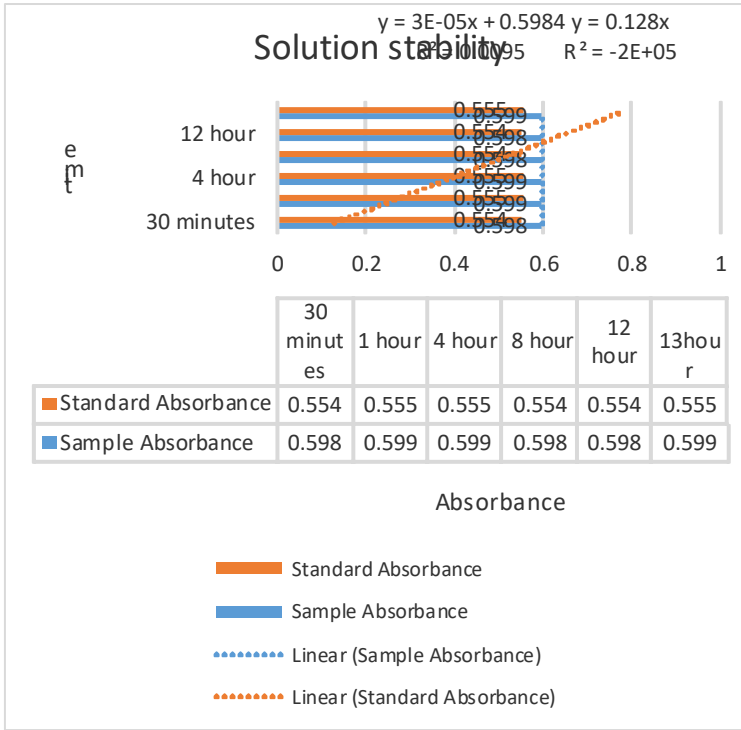
The specified range is normally derived from linearity studies and depend on the intended application of the procedure .The standard calibration curve of ITOPRIDE HYDROCHLORIDE was prepared in water media. The equation of line was found to be the equation obtained from these curve was used to calculate cumulative % release of drug from pellets dosage form in dissolution study.

Solution Stability: The stability of ITOPRIDE HYDROCHLORIDE in water solution was studied by the UV method. Sample solutions were prepared in duplicate and stored at 37.5°C for30minits, 1, 4, 8, 12, 13, hours. The stability of these solutions was studied by performing the experiment and looking for the change in the spectrophotometric pattern compared with freshly prepared solutions.

Solution Stability at 37.5°c, in water stability test solution table-9

SL.NO	Hours	Sample Absorbance	Standard Absorbance
1	30 minutes	0.598	0.554
2	1 hour	0.599	0.555
3	4 hour	0.599	0.555
4	8 hour	0.598	0.554
5	12 hour	0.598	0.554
6	13hour	0.599	0.555

Solution stability Table-10



	30 minutes	1 hour	4 hour	8 hour	12 hour	13hour
Standard Absorbance	0.554	0.555	0.555	0.554	0.554	0.555
Sample Absorbance	0.598	0.599	0.599	0.598	0.598	0.599

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The development of a simple, rapid, sensitive, and accurate analytical method for the routine quantitative determination of samples will reduce unnecessary sample preparations and the cost of materials.

Itopride hydrochloride is a UV-absorbing molecule with specific chromophores in the structure that absorb at a particular wavelength and this fact was successfully employed for their quantitative determinations using the UV spectrophotometric method. The absorption spectrum of ITOPRIDE HYDROCHLORIDE water, maximum absorbance at 258 nm.

Calibration curve data was constructed in the range of the expected concentration of (6.056-13.504)×10-2 Beer's law was obeyed over this concentration range. The regression equation was found to be y = 5.5647x - 0.0045. The correlation coefficient R of the standard curve was found to be R_2=1.The stock solution and working standards were made in water .The λmax of the drug for analysis was determined by taking scans of the drug sample solution in the entire U.V region. i.e 258nm

The characteristic of the calibration plot is presented in Table-8 and the analytical characteristics and necessary validation parameters for the UV techniques for ITOPRIDE HYDROCHLORIDE is presented. Performing replicate analyses of the standard solutions was used to assess the accuracy, precision, of the proposed methods.

Acknowledgement: Here with i am submitting research paper entitled

"ANALYTICALMETHODFORTHEDTERMINATION OF DISSOLUTION AND ASSAY FOR ITOPRIDE HCL SR 60 % W/W PELLETS" for publishing in your journal, this work is original, and this work is not incorporated / not published any journal, book, magazine

CorrespondingAuthor;

Dr.Srinivasarao.Tumati (On behalf of all authors)

Competing interest: I/We declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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