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Development And Validation Of A Simple Method To Determine Berberine Hydrochloride By UV Spectrophotometry

Yogesh S. Thorat[1], Shrinath S. Diwate*[2], Samiksha. S. Upadhye[3], Mansi B. Kalyani[4], M Kais S. Attar, Suraj R. Chakre

D.S.T.S Mandal's College of Pharmacy, Jule Solapur, Solapur-413003, Maharashtra, India

ABSTRACT:

For the purpose of quantifying berberine hydrochloride in active pharmaceutical components and tablet dose formulation, an affordable, straightforward, accurate, precise, and versatile UV spectrophotometric approach based on absorption ratio has been developed and verified in accordance with ICH requirements. In the current investigation, berberine hydrochloride was estimated using the absorbance values at 246 nm. The analysis findings for linearity, accuracy, precision, LOD, and LOQ have all been statistically confirmed. With a correlation coefficient of 0.9995, the procedure was shown to be linear in the concentration range of 10–50 µg/ml. The results for the validation parameters also showed that the suggested approach was determined to be appropriate, sensitive, repeatable, accurate, and exact. As a result, this technique is helpful for routine quality control analysis to estimate berberine hydrochloride in pharmaceutical.

Keywords: Berberine HCl, Beer's law, phosphate buffer pH 6.8 ,Water, Validation,

INTRODUCTION:

Berberine hydrochloride is an isoquinoline alkaloid found in a variety of medicinal plants, mainly in the Berberis genus and the Berberidaceae family. *Berberis vulgaris*, goldenseal, goldthread, Oregon grape, rosid dicot genus and turmeric, Guduchi, and other plants contain this chemical component.1,2 Berberine alkaloids have a wide range of pharmacological activities, including bactericide, antiviral, blood pressure reducing, hypoglycaemic, medicine, and tumour metastatic effects.3,4 Glyco-X 500 capsules, Bio-Berberine capsules, Berbeshine tablet, and other formulations with Glyco-X 500 capsules, Bio-Berberine capsules, and Berbeshine tablet, for example. In some malignant cells, it inhibits cell proliferation while encouraging programmed cell death. Biodegradable and biocompatible polymers are supported by natural and artificial components in nanoparticles for drug delivery applications. Poly lactic co glycolic acid nanoparticles have also demonstrated cvbbtheir efficacy as drug delivery vehicles for a variety of medicinal treatments. Different

researchers employ only a few UV-Spectrophotometric techniques to examine berberine hydrochloride in commercial formulations, nanoparticles, and other food products.6-16 The reported methods have their own limitation such as use of costly and hazardous solvent and also reported method have not fully validated the results. Thereportedmethodshave their own set of limitations, such as the use of a pricey and hazardous solvent,and the results have not been completely confirmed. As a result, a UV-Spectrophotometric method for estimating Berberine hydrochloride in marketed formulations must be developed and standardized.

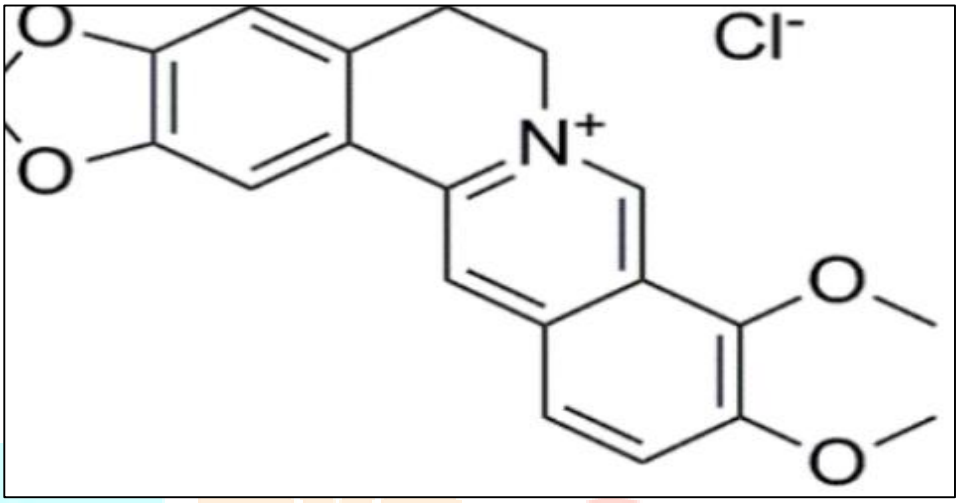

Figure 1: Structure of Berberine Hydrochloride.

MATERIALS

Instrumentation: Double beam UV Spectrophotometer (Systronics-2201) and Weighing balance.

Drug Sample : Berberine hydrochloride was provided as a free sample
by world OF Nature pvt Ltd , Kunal Aspiree, 1104, Balewadi Baner, Pune.

Reagents and Chemicals: phosphate buffer pH 6.8

Selection of wavelength : Berberine hydrochloride was employed throughout the study since it is soluble in phosphate buffer pH 6.8 . Berberine hydrochloride 10 µg/ml of working standard solution was scanned in the UV – Spectrophotometer between 200 nm and 400 nm, with the highest absorption at 266 nm (Figure 1).

Method Development: Solvent selection: The choice of solvent was made after solubility testing in a phosphate buffer pH 6.8 showed a greater absorbance value at λmax phosphate buffer pH 6.8. were chosen as the solvent for additional research.

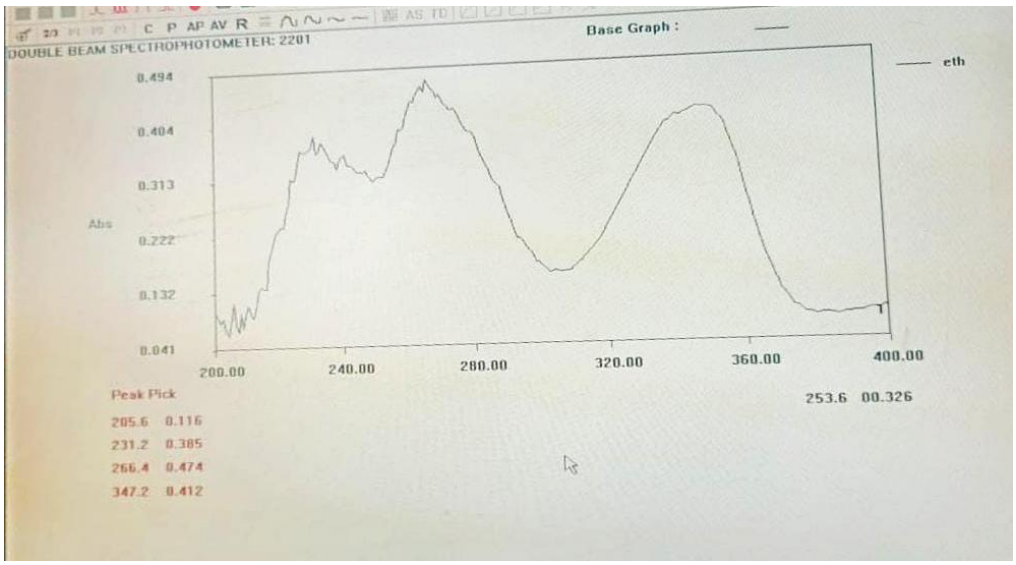

Figure 2: λmax of Berberine hydrochloride

Preparation of stock solution : A precisely weighed 10mg of berberine hydrochloride was dissolved in phosphate buffer pH 6.8 in a clean and dried 100ml volumetric flask, and the volume was calculated using the same. This was considered a standard stock solution with a 100µg/ml concentration. Further dilutions were made using this standard stock solution.

Preparation of calibration curve

A concentration range of 10-50 µg/ml was used for the calibration curve, and six distinct concentrations were generated and measured at 266nm. There was a straight line on the generated graph.

Method validation: Method Validation was performed according to ICH [Q2 (R1)] guidelines.

Specificity and selectivity: Berberine hydrochloride has the highest absorbance at 266 nm, indicating that the procedure is selective. And because the spectra of the solvent revealed no absorbance at the wavelength of berberine hydrochloride, 266 nm, this approach was determined to be selective.

Linearity: Using the stock solution (10µg/ml) as a blank, different aliquots ranging in size from 10 to 50µg/ml were produced and scanned at 266 nm in a UV-VIS spectrophotometer. The results showed a regression coefficient of 0.9988 and absorbance within the allowable range.

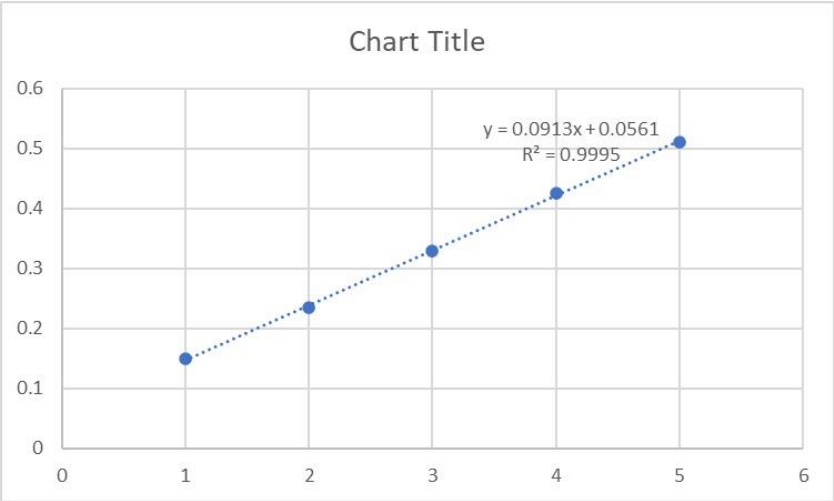

Figure 3: Calibration curve of berberine hydrochloride

Table. No:1 Optimization parameters of Berberine hydrochloride

Parameters	**Method values**
Wavelength detection	266
Beers law	1 µg/ml -5 µg/ml
Correlation coefficient	0.9995
Regression coefficient	Y=0.913x+0.0561
Slope	0.913
Intercept	0.0561

1. **Precision:** For precision assessment, conc. of 5µg/ml was used to perform inter-day and intra-day precision. Results obtained fell within the acceptable limit, demonstrating a relative standard deviation (RSD) of less than 1%

Table 2: Inter-Day Precision

Sr. No	**Concentration**	**Absorbance**
1	5 µg/ml	0.230
2		0.232
3		0.235
4		0.234
5		0.233
6		0.236
	Mean	0.233
	SD	0.002
	%RSD	0.88%

2. **Range:** Range was fixed for prazosin hydrochloride (10-50µg/ml).

3. **Accuracy**: For Accuracy, percentage recovery of prazosin hydrochloride was determined. This involved adding the analyte at concentration levels of 80%, 100%, and 120%.

Table 3: Result of accuracy

Recovery level in %	Concentration of sample (µg/ml)	Concentration of drug (µg/ml)	Amount recovered (µg/ml)	% Recovery
80%	1	0.8	13.83	61.3%
100%	1	1	17.57	99.7%
120%	1	1.2	18.16	104.6%

4. Detection Limit: Detection Limit is the lowest amount of analyte in sample that can be detected. It was calculated by following formula.

Detection limit = 3.3*σ/S Where, σ and S are the standard deviation of the response and the slope of calibration curve. The detection limit was found to be 0.144

5. Quantitation Limit: Quantitation limit is the lowest amount of analyte in sample that can be quantified. It was calculated by following formula.

Quantitation limit = 10*σ/S Where, σ and S are the standard deviation of the response and the slope of calibration curve. The quantitation limit was found to be 0.438.

6. Robustness:

Table 4: Result of Robustness

Sr. No	**Absorbance at 264**	**Absorbance at 268**
1	0.470	0.475
2	0.469	0.468
3	0.470	0.473
SD	0.0005	0.003
%RSD	1.06%	0.6%

7. Assay: Assay of sample solution was also determined.

Table 5: Result of Assay

Formulation	Concentration (µg/ml)	Obtained amount (µg/ml)	% purity
Berberine hydrochloride 50mg Tablet	5	4.85	99.4%

Results and discussion: With favourable drug recoveries and %RSD values of inter-day experiments less than 1%, the method showed accuracy, simplicity, precision, and repeatability. The technique demonstrated robustness with %RSD values less than 2%, and the detection and quantitation limits were determined to be (0.144, 0.438). Specificity was verified, and Table No. 6 presents validation respectively.

Table 6: Validation parameters

Sr. No	Parameters	Result
1	Linearity indicated by correlation coefficient	0.995
2	Linear Regression Equation	0.0913x+0.0561
3	Range	10µg/ml -50 µg/ml
5	Interday Precision	0.36%
6	Detection limit	0.144µg/ml
7	Quantitation limit	0.438µg/ml
8	Recovery indicated by%	95-105%
9	Robustness indicated by %RSD	0.61%

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