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VALIDATION OF HERBOSOMAL GEL BY ICH GUIDELINES FOR ANTIINFLAMMATORY ACTIVITY

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Abstract

Manjistha used in the treatment of various diseases and disorders, some of the major ones are inflammation and cancer. In the present study, the Manjistha herbosomal gel were used for an analytical method that is Ultraviolet spectroscopy (UV) which is developed and validated in accordance with International Council for Harmonization guidelines. In the method development solvent used is distilled water. The method is validated for linearity, range, limit of detection, limit of quantification, precision, and robustness. The developed analytical method was found to be simple, reliable, precise, and robust. The validated UV Spectroscopy method was successfully applied for quantification of Manjistha loaded Herbosomal gel.

Keywords: Herbosomal gel, UV spectroscopy, Validation.

Introduction

Traditional medicines play an important role in health services around the globe. About three quarters of the world population relies on plants and plant extracts for health care. A number of Indian plants are attributed with various pharmacological activities as they contain diversified classes of photochemical. The opoids or non-steroidal anti-inflammatory drugs, widely used to reduce the inflammation of various types, suffer from severe side effects like redness, itching etc. As a result, a search for other alternatives seems to be necessary which would be more beneficial. The literature survey revealed that various plants scattered throughout the plant kingdom anti-inflammatory activity. The plant selected for present work is Manjistha (Rubia cordifolia) and from the extract herbosomes are prepared. Herbosomes, where "HERBO" refers to a plant and "SOME" refers to a cell-like structure. Herbosomes are another name for phytosomes. Herbosome technology enhances the bioactivity of plant extracts and serves as a link between the NDDS and traditional systems. It is a complex of phytoconstituents and lipid molecules that improve plant extract permeability. Lipophilicity and multiring molecular architectures are two

primary limitations for molecules to pass the cell membrane for absorption in the systemic circulation. Many plant extracts have excellent bioactivity in vitro but poor or low bioactivity in vivo due to poor lipid solubility and/or molecule size, which result in poor absorption and bioavailability of constituents from plant extracts and are destroyed in gastric fluids when taken orally.

Gel formulations are used to deliver the drug topically because of easy application, increase contact time and minimum side effects as compare to other topical preparation.

Pharmaceutical analysis is a branch of practical chemistry which involves a set of procedures to classify, determine, quantify, purify a substance, separate the compounds of a solution or mixture, or determine the structure of chemical substances., atomic spectroscopy, UV-visible spectroscopy is most frequently used techniques in pharmaceutical analysis. Validation of the method is the mechanism used to ensure that the analytical technique employed for a specific test is appropriate for its intended use. Method validation can be used to assess the quality, reliability, and consistency of the analytical results and it is an essential part of good analytical practice. Different parameters of analytical validation are system suitability test, specificity, accuracy, range, linearity, precision, etc. The aim of this research was to validate a Herbosomal gel of Manjistha extract.

Material and methods

Materials

Amruta herbals Pvt. Ltd., India, has given Manjistha extract as a gift sample and Lecithin were obtained from Shivabiochem industries. Maharashtra, India.

DEVELOPMENT AND VALIDATION

Derivative UV spectroscopy has been widely used as a tool for quantitative analysis and for quality control. This technique has various advantages over the conventional absorbance methods such as the discrimination of the sharp spectral features over the large bands and the enhancement of the resolution of the overlapping spectra.

UV analysis of Manjistha:

The standard stock solution was prepared with weighed amount of Manjistha (10 mg).The stock solution was dissolved separately in 10mL of water in a volumetric flask. A series of dilutions were prepared, and absorbance was measured at 254nm.

Table No.1: Standard calibration curve of Manjistha extract at 254 nm.

Concentration	Absorbance
10	0.116
20	0.171
30	0.210
40	0.258
50	0.304

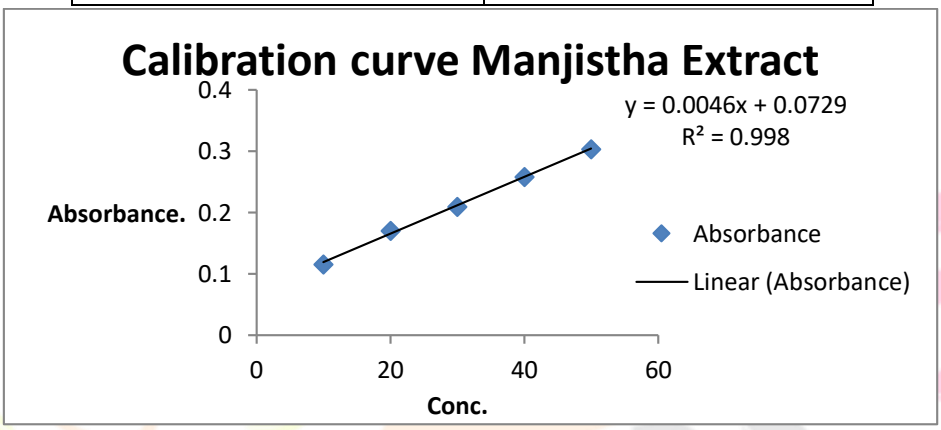

Fig no.1: Calibration curve of manjistha

VALIDATION PARAMETERS OF HERBOSOMAL GEL

LINEARITY:

Linearity Curve at 254nm

Table no 2: Data of linearity for Herbosomal gel at 254nm

Concentration	Absorbance
10	0.110
20	0.165
30	0.199
40	0.245
50	0.310

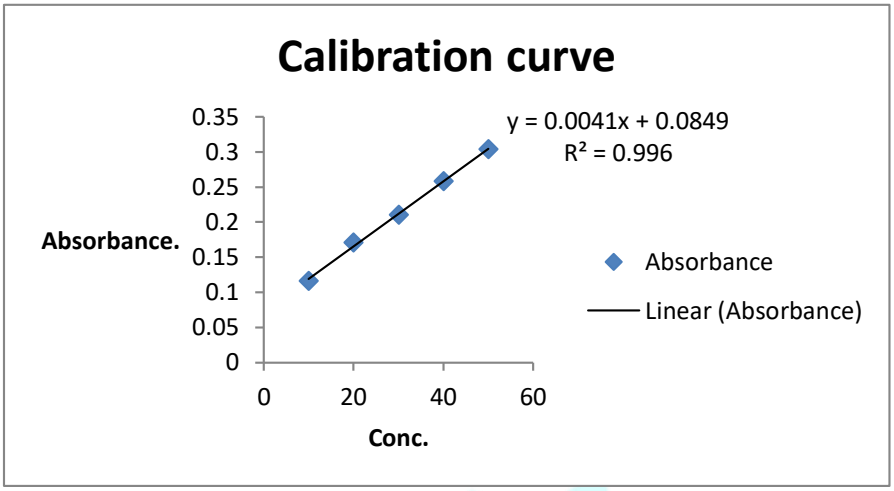

Fig no 2: Standard Calibration Curve of Linearity

Precision

The precision of the method was checked by carrying out repeatability of measurement, intraday and interday precision. To check the repeatability, peak amplitude of derivative spectra of standard solution of concentration 20 µg/ml was measured. Extract were subjected to nine times analysis and % RSD was calculated in table no.4.

Intraday precision was carried out by repeated measurements of the peak amplitude of derivative spectra of standard solutions i.e. 20 µg/ml. at same concentration levels for three times on the same day. Interday precision was studied by comparing the results on three different days analyzing 20 µg/ml.of solution. The calculated % RSD of each parameter is given in table no.3.

Table no. 3: Intraday precision (on same day) data

Sr no.	Concentration (µg/ml)		Absorbance	Mean	SD	% RSD
1.	20	Morning	0.174	0.177	0.0032	1.80%
2.	20		0.180			
3.	20		0.179			
4.	20	Afternoon	0.176	0.176	0.0015	0.86%
5.	20		0.178			
6.	20		0.175			
7.	20	Evening	0.181	0.179	0.0015	0.85%
8.	20		0.178			
9.	20		0.180			

Table no 4: Interday precision (on different day) data

Sr no.	Concentration (µg/ml)		Absorbance	Mean	SD	% RSD
1.	20	Day 1	0.174	0.176	0.0030	1.72%
2.	20		0.180			
3.	20		0.176			
4.	20	Day 2	0.176	0.176	0.0025	1.42%
5.	20		0.174			
6.	20		0.179			
7.	20	Day 3	0.181	0.177	0.0035	1.98%
8.	20		0.174			
9.	20		0.177			

Accuracy

Recovery studies were carried out by measuring the absorbance of derivative spectra at the specified wavelength of the added standard drug to pre-analyzed sample solution at three different levels: 80, 100, and 120% at 254nm to check the accuracy of the method. The resulting solutions were reanalyzed and % recovery was calculated and mentioned in table no.5.

Table no.5: Determination of Accuracy

Sr no.	Concentration (%)	Original level (µg/ml)	Amount added (µg/ml)	Recovery (µg/ml)	% Recovery	Mean % Recovery	% RSD
1.	80	50	40	88.51	98.35	99.47	1.85%
	80	50	40	91.44	101.6		
	80	50	40	88.61	98.46		
2.	100	50	50	101.86	101.86	101.14	0.73%
	100	50	50	101.18	101.18		
	100	50	50	100.38	100.38		
3.	120	50	60	111.34	101.21	100.19	1.12%
	120	50	60	108.88	98.98		
	120	50	60	110.42	100.38		

LOD and LOQ

Limit of detection (LOD)

LOD is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value. LOD value was calculated from the calibration curve by using the equation.

$LOD=3.3 \times \sigma/S$

where, SD is standard deviation of the standard curve.

Limit of quantitation (LOQ)

LOQ is the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy. The quantitation limit is a parameter of quantitative assays for low levels of compounds in sample matrices, and is used particularly for the determination of impurities and/or degradation products. LOQ value can also be calculated from the calibration curve using the equation .

$LOQ=10x\ \sigma/S$

Where, σ = Standard deviation of the response S = Slope of the calibration curve.

RESULTS AND DISSCUSION

The standard calibration curve of Extract(= 0.0046x + 0.0729 R^2 = 0.998) were essentially linear with good correlation coefficient. These equation were used to extrapolate the amount of drug from measured absorbance when required.

Linearity

The analysis of herbosomal gel formulation containing manjistha extract revealed strictly linear relationship with absorbance in the studied concentration range (Figure 2).

Precision

Intra-day and inter-day precision experiments were performed. The %RSD values for precision were less than 2, there by indicating that the method was sufficiently precise (Table 2).

Accuracy

The values of recovery were in between 98 – 100% and percent relative standard deviation was less than 2 indicating that the method is accurate.(Table 3,4)

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

The value of LOD and LOQ was found to be 2.820 µM and 8.546 µM .

Conclusion

Formulation was validated by UV- spectroscopy methods by using distilled water as a solvent. The developed UV-spectroscopic method was found to be simple, accurate, sensitive, precise, specific, economical and rapid. The Herbosomal gel was well validated and optimized by this method. This method was found to be highly specific. The UV Spectroscopic method was found to be linear over wider concentration range. Therefore, the developed method can be applied for routine quantitative and qualitative analysis of Herbosomal gel. This method was validated as per the ICH guidelines. The developed UV spectroscopic method can be employed for pharmaceutical preparations within pharmaceutical industry.

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