Development and Validation of Ultraviolet Spectroscopic Method for Estimation of Methoxsalen in Bulk Using Methanol and Phosphate Buffer (pH 7.4)

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ABSTRACT

Background: Psoriasis is an inflammatory condition of a body wherein erythematous, sharply demarcated papules and round-shaped plaques appear onto skin due to the hyperproliferation of epidermis. Psoralens are the class of furanocoumarins that are effectively used in the treatment of psoriasis and vitiligo in conjunction with exposure to a dose of ultraviolet radiation. It is crucial to develop and validate the suitable analytical method for its quantitative estimation. The present work aims to develop and validate simple, rapid, accurate and cost-effective (as compared to other sophisticated techniques of analysis) Ultraviolet-Visible Spectrophotometry in methanol and phosphate buffer saline (pH 7.4). **Materials and Methods:** Methanol and phosphate buffer saline (pH 7.4) were the two solvents chosen for method development and results of validation parameters were calculated. **Results:** Methoxsalen showed maximum absorbance at 249 nm in methanol and at 247 nm in phosphate buffer saline (pH 7.4). The percent recoveries for determination of accuracy and repeatability were found within a suitable confidence interval of 98 %- 102 %. **Conclusion:** The developed method was evaluated quantitatively for accuracy, precision, robustness, ruggedness and other parameters.

Key words: Methoxsalen, UV- Visible Spectroscopy, Methanol, Phosphate Buffer Saline (pH 7.4),Validation.

INTRODUCTION

Methoxsalen is an anti-psoriatic drug which is also knows as xanthotoxin or 8-methoxypsoralen. It is extracted from the plant *Ammi majus* belonging to the family Apiaceae. The IUPAC nomenclature of this molecule is 9-methoxy-7H-furo [3,2-g] chromen-7-one. Tablets of 10 mg dose are widely prescribed by the physicians as a part of PUVA (Psoralen + UVA) therapy in the treatment of vitiligo and psoriasis.[1] Methoxsalen belongs to the class of furanocoumarins, a class of organic natural molecules which comprises of coumarin moiety annulated with furan[2] (Figure 1).

Psoralens are estimated and quantified using numerous analytical methods such as Reversed phase-High Pressure Liquid Chromatography (RP-HPLC),[1-7] ultra-performance liquid chromatography-tandem mass spectrometry (UPLC–MS/MS),[8] LC-MS-MS,[9] Ultraviolet-Visible Spectrophotometry (UV-Vis Spectrophotometry),[10] Thin-layer chromatography (TLC)[11] and other methods. The current literature exists with UV spectrophotometric determination of methoxsalen in different medium such as ethanol.[10]

Since the drug belongs to BCS Class II, it has poor solubility in aqueous media. This calls for the development and validation of an analytical method in a suitable organic solvent such as methanol. The accurate

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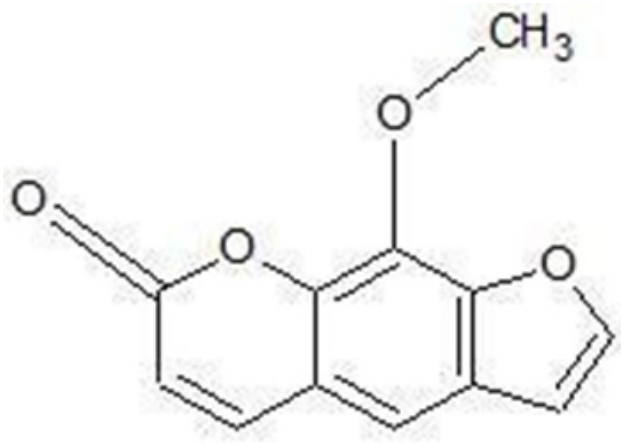

Figure 1: Molecular Structure of Methoxsalen.

and precise method developed in methanol would have wider applications in determining the entrapment efficiency of the drug-containing nanoformulations and in estimating drug content. Also, the development of the analytical method in simulated body fluids such as phosphate buffer saline (PBS) 7.4 would be applicable to determine the amount of drug penetrated in topical drug delivery systems.

The current research aims to develop a specific, accurate and precise analytical method and validate it as per ICH guidelines to ensure exact estimation of an analyte during routine analysis in two different solvents such as methanol and PBS (7.4).

MATERIALS AND METHODS

Instrument and apparatus

The measurement of the UV spectra and absorbance readings was conducted using the Jasco UV-Visible Spectrophotometer 625 model with bandwidth 1 nm, wavelength accuracy 0.2 nm and quartz cuvettes with 1 cm path length over the specific λ_{max} at 200-400 nm. The glassware used during method development and validation were treated with a mixture of sulphuric acid and chromic acid rinsed thoroughly with double distilled water and dried in the hot air oven.

Chemicals and reagents

Pharmaceutical grade methoxsalen was kindly provided as a gift sample from Gary Pharmaceuticals Ltd. India. All analytical grade chemicals, solvents and double distilled water were used to prepare the stock solutions and working standards. Disodium hydrogen phosphate, potassium dihydrogen phosphate and sodium chloride were procured from Loba Chemie Pvt Ltd.

Preparation of Phosphate Buffer Saline (pH 7.4)

Phosphate buffer saline was prepared by dissolving 2.38 g of disodium hydrogen phosphate, 0.19 g of potassium dihydrogen phosphate and 8.0 g of sodium chloride in sufficient quantity of double distilled water to produce 1000 ml and pH of the solution was adjusted with 0.1 M hydrochloric acid solution to 7.4 if necessary.[12]

Preparation of primary standard stock solution

A stock standard solution of 1000 µg/ml was prepared by dissolving accurately weighed 10 mg of pure drug in 10 ml of methanol.[13]

Preparation of secondary standard stock solution

From the primary standard stock solution, 1 ml of the aliquot was removed and diluted to make up the volume up to 10 ml with methanol in a volumetric flask which is equivalent to 100 µg/ml. During analytical method development in PBS; methanol was used as a solvent to prepare a secondary stock solution of 100 µg/ml since analyte is found to be insoluble in PBS at the concentration of 100 µg/ml.[13]

Preparation of the test solutions

To develop and validate a method in methanol, 0.1 ml, 0.2 ml, 0.3 ml, 0.4 ml, 0.5 ml, 0.6 ml and 0.7 ml of secondary stock solution was diluted to 10 ml of methanol to achieve the test solutions of concentrations 1 µg/ml, 2 µg/ml, 3 µg/ml, 4 µg/ml, 5 µg/ml, 6 µg/ml and 7 µg/ml respectively. The same procedure was followed and dilutions were made using phosphate buffer saline (pH 7.4) to develop the method in the PBS media.

Estimation of λ_{max} in media

The solution with a concentration of 10 µg/ml was scanned from 200 nm - 400 nm against both the media. The wavelength of maximum absorbance was recorded.

Method Validation

Method validation is the process of proving that a particular developed analytical method is acceptable for its intended use. The analytical method validated of an acceptable standard has to be proven for its trueness and usefulness. The method validation defines an analytical requirement that confirms the method under consideration has performance capabilities consistent with the desired applications. The progressively optimized analytical methods are furnished part of the Investigational New Drug (IND) application before the initiations of phase I clinical trials. The fully optimized and validated analytical methods are necessary to be developed before the New Drug Application (NDA) is submitted at the end of phase III of the clinical trials.

The final goal of method validation involves ensuring its applicability in the routine analysis.[14]

Specificity

The solution of strength 10 µg/ml of a drug was scanned from 200-400 in methanol and PBS (7.4) with respective solutions as a blank to determine λ_{max} (wavelength of maximum absorption) in both the media. This scanning helps us to determine the specificity of the method by studying the interactions of an analyte with these two media as a change in the spectra or shift in the wavelength of maximum absorption.[14]

Linearity and range

The series of concentration 1 µg/ml to 7 µg/ml was prepared and their absorbance was recorded at 249 nm and 247 nm to validate the method in methanol and PBS (pH 7.4) to confirm the linearity. The construction was calibration curve was carried out followed by the calculation of the linear regression equation and coefficient of correlation.[14]

Accuracy

Accuracy by recovery was evaluated through the standard addition method. In this, a known concentration of an analyte was added to the pre-analyzed samples. The concentration of 2 µg/ml was considered as 100 % and recovery studies were performed at its 50 %, 100 % and 150 % of the concentration as 1 µg/ml, 2 µg/ml and 3 µg/ml respectively. Mean % recovery and % RSD of the samples was calculated.[14]

Precision

The precision of the method was determined by measuring the absorbance of the particular concentration six times a day and carrying out the same measurements on the next day. The % RSD was calculated.[14]

Robustness

The robustness was evaluated by the stability study of methoxsalen on the same day and on two consecutive days. The mean and % RSD were calculated.[14]

Ruggedness

During this study, conditions like different analysts, reagents, laboratories, days, and other parameters are varied and the degree of reproducibility of the test is evaluated by measuring its absorbance. During the present work, the linearity was performed by two different analysts and the changes in the absorbance were recorded. The % RSD was calculated.[14]

LOD and LOQ

Limit of detection (LOD) and Limit of quantitation (LOQ) for the assay was calculated using the following formula[14]

$$LOD = 3.3 \times (Standard\ deviation\ of\ the\ y-intercept\ of\ the\ regression\ line \div Slope\ of\ the\ calibration\ curve)$$

$$LOQ = 10 \times (Standard\ deviation\ of\ the\ y-intercept\ of\ the\ regression\ line \div Slope\ of\ the\ calibration\ curve)$$

Application of the developed analytical method to determine an entrapment efficiency of methoxsalen loaded lipid nanocapsules

Methoxsalen loaded lipid nanocapsules (MOP-LNCs) were prepared by interfacial deposition of the preformed polymer method. The fixed quantity (1.5 ml) of lipid nanocapsule (LNC) dispersion was transferred to an eppendorf tube. The dispersion of loaded nanocapsules was separated by subjecting it to ultracentrifugation. Samples were centrifuged at 12000 rotations per minute (rpm) for 30 min. The pellet of nanocapsules entrapped with the drug was obtained at the sidewall of an eppendorf tube however unentrapped drug was present in the clear white supernatant. Clear supernatant (0.1 ml) was dissolved to prepare a 5 ml solution. The dilutions were performed with methanol if necessary and solutions were analyzed by UV-spectrophotometry against the solution of methanol prepared by treating the blank formulation in the same manner. All the estimations were done in triplicate. The entrapment efficiency was calculated using the formula as follows:[15]

$$Entrapment\ efficiency\ (\%) = [(Td - Tf) \times 100] \div Td$$

Whereas, Td= Total amount of drug added to the formulation and Tf= Amount of free drug present in the formulation. Entrapment efficiency was calculated using the indirect method of analysis.

RESULTS AND DISCUSSION

Specificity

Spectra for methoxsalen reference standard in methanol and PBS (7.4) are illustrated in Figure 2, 3. The λ_{max} of methoxsalen was found to be 249 nm and 247 nm in methanol and PBS (7.4). In the present study, no interfering peak of the drug was observed in above-mentioned media as shown in Figure 2 and Figure 3. The developed analytical method was found to be specific to the analyte.

Linearity

The drug was analyzed at a λ_{max} of 249 nm in methanol and the linearity range was found between 1µg/ml to

7 µg/ml. The absorbance of various concentrations at 249 nm and 247 nm is shown in Table 1. The linearity was confirmed for the drug in the range of 1 µg/ml – 7 µg/ml in both the media. The co-efficient of correlation (R^2) was found to be 0.9991 and the equation of the line was y = 0.1048x + 0.0071 in methanol as evident from the above calibration curve. For PBS (7.4) media, the coefficient of correlation (R^2) was found to be 0.9994 and the equation of the line was y = 0.1044x - 0.0044. Thus, the data shows that the response was found to be linear. This clearly indicates that an excellent correlation existed between absorbance and concentration of the analyte (Table 1, Figure 4, Figure 5, Table 2).

Accuracy

The result for accuracy at 50 %, 100 % and 150 % in various solvents are mentioned in Table 3. Accuracy ranged from 98.14 % to 100.92 % and 98.09 % to 100.76 % in the methanol and PBS (7.4) media, respectively. In the methanol, the percentage recoveries for lower, intermediate and higher concentrations were found to be 99.45 (2.99 µg/ml), 98.1416 (3.97 µg/ml) and 100.9298 (5.16 µg/ml), respectively. In PBS (7.4) the percentage recoveries for lower, intermediate and higher concentrations were found to be 100.76 (3.21 µg/ml), 99.53 (411 µg/ml) and 98.09 (4.99 µg/ml), respectively. So, with this proposed method even the small change in the concentration of an analyte can be accurately determined (Table 3).

Acceptance criteria: Mean recovery should be in the range of 98.0% - 102.0% as per ICH guidelines. The % mean recovery of the drug is within the acceptance criteria of 98.0% - 102.0%.

Precision

The data for the precision studies of inter-day and intraday is shown in Table 4 and Table 5. Repeatability (% R.S.D.) ranged from 0.018 % to 1.72 % and 0.013 to 0.11 % in the methanol and PBS (pH 7.4) medium, respectively, at all three levels of concentrations (Table 4 and Table 5). Repeatability results determine the precision under the same operating conditions over a short period of time and inter-assay precision. Relative Standard Deviation (RSD) values were within the acceptable range indicating that these methods have excellent repeatability and intermediate precision.

Table 1: Concentrations and absorbances for Reference Standard of Methoxsalen in Methanol and PBS (7.4).

Solvents	Methanol		PBS (7.4)	
	Concentration (µg/ml)	Absorbance at λmax of 249 nm	Concentration (µg/ml)	Absorbance at λmax of 247 nm7
1	1	0.1091	1	0.1171
2	2	0.2118	2	0.213
3	3	0.3334	3	0.3097
4	4	0.4245	4	0.4268
5	5	0.5363	5	0.5206
6	6	0.6269	6	0.6379
7	7	0.7433	7	0.7317

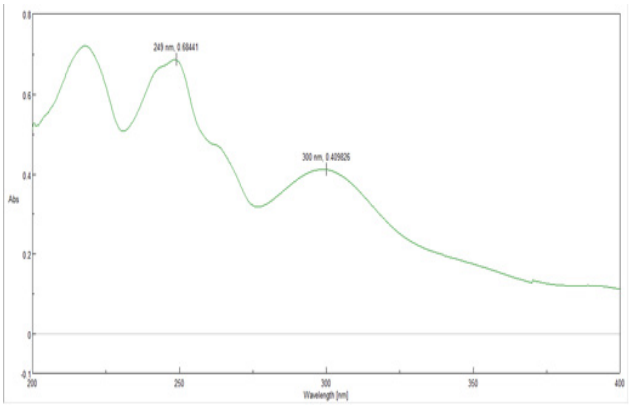

Figure 2: 10 µg/ml Spectra of Methoxsalen in Methanol.

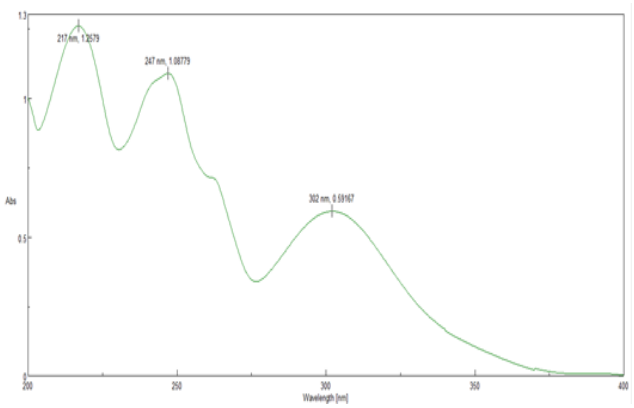

Figure 3: 10 µg/ml Spectra of Methoxsalen in PBS 7.4.

Acceptance criteria: The % RSD of six replicate of Standard solution should be not more than 2.0 % for both intraday as well as inter-day precision. The precision of the method for the standard solution of the above drugs shows that the RSD for both intraday and inter-day falls within the limits i.e. within 2 %.

Table 2: Characteristics of the UV-method by parameters of regression equations.

Sr. No.	Parameters	Methanol	PBS (7.4)
1.	λmax(nm)	249	247
2.	Concentration range (µg/ml)	1-7	1-7
3.	Regression equation	y = 0.1048x +0.0071	y = 0.1044x – 0.0044
4.	Slope (a)	0.1048	0.1044
5.	Intercept (b)	0.0071	0.0044
6.	Correlation coefficient (R2)	0.9991	0.9994
7.	Detection Limit (µg/ml)	0.05	0.05
8.	Quantification limit (µg/ml)	0.15	0.15
9.	Robustness (mean % recovery ± S.D.)	99.51 ± 1.4362	99.87 ± 1.145

Robustness

A small variation of pH of the selected media by ± 0.1 did not change the absorbance of the test solution significantly. The mean % recovery (± S.D.) were found to be 99.51 (± 1.4362) and (99.87 ± 1.145) in the methanol and PBS (7.4) media, respectively as shown in Table 2.

Ruggedness

The result validating ruggedness of the method is shown in Table 6. The ruggedness of the method for the standard solution of the above drugs shows that the Relative Standard Deviation (RSD) for both the analysts falls within the limits i.e. within 2%.

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

The results for LOD and LOQ are shown in the Table 7. The LOD and so on. LOQ of Model Drug was found to be 0.5 µg/ml and 1.5 µg/ml respectively. These values indicate that the method developed is sensitive.

Entrapment efficiency

The entrapment efficiency of the methoxsalen loaded lipid core nanocapsules (MOP-LNC) was found to be 82.65 ± 1.67 %.

Table 3: Results for Accuracy (by Recovery) in two solvents.

Drugs	Solvents	Levels	Working Concentrations (µg/ml)	Spiked Concentration (µg/ml)	Amount Recovered (µg/ml)	% Recovery	Mean Recovery (%)
Methoxsalen	Methanol	50 %	2	1	2.99	99.45	
		100 %	2	2	3.98	98.14	
		150 %	2	3	5.16	100.93	
	PhosphateBuffer (pH 7.4)	50 %	2	1	3.21	100.77	
		100 %	2	2	4.11	99.53	
		150 %	2	3	4.99	98.09	

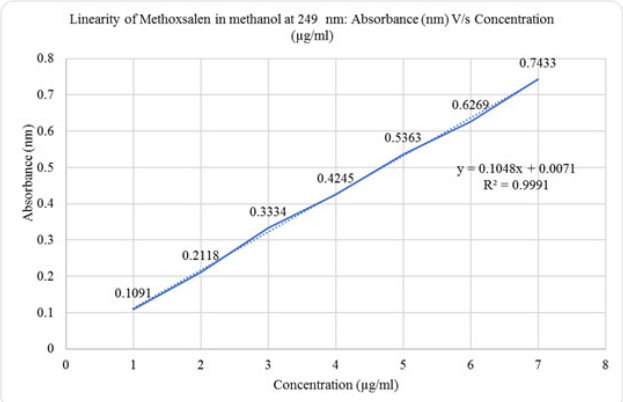

Figure 4: Standard Plot of Methoxsalen in Methanol.

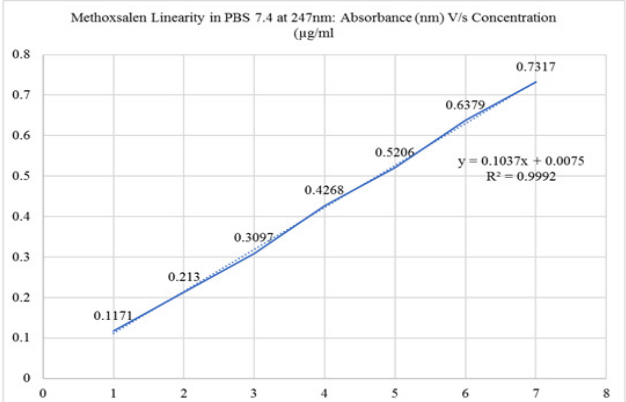

Figure 5: Standard Plot of Methoxsalen in PBS (pH 7.4).

Table 4: Results for Inter-day Precision in two solvents.

Solvents	Concentration (µg/ml)	Absorbance			Mean	Standard Deviation	% RSD
		M	A	E			
Methanol	4	0.4245	0.4248	0.4247	0.42	0.0001	0.04
	5	0.5363	0.5365	0.5366	0.54	0.0001	0.03
	6	0.6269	0.6269	0.6271	0.63	0.0001	0.02
Phosphate Buffer Saline (pH 7.4)	4	0.4268	0.4269	0.4268	0.43	0.00006	0.01
	5	0.5206	0.5207	0.5205	0.52	0.0001	0.02
	6	0.6379	0.6378	0.6381	0.64	0.0001	0.02

M: Morning; A: Afternoon; E: Evening

Table 5: Results for Intraday Precision in two solvents.

Solvents	Concentration (µg/ml)	Absorbance			Mean	Standard Deviation	% RSD
		Day 1	Day 2	Day 3			
Methanol	4	0.4245	0.4494	0.4391	0.44	0.01	1.72
	5	0.5363	0.5429	0.5386	0.54	0.003	0.62
	6	0.6269	0.6459	0.6319	0.63	0.009	1.55
Phosphate Buffer Saline (pH 7.4)	4	0.4268	0.4266	0.4259	0.43	0.0004	0.11
	5	0.5206	0.5208	0.5212	0.52	0.0003	0.06
	6	0.6379	0.6378	0.6381	0.64	0.0001	0.02

Table 6: Results for Ruggedness in Methanol and PBS (7.4).

Solvents	Concentration	Absorbance			Standard Deviation	% RSD
		Analyst 1	Analyst 2	Mean		
Methanol	1	0.1151	0.1165	0.12	0.0009	0.85
	2	0.2118	0.2169	0.21	0.0036	1.68
	3	0.3334	0.3415	0.34	0.005	1.69
	4	0.4345	0.4425	0.44	0.005	1.29
	5	0.5363	0.5310	0.53	0.003	0.70
	6	0.6269	0.6398	0.63	0.009	1.44
	7	0.7433	0.7564	0.75	0.009	1.23
Phosphate Buffer (7.4)	1	0.1171	0.1156	0.12	0.001	0.91
	2	0.2221	0.2233	0.22	0.0008	0.38
	3	0.3097	0.3115	0.31	0.001	0.41
	4	0.4268	0.4184	0.42	0.005	1.40
	5	0.5206	0.5215	0.52	0.0006	0.12
	6	0.6379	0.6325	0.63	0.003	0.60
	7	0.7317	0.7294	0.73	0.001	0.22

Table 7: Results for LOD and LOQ in various solvents.

	Methanol	Phosphate Buffer (7.4)
LOD	0.5 µg/ml	0.5 µg/ml
LOQ	1.5 µg/ml	1.5 µg/ml

CONCLUSION

UV-spectrophotometric method for determination of methoxsalen in methanol and PBS (7.4) was validated for analytical parameters: specificity, selectivity, linearity, LOD, LOQ, accuracy, precision and robustness. Results for accuracy and repeatability are within the limits as stated by ICH guidelines. The validated method can be applied for the determination of entrapment efficiency

of methoxsalen, to estimate the drug content in pharmaceutical dosage, to quantify the amount of drug penetrated through the skin layers when delivered by topical route of administration and so on.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

UV: Ultraviolet; **PBS:** Phosphate Buffer Saline, **IUPAC:** International Union of Pure and Applied Chemistry; **mg:** Milligram; **µg:** Microgram; **ml:** Millilitre; **µl:** Microlitre; **nm:** Nanometre; **cm:** Centimetre; **PUVA:** Psoralen + UVA; **RP-HPLC:** Reversed phase- High Pressure Liquid Chromatography; **UPLC–MS/MS:** Ultra-Performance Liquid Chromatography- Tandem Mass Spectrometry; **LC-MS-MS:** Liquid Chromatography- Tandem Mass Spectrometry; **UV-Vis Spectrophotometry:** Ultraviolet-Visible Spectrophotometry; **TLC:** Thin-layer Chromatography; **BCS:** Biopharmaceutical Classification System; **g:** gram; **IND:** Investigational New Drug; **NDA:** New Drug Application; **RSD:** Relative Standard Deviation; **LOD:** Limit of detection; **LOQ:** Limit of Quantitation; **rpm:** Rotations per Minute; **ICH:** International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

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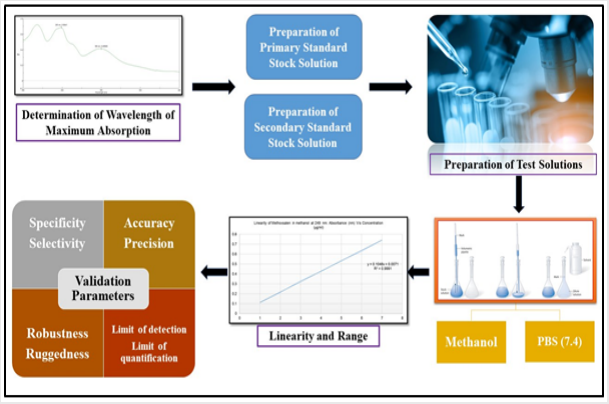
PICTORIAL ABSTRACT



SUMMARY

Analytical method was successfully developed for the determination of methoxsalen in the bulk drug using UV-Vis spectroscopy. The developed method was validated, and it indicated that the method is simple, robust, accurate, precise and stable. Development of analytical method of bulk drug in two different media such as methanol and PBS (7.4) has enabled us to determine the drug in organic solvent and biological fluids respectively and it has applications in variety of domains such as development of nanoformulations. The method clearly indicated that an excellent correlation existed between absorbance and concentration of the analyte since the co-efficient of correlation (R2) was found to be 0.9991 and 0.9994 in methanol and PBS (7.4) The percent recoveries for determination of accuracy, repeatability, robustness and ruggedness were found within a suitable confidence interval of 98 %- 102 %.

About Authors

Shraddha Unde is supporting business quality operations at a renowned organization and pursued a Master's in Pharmacy in Pharmaceutics from K. M. Kundnani College of Pharmacy, affiliated to University of Mumbai. Her research mainly focused on the formulation and development of a nano-carrier system for the treatment of inflammation and psoriasis. She worked on analytical method development for synthetic drugs and evaluated formulations for their skin irritation potential.

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