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Development, Validation, Identification and Estimation of Quinoline Yellow in the Levodopa and Carbidopa Pharmaceutical Combined dosage form by Ultra violet Visible Spectrophotometer

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ABSTRACT

A simple, cost-effective, précised, accurate and robust Ultra Violet spectrophotometric method [1, 2] has been developed for the Identification and estimation of Quinoline Yellow in the Levodopa and Carbidopa tablet dosage forms. It is used as a colourant in the pharmaceutical tablet's dosage form. UV scan of Quinoline yellow was taken from the entire UV range of 200 to 800 nm. From the spectrum, maximum absorption was observed at 414nm (λmax) for the Quinoline Yellow. Method was found to be specific with no interference due to blank and placebo, The method was linear with a correlation coefficient of more than 0.999, and Accuracy was in the range of 98.3 to 101.3, In the robustness study employed for standard and sample preparation showed no impact on the results, by deliberate changes proves method is robust and can be utilized for regular analysis. Method validation was performed with reference to ICH guidelines Q2R1

Keywords : Quinoline Yellow, Levodopa and Carbidopa, Pharmaceutical Drug, Ultraviolet Spectrophotometric.

I. INTRODUCTION

Quinoline yellow is usually obtained from the spirit-soluble dye of Quinoline yellow [3]. It consists of sulfonate groups which are water soluble and it is the combination of the organic compounds. Application of Quinoline yellow is used as a colourant or dye [4,5] in various cosmetics and pharmaceutical industries.

It is used in Levodopa and Carbidopa tablets as a colourant. As per European regulatory [6,7,8] any colour used in pharmaceutical dosage form, for this purpose identification test is mandatory. Whereas Levodopa and Carbidopa tablets is used to cure Parkinson's disease. Different TLC methods are available for synthetic food dyes [9,10] Literature search for was done for the Quinoline yellow method, various HPLC [11,12] method was available for the

dyes, all the methods were for mix dyes. No individual method was available for Levodopa and Carbidopa tablets colour identification test. Therefore, it was decided to develop and validate an easy and cost-effective UV spectroscopy technique [14] were considered and finalized. Chemical name of Quinoline yellow is Sodium 2-(2-quinolyl)-indan-1,3-dionedisulfonates and related mono- and tri-sulfonates [15] Molecular Formula $C_{18}H_9NNa_2O_8S_2$ Molecular Weight is 477.38

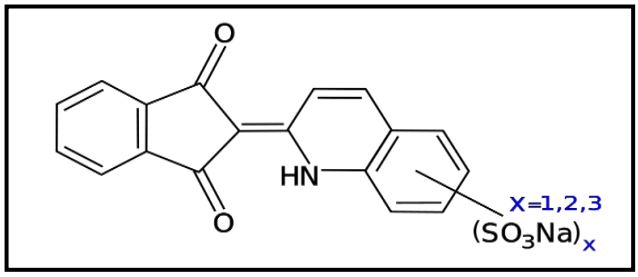


Figure 1: Structure of Quinoline Yellow

II. METHODS AND MATERIAL

The instrument used for Analysis: Ultra Violet Visible Spectrophotometer 1800 make Shimadzu
1cm path-length Quartz cell was used [16].
Reagents and chemicals: Purified water has been used for standard and sample preparation.
Standard solution preparation
Weighed and transferred about 13.121mg of Quinoline Yellow standard in a 100 mL standard volumetric flask. Added 60mL of diluent and sonicated for 15 minutes with intermittent shaking, further diluted up to the mark with diluent. From the above solution, 5 mL solution was taken in 100 mL volumetric flask and diluted up to the mark with diluent.

Test solution preparation

The average Weight of 20 tablets was calculated, further tablets were crushed and transferred four tablets equivalent of Quinoline Yellow in 100 mL volumetric flask. 60 mL of diluent was added and sonicated for 15 minutes with intermittent shaking, further diluted up to the mark with diluent. Filtered the solution 0.45µm PVDF filter, from above solution 5 mL solution was taken in 20 mL volumetric flask and diluted up to the mark with diluent.

Placebo solution preparation

Weighed and transferred the placebo of four tablets equivalent of Quinoline Yellow [17] in a 100 mL volumetric flask. Added 60mL of diluent and sonicated for 15 minutes with intermittent shaking, further diluted up to the mark with diluent. Filtered the solution 0.45µm PVDF filter, from above solution 5 mL solution was taken in 20 mL volumetric flask and diluted up to the mark with diluent.

Experimental Procedure: Correction was done with blank solution, and scan was taken for Blank solution, placebo solution and test solution, Scanning was done for the entire Ultra Violet visible range from 200 nm to 800 nm with medium scanning speed. Lambda max was identified which showed maximum adsorption at the wavelength of 414 nm [18,19].

III. METHOD DEVELOPMENT

Various solvent was tried, with different combinations for the sample and placebo preparation, in the placebo solution interference was observed with water: methanol (50:50) v/v and other combinations. Therefore, it was decided to proceed with purified water in which no interference was observed. On the successful method development further, Validation [20,21] was carried out on the below-mentioned parameters.
Specificity
The specificity of Quinoline Yellow was evaluated for the interference due to Blank, Placebo, Standard preparation and test preparation, all the preparations were scanned between 200 to 800 nm. Based on the spectrum of blank and placebo, it is concluded that there is no interference of blank and placebo at the maxima of Quinoline Yellow.

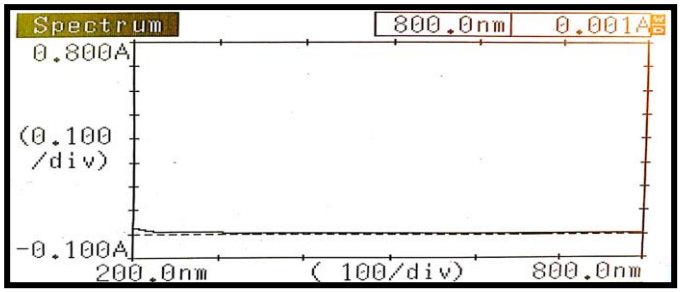


Figure 2 Spectrum of Blank

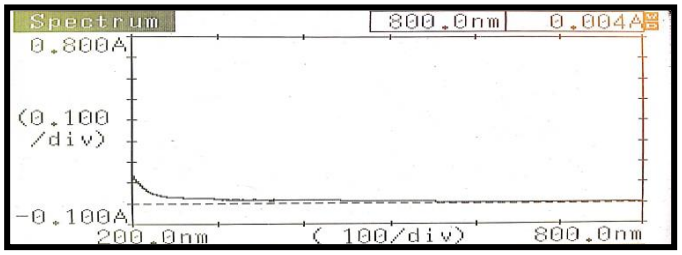


Figure 3 Spectrum of Placebo

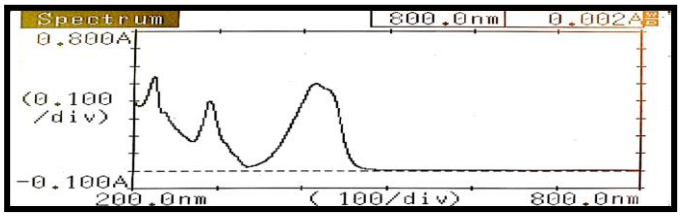


Figure 4 Spectrum of Quinoline Yellow Standard

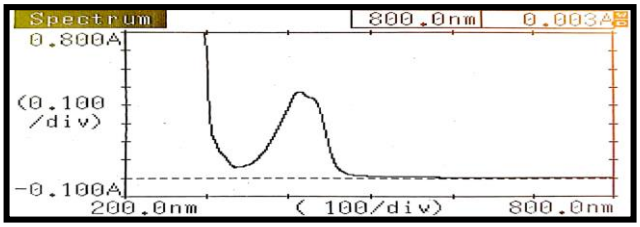


Figure 5 Spectrum of test preparation

Precision

Precision was checked by analyzing six replicate readings of the standard solution, percent relative standard deviation was not more than 2.0. Method precision of the sample was performed by preparation of six individual samples, obtained results are not more than 2.0%

Table 01. Summary of % content of Quinoline Yellow

Sr.no	Test Preparation	% Content
1.	Preparation-1	99.4
2.	Preparation-2	100.2
3.	Preparation-3	98.4
4	Preparation-4	98.1
5	Preparation-5	97.6
6.	Preparation-6	98.3
	Mean	98.7
	% RSD	0.99

Intermediate Precision

Intermediate Precision was performed on different days, with another analyst to check the exactness of the method, from the obtained results showed that it had no impact due to analyst change. The percentage relative standard deviation is not more than 2.0%

Table 2. Summary of intermediate precision % content of Quinoline Yellow

Sr.no	Test Preparation	% Content
1.	Preparation-1	99.2
2.	Preparation-2	98.1
3.	Preparation-3	97.7
4	Preparation-4	100.2
5	Preparation-5	98.5
6.	Preparation-6	99.7
	Mean	98.9
	% RSD	0.97

Overall % RSD of Precision and Intermediate precision was within 2.0% acceptance criteria

Linearity

Linearity is the capacity of the analytical method to produce the results, directly proportional to the concentration of the analyte in the samples within the given range.

It is performed with Quinoline yellow in the range of 50% to 150% of the working concentration

Recorded the area response at each level and calculated the slope correlation coefficient. plotted the graph of concentration in ppm on the x-axis and absorbance on the Y-axis

Table 3. Linearity of Quinoline Yellow

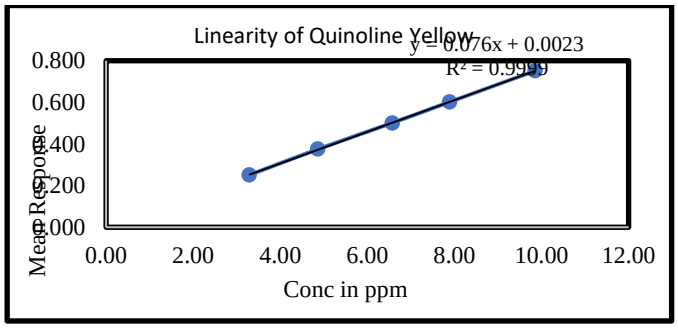
Linearity Level	Conc. of Quinoline yellow µg/mL	Mean Response
Level-1 50%	3.29	0.251
Level-2 75%	4.86	0.375
Level-3 100%	6.57	0.501
Level-4 120%	7.89	0.602
Level-5 150%	9.86	0.752

Table 4. Summary of Linearity

	Results	limits
Coefficient of Correlation	0.99996	NLT 0.995
Slope	0.08	-
Intercept	0.00	-
% Y- Intercept	0.46	± 2.0%

From the above data of linearity, it met the Acceptance criteria in the given range of 3.29 µg/mL to 9.86 µg/mL.

Table 5. Linearity Plot of Quinoline Yellow



Accuracy

The Accuracy of an analytical method was established across its range by analyzing at three levels. It was performed by spiking standard into placebo at 50%, 100% and 150% levels with respect to 100% specification level.

Table 6. Quinoline Yellow Recovery at various levels

Accuracy Level	% Recovery of Quinoline Yellow	Mean	% RSD
50%	98.5	99.3	0.80
	100.1		
	99.3		
100%	98.9	99.1	0.81
	98.3		
	99.9		
150%	101.3	99.7	1.49
	98.4		
	99.3		
Overall Mean		99.4	

The accuracy of all three levels is between 98.0 to 102.0. The % RSD for % recovery at each level is Not more than 2.0%

Filter study Validation

It is performed to check the suitability of the filter and to know whether any drug is retained on the filter, two different filters are used to check the filter suitability. Sample solutions are filtered through 0.45um PVDF and 0.45um Nylon filter and compared with the centrifuged sample.

Table 7. Filter interferences study

	% content	% variation
Centrifuged sample	98.9	-
0.45um PVDF filter	98.3	0.6
0.45um Nylon filter	98.1	0.8

The % variation between the % content obtained by using different filters is not more than ± 2.0

Robustness.

The robustness of an analytical method is a measure of its capacity to remain unaffected by intentional variations in the method parameters and provides an indication of its reliability during normal usage.

Table 8. Robustness study summary

Parameter under study	% RSD of standard solution	% content Quinoline Yellow
Unaltered as per method	0.27	99.4
Change in sonication time of the sample		
10 minutes	0.39	99.6
20 minutes	0.43	98.4
Wavelength Alteration		
412	0.63	99.3
416	0.34	97.9

%RSD of the standard solution and % content of Quinoline Yellow is within the limit and comply with the acceptance criteria.

IV RESULTS AND DISCUSSION

The current method for the estimation of Quinoline Yellow [22] showed the method is specific with no interference of blank and placebo, it is soluble in water whereas other active ingredients Levodopa and Carbidopa are insoluble in water. In the method precision, the relative standard deviation for % content of six preparations meets the acceptance criteria. Hence the method found précised. The percentage relative standard deviation for 12 samples from precision and intermediate precision, that is % content found within the acceptance limit of 2.0%. It shows that the method is found to be rugged. From the statistical treatment of the linearity data, it is evident that the UV response is linear from 50 to 150% of the working concentration. Hence the method was found linear within the range of the Quinoline Yellow. The mean % Recovery and % relative standard deviation is well within the limits. Hence the method is considered Accurate. In the filter validation study % content differences between centrifuged sample and 0.45um PVDF filtered and 0.45um Nylon filtered sample met the acceptance criteria. Hence it is concluded that both filters are suitable and can be used for sample preparation. The robustness parameter was performed for the change in sonication time and alteration of wavelength parameters, both the parameters met acceptance criteria. Hence, the method is found robust for the mentioned parameters.

Conflict of Interest

There is no conflict of interest.

V. CONCLUSION

A rapid simple and cost-effective ultraviolet spectroscopy method was developed and validated for the estimation of Quinoline yellow in the pharmaceutical tablet dosage form which complies with regulatory guidelines. Based on the results, this method is suitable for the identification of Quinoline Yellow in Levodopa and Carbidopa tablets dosage forms. All the parameters met acceptance criteria, therefore current method can be used for routine analysis.

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