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Development and Validation of UV Spectrophotometric Method for determination of Bisacodyl in Suppositories

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Abstract: A simple, precise, accurate, rapid and economical method for determination of bisacodyl has been developed using UV spectrophotometry. The determination was carried out at absorption maxima of 264nm using methanol and 1M glacial acetic acid as solvents. The analytical method was validated for linearity, accuracy, robustness and specificity and system suitability for both the solvents namely methanol and 1M glacial acetic acid. The method used for determination of bisacodyl using solvents (methanol and 1M glacial acetic acid) complies with the acceptance criteria set for the aforementioned analytical parameters. Hence, the current method stands validated. The currently developed method can be used for routine QC quantitation of bisacodyl in Suppositories.
Keywords: bisacodyl, UV spectrophotometry, suppositories, 1M glacial acetic acid, methanol.

INTRODUCTION:

Bisacodyl is a laxative usually administrated on a short-term basis for treatment of constipation. It also is used to empty the bowels before surgery and examinations such as X-ray procedures using barium enemas.[1] When given as suppositories; it stimulates the rectal mucosa, which increases peristaltic movements and causing defecation in 15-30 minutes.[2,3,4] It chemically belongs to Diphenylmethane class with chemical name 4,4'-(pyridin-2-ylmethylene)bis(4,1-phenylene) diacetate[5] [Figure 1]

Literature survey reveals a few suggested methods for determination of Bisacodyl like continuous square-wave voltammetric study,[6] HPLC method,[7] HPTLC method,[8] potentimetric method based on ion pair complex of bisacodyl and phosphotungstate,[9] reverse phase liquid chromatography based on the hydrolytic degradation products of Bisacodyl namely: monoacetylbisacodyl and desacetylbisacodyl.[10] The suggested HPTLC and HPLC methods are expensive and require sophisticated instrumentation and lot of solvent consumption adds to the cost of the assay.

The spectroscopic methods are not reported in the literature, since Bisacodyl is insoluble in water[11] and the Indian Pharmacopoeia suggests non-aqueous titrimetric method for determination of bisacodyl[12], but the current method suggests a simple, precise, accurate, selective and rapid method for determination of bisacodyl, using methanol and 1M glacial acetic acid as solvents.

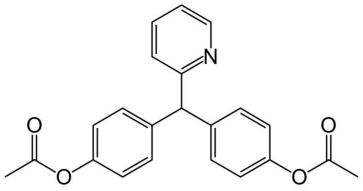

Figure 1: Bisacodyl structure

METHODS AND MATERIALS:

Elico SL-159 UV-visible spectrophotometer equipped with a matched quartz cells ultrasonic bath was used to carry out the assay. Spectroscopic determination was carried out at absorption maxima of 264nm using methanol as first solvent and 1M glacial acetic acid as

the second solvent. The bisacodyl suppositories of 5mg and 10 mg were extracted using 1M glacial acetic acid and methanol.

Method using methanol: Suppositories 10 in number were powdered and weight equivalent to 10mg of bisacodyl was transferred to 100mL volumetric flask. Methanol was added and shaken vigorously for 15 min, and then volume was made up using same solvent. 4mL of this solution was further dilute to 10mL using same solvent and the absorbance was checked at 264nm.

Method using 1M glacial acetic acid: Suppositories 10 in number was powdered and weight equivalent to 10mg of bisacodyl was transferred to 50mL volumetric flask. 1M Glacial acetic acid was added and shaken to dissolve and the volume was made up using the same solvent. 0.5mL of this solution was diluted further to 10mL using same solvent and absorbance was checked at 264nm.

Table 1: Quantification results of bisacodyl in suppositories formulation

LABEL CLAIM	ASSAY	
	METHANOL	1M GLACIAL ACETIC ACID
5 mg	99.5%	99.6%
10 mg	99.6%	99.4%

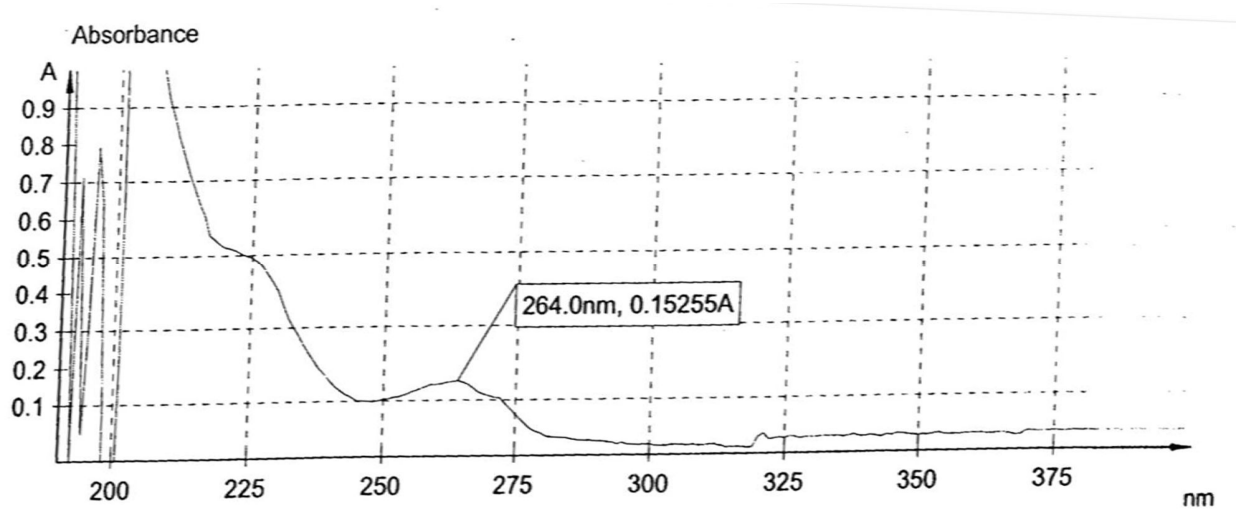

Figure 2: UV scan of Bisacodyl using methanol

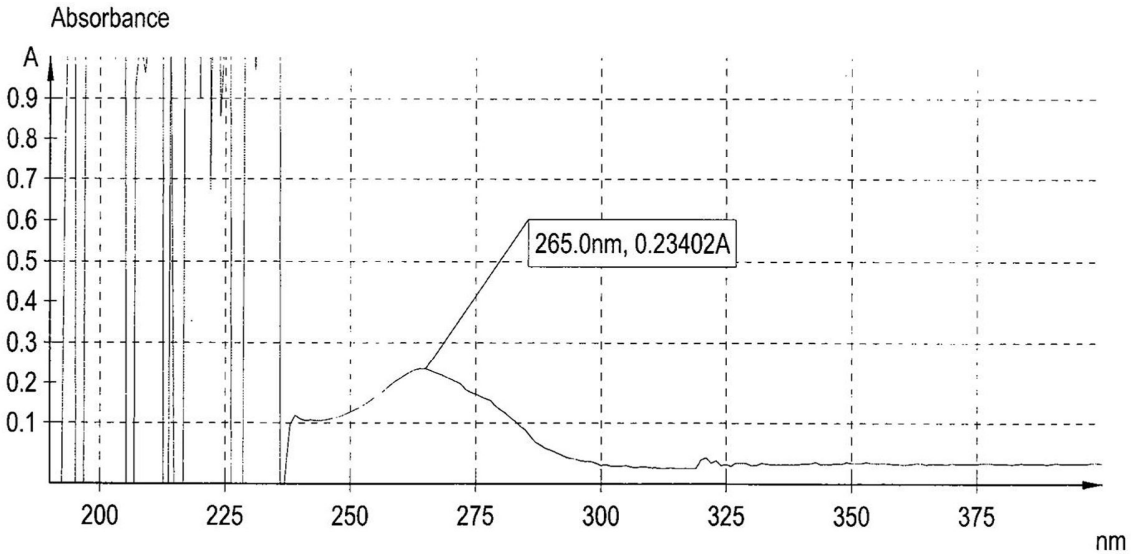

Figure 3: UV scan of bisacodyl using 1M glacial acetic acid

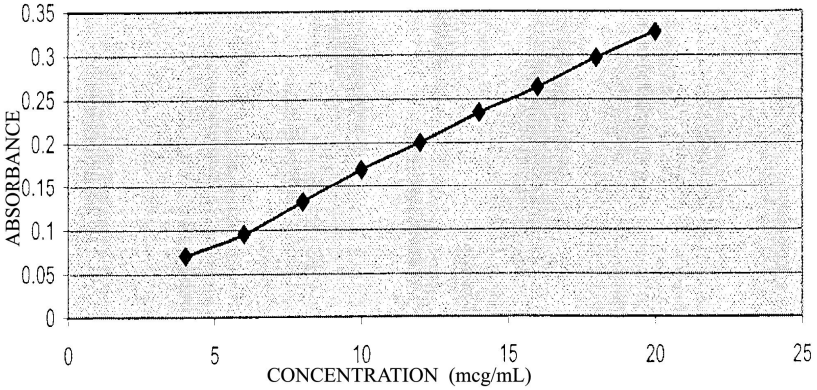

Figure 4: Linearity experiment using methanol

VALIDATION:

The method was validated for linearity and range, precision, specificity and system suitability, robustness, accuracy for both solvents (methanol and 1M glacial acetic acid)

For methanol

Linearity and range: The absorbance of the solution containing bisacodyl in the concentration range of 4% to 20% of the working level was determined. The absorbance was found to be linear with respect to concentration. The linearity regression coefficient was found to 0.9995 (Not less than 0.999) and %Y-intercept was 1.7204 (within ±2.0).

Precision: %RSD for the assay carried out on six samples was found to be 0.48% (Not more than 2%) and assay in percentage was found to be 99.29% (98.0% to 102.0%).

Accuracy: The recovery of the solutions containing concentrations in the range of 5%, 10% and 20% spiked in working level was determined. The similarity factor between the standard sample and test sample was found to be 1.00 and %assay was 98.72% to 101.67% (98% to 102%).

Ruggedness: The ruggedness of the method was established by having performed the precision study by another analyst, the %assay of bisacodyl was found to be 98.91% (between 98% to 102%), similarity factor between two sample preparations was 0.99 (0.98 to 1.02) and %RSD of ruggedness study was 0.33% (Not more than 2.0%).

Specificity and system suitability: The blank (methanol) and sample solution were scanned in the range of 190-400nm no interference due to blank and sample (limit not more than 1.0%) was observed at 264.0nm. system suitability was determined by measuring the absorbance of standard solutions, similarity factor between two solutions was found to be 0.98 (0.98 to 1.02).

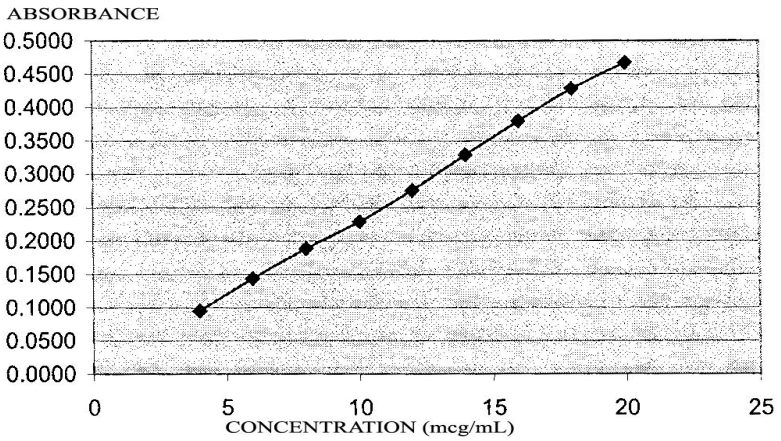

Figure 5: Linearity experiment using 1M Glacial acetic acid.

For 1M Glacial acetic acid

Linearity: The absorbance of the solutions containing concentrations of bisacodyl in the range of 4.0% to 20.0% of the working level was determined. The absorbance was found to be linear with respect to concentration. The linearity regression coefficient was found to 0.9995 (Not less than 0.999) and %Y-intercept was -0.6719 (within ±2.0).

Precision: %RSD for the assay carried out on six samples was found to be 0.26% (Not more than 2%) and assay in percentage was found to be 99.15% (98.0% to 102.0%).

Accuracy: The recovery of the solutions containing concentrations in the range of 5%, 10% and 20% spiked in working level was determined. The similarity factor between the standard sample and test sample was found to be 1.00 and %assay was 99.36% to 101.37% (98% to 102%).

Ruggedness: The ruggedness of the method was established by having performed the precision study by another analyst, the %assay of bisacodyl was found to be 98.91% (between 98% to 102%), similarity factor between two sample preparations was 0.99 (0.98 to 1.02) and %RSD of ruggedness study was 0.33% (Not more than 2.0%).

Specificity and system suitability: The blank (methanol) and sample solution were scanned in the range of 190-400nm no interference due to blank and sample (limit not more than 1.0%) was observed at 264.0nm. System suitability was determined by measuring the absorbance of standard solutions, similarity factor between two solutions was found to be 1.01(0.98 to 1.02).

CONCLUSION:

The developed method was simple, accurate and reproducible when compared with titrimetric method given in the Indian Pharmacopoeia. The spectrophotometric method can also be applied for routine QC analysis of the finished formulations.

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