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TO DEVELOP UV-VISIBLE SPECTROSCOPIC METHOD FOR ESTIMATION OF METFORMIN HCL IN TABLET DOSAGE FORM

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ABASTRACT

A simple analytical spectroscopic method for estimation oeveloped for Metformine HCl in tablet dosage form. This method is rapid, sensitive, & specific UV-Visible method was Metformine HCl in tablet dosage form, The analysis complied with Beer's law in the concentration range 8-13µg/ml at λmax 233nm for Metformine HCl. For this method Distlled Water is used as solvent. The validation of Metformine HCl in tablet dosage form was performed as ICH guidlines for linearity, precision, accuracy, limit of detection, limit of quantitation. This proposed method was successfully applied for the quantitative determination of Metformine HCl in tablet dosage form.

KEYWORDS: Metformine HCl(MET), LOQ, LOD.

INTRODUCTION

In market MET is available to treat type-2-diabetes in tablet dosage form. This type of diabetes is a due to long-term metabolic disorder where as the body becomes resistant to the effects of insulin, a hormone that regulates sugar absorption. For quantitative estimation of MET several method is used such as HPLC with UV-detection, or Flurosence with UV-detection & Capillaryelectrophorosis (CE) with UV-detection. From above mentioned & other some methods are tedious, time – consuming & economic involving complex sample preparation using high price solvent. For this many more problem need to devlopement of new method which is simple, sensitive, effective, economic methods and hence the present work is to be planned to validate the UV-spectroscopic method for MET in tablet dosage form, By measuring some following measurable parameter such as accuracy, precision,

linearity And limit of quantitation, limit of detection, recovery study as per ICH guidlines.[6,7,8,9]

EXPERIMENTAL METHOD

MET was recived as gift sample in tablet form from local market. Each uncoated tablets conatins Metformine HCl IP 500mg and Director, Callidus Research Lab. Pvt. Ltd, Chakan, Pune, for providing the gift samples of metformin hydrochloride. Distilled water is used as solvent which is procured from our college. For experimental analysis by using UV-spectroscopy (LABINDIA UV 3000). UV-Visible spectrophotometer with 1cm matched quartz cells was used for the measurement of the absorbance. For sample weighing electronic balance (way-MAX, Cap = 300gm) was used.

Method Development

Selection of λmax by preparing stock solution (100mg in 100ml Dist. water) it is stock I solution. From this take 10ml & dilute upto 100ml by dist.water (100µg/ml) stock II solution. From this take 1ml & dilute to 10ml by dist. Water (10µg/ml). This 10 µg/ml solution is scanned at wavelength range from 400-200nm and from this 233nm was selected as λmax for further analysis. The series of different concentration range such as (8-13 µg/ml) for MET was prepared from working standard solution. This concentration range was analysed at λmax 233nm. The calculated values were the mean of 3 independant determination. By this check the validity with the accordance of parameter including accuracy, precision, and LOD, LOQ.[8,9]

Sample Preparation

20 tablets was accurately weighed and finely powdered by using morter and pestel. About 100mg equivalent of MET was poured in 100ml volumetric flask and add 25ml dist.water. Filter the above solution in 100ml volumetric flask and made up volume by dist.water(1000 µg/ml). From this solution withdarw 10ml solution in 100ml volumetric flask and dilute by using dist.water as solvent (100 µg/ml). Take 1ml from above solution to 10ml volumetric flask and made up volume by using dist.water as solvent(10 µg/ml). This prepared solution was analysed for UV-detection. The absorbance of sample and standard preparation was measure at λmax 233nm using dist. water as blank.[1,2,3,4]

RESULT AND DISCUSSION

The above proposed UV- spectroscopic method for MET requires less reagents and it is very simple, very less time consuming, also less economic process. The above mentioned method for MET should be used in quality control testes in pharmaceutical industries; Calibration curve of Std MET is shown in figure-1 and their data given in table no- 1. The obtained values after performing analysis were with in the standard range. This validation parameter results shown in table no -2. The response for the detector was determined to be linear over the range of 8-13 µg/ml. This proposed method was evaluated for, it's intercept and it's correlation coefficient value calculated in the statistical study. They were represented by the linear regression equation; Y MET = 0.07525 X + 0.051167.

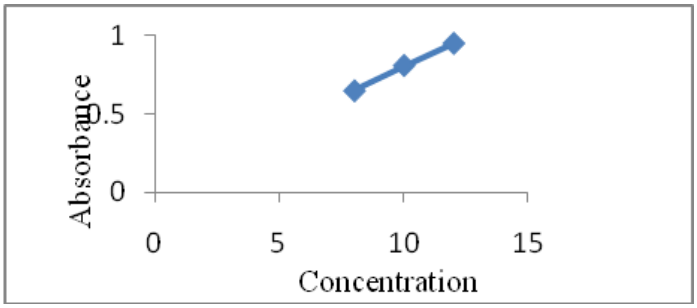

Fig 1: Linerity Study of MET HCl In Tablet Formulation.

Table 1: Assay of metformine HCl.

Sr.No.	Concentration (µg/ml)	Absorbance
1.	8	0.654
2.	10	0.810
3.	12	0.951

Table 2. Analytical method validation.

Validation Parameter	MET HCl
Correlation coefficient (r^2)	0.999337
Slope(m)	0.07525
Intercept(c)	0.051167
Accuracy	100.07
LOD(µg/ml)	0.835
LOQ(µg/ml)	2.531
Recovery (%)	99.87
Specificity	Specific
Linearity(r^2)	0.999337
Intraday precision,%RSD	1.29
Interday precision,%RSD	0.81

**LOD is the limit of detection while *LOQ is limit of quantification, *RSD is a relative standard deviation and r^2 is Correlation coefficient.*

The slopes and intercept were obtained by using regression equation (y = mx + c), where 'r' value is 0.999337 and confirmation of linearity by using least square method to treatment of result were then linearity confirmed. The accuracy of this method was determined by recovery studies. For this recovery studies were carried out 9 times and % recovery were calculated. From the obtained data, we found that from recoveries of standard drug were found to be accurate (Table no.3).

Recovery Study of Metformin HCl

The Recovery Studies were carried out by adding known amount of standard solution of metformin HCl to pre-analysed tablet solution. The resulting solution wre re-analysed at λmax 233nm. The recovery studies carried out at three different levels i.e 80%, 100% and 120%.

Table 3: Recovery studies of metformin HCl.

Sr.No.	%Recovery / concentration	Test	Standard	Absorbance of sample	% Recovery
1.	80	10	8	1.412	99.62
2.	80	10	8	1.413	99.75
3.	80	10	8	1.414	100.00
4.	100	10	10	1.570	99.70
5.	100	10	10	1.572	100.00
6.	100	10	10	1.571	99.80
7.	120	10	12	1.730	100.00
8.	120	10	12	1.732	100.16
9.	120	10	12	1.729	99.83
Mean					99.87

This method is specific, simple and very less time required to analyze the samples. Also in this method used solvent is economic and easily available. Low limit of quantification and limt of detection makes this method suitable for use in quality control testing.

CONCLUSION

In the present study, we found that new developed method for metformin HCl. The developed new method found to be precise, accurate and economic.

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