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Separation and Validation of Manganese in Various Multimineral Formulations by using UV Spectrum Technique

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ABSTRACT

Manganese is necessary for the proper function body containing enzyme & the necessary small size nutrient for the function of the brain, nervous systems or normal growth. It optimizes enzyme and membrane transport function. It plays an role in the plants respiratory process such as oxidation of carbohydrate to CO_2 and H_2O. This process is catalysed by enzyme which activated by manganese. The deficiency of manganese has been observed main with vitamin deficiency, similar to other essential metal both excess on deficiency of manganese in the bad cause serious impairment of vital physiological and biochemical process. Lot of time and resources are used to separation and identification of manganese. The most of case Manganese are separate by using atomic absorption spectroscopy & radio analytical process. The costly and time-consuming method are difficult in all formulation are separate manganese. We are developing a new method are very accurate and reproducible result at wavelength 525nm in UV spectrophotometer. Oral solution, Tablets, Capsule formulation was separated and identified in same method. Potassium meta iodate are catalyst in colorimetric reaction used manganese detection. That type methods first choice to upcoming research of method development in analytical R&D.

Keywords: Manganese deficiency, separation & identification of manganese, colorimetric reaction, validation

Abbreviations: UV- Ultraviolet, ICH- International conference of harmonization

I. INTRODUCTION

Manganese is necessary for the proper function body containing enzyme & the necessary small size nutrient for the function of the brain, nervous systems or normal growth. It optimizes enzyme and membrane transport function. It plays an role in the plants respiratory process such as oxidation of

carbohydrate to CO_2 and H_2O. This process is catalysed by enzyme which activated by manganese Manganese deficiency has been observed main with Vitamin K deficiency, similar to other essential metal both excess on deficiency of manganese in the bad can cause serious impairment of vital physiological and biochemical process. Mental behaviour, drowsiness & other related symptom or disease. The analysis of manganese in biological and environmental sample is usually performed using radioanalytical and atomic absorption spectrometric methods. These types of instruments are required research and development department in pharmaceutical industry. The alternative method develops tress analysis of manganese using UV spectroscopic method.

Spectroscopy is a branch of science concerned with the investigation & measurement of spectra product when matter interacts with or emits electromagnetic radiation. It is a branch of science that deals with interaction of matter with light or electromagnetic radiation [1]. Spectral measurement devices are referred to as spectroscopy. Spectrophotometers, spectrograph or spectral analysers. Spectroscopy as a science began with Isaac newton splitting light with a prism and was called Optics [2]. Until recently all spectroscopy involved the study of line spectra and most spectroscopy still does[3]. Vibration spectroscopy is the branch of spectroscopy that studies the spectra[4].

Fig. 1. Shimadzu 1900 UV Spectrophotometer

II. MATERIALS AND METHODOLOGY

Standard solution [25ppm]: Weigh accurately and transfer about 100 mg of manganese Sulphate in 100 mL volumetric flask. Add 5 mL of phosphoric acid, about 20 mL of water and sonicate to dissolve for about 5 minutes. Dilute to volume with water and mix. Transfer 5 mL of this solution in 50 mL volumetric flask, dilute to volume with water and mix.

Sample Preparation [Oral solution, Tablets Capsule formulation]:

Weigh accurately and transfer about 5.0 g of oral solution sample, 1.5 g tablets & 1.34 g of capsule sample in each separate silica crucible. Digest on a hot plate for about 20 minutes. Add about 0.15 g powdered sodium hydroxide (sprinkled on a sample surface) and digest for about 10 minutes. Cautiously, moisten the charred mass with 1 mL of sulfuric acid added drop-wise. Ignite at 650°±25° for about 30 minutes, then until sample cool at room temperature. Dissolve the residue in 5 mL of phosphoric acid and transfer all the solution into a 100 mL volumetric flask. Rinse the silica crucible with 4 x 10 mL of water. Dilute to volume with water, sonicate for about 10 minutes and mix. Filter the solution through 0.45 µ membrane filter.

Procedure

Transfer 20 mL of standard solution and test solution into a 30 mL capacity stoppered test tubes. Add 0.5 g of potassium metaperiodate, sonicate for about 5 minutes and mix. Loosely stopper the test tubes and heat on a boiling water-bath for about 20 minutes. Allow to cool and mix.

Measure the absorbance of standard solution and test solution in 1 cm cell on a suitable UV-Visible Spectrophotometer at 525 nm, using water as blank

III. RESULT AND DISCUSSION

VALIDATION RESULTS:

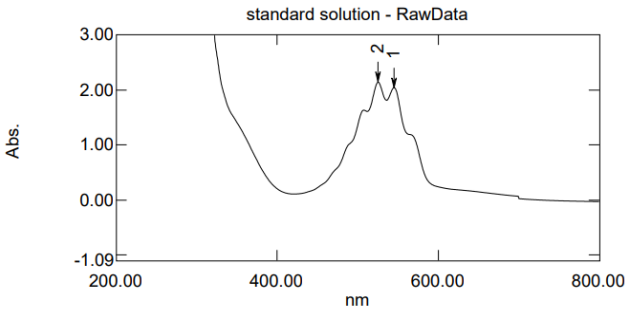
The validation data is summarized as below:

System Suitability: It is demonstrated by making five replicates of standard solution as per the analytical method described above. The absorbance in each replicate of standard solution was recorded and results are reported in Table 1.

Table 1 : System Suitability

Sr. No.	Absorbance
1.	0.582
2.	0.576
3.	0.571
4.	0.578
5.	0.563
Average	0.574
SD	0.007
% RSD	0.013%

Specificity:



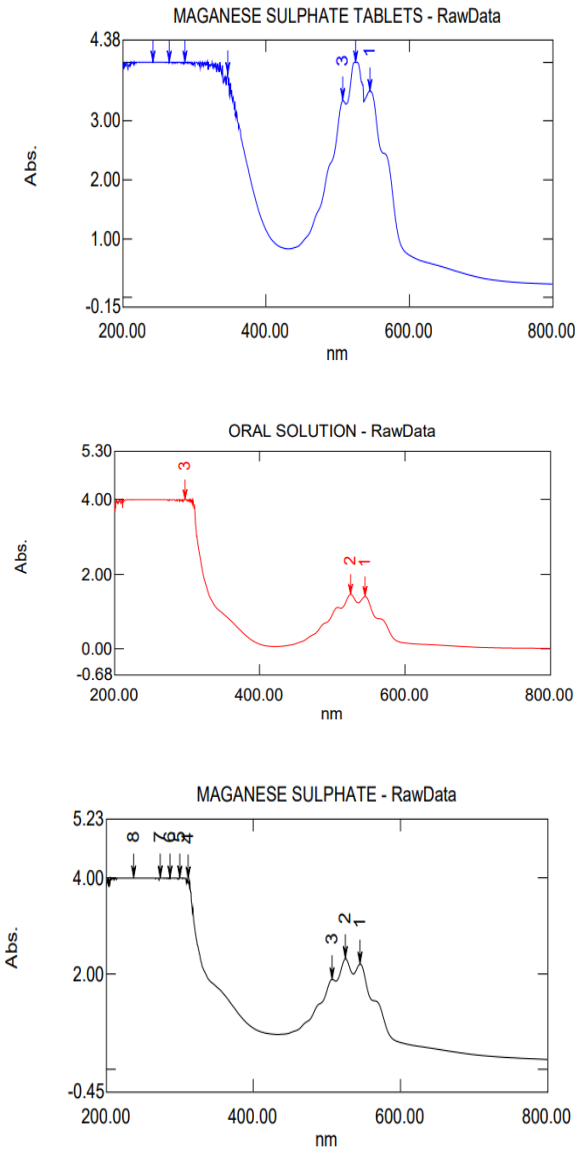


Fig. 2. Manganese sulphate standard and sample solution

Selectivity:

Prepared diluent, placebo solution, standard solution and test solution as directed in analytical method and recorded in Table 2.

Table 2 : Selectivity

Solution	Abs	Observations
Diluent	-0.001	less than 0.005 AU
Standard	0.480	Purity passes for the analyte
Test	0.567	Purity passes for the analyte

Linearity and Range

The linearity of the method for the Manganese Sulphate was demonstrated by preparing solutions over the concentration levels ranging from 20% to 120% of Manganese Sulphate standard concentration. These solutions prepared in triplicate and the absorbance of the analyte recorded. Linearity graph of Concentration (ppm) Vs Average Absorbance of analyte plotted separately. Correlation co-efficient between concentration (ppm) & absorbance slope and intercept evaluated. The results are given in Table 2 and graph of Concentration Vs Absorbance of the analyte fig no. 3

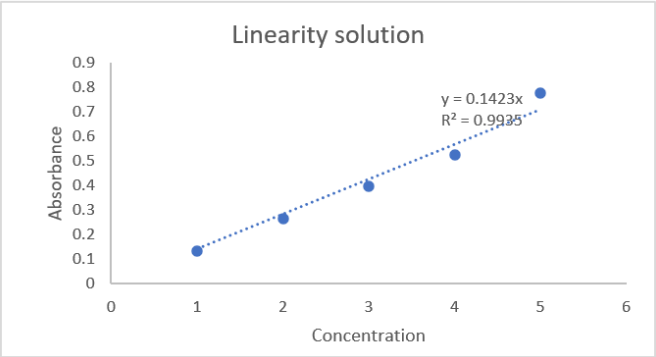


Fig. 3. Linearity graph of Concentration (%) Vs average Absorbance of analyte

Table 3 : Linearity Study for Manganese Sulphate

Linearity Level	Conc. (%)	Average Absorbance
1	20	0.134
2	40	0.264
3	60	0.396
4	80	0.526
5	120	0.775
Slope		0.142
Correlation Co-efficient		0.9935

Precision:

The precision of an analytical procedure expresses the closeness of agreement between a series of measurement obtained from multiple sampling of the same homogeneous sample under the prescribed conditions.

System Precision:

Standard solution was prepared as described in analytical method and measured the absorbance of six replicates. Result obtained is given in Table 4

Table 4 : System Precision of Manganese Sulphate

Sr. No.	Absorbance
1.	0.513
2.	0.513
3.	0.513
4.	0.507
5.	0.508
6.	0.511
Average	0.511
SD	0.003
% RSD	0.530%

Method Precision (Analyst A)

Three samples were prepared as per the analytical method representing a single batch. The % assays of these samples were determined for the analyte and the precision of the method was evaluated by computing the % Relative standard deviation of the results. Results are illustrated in Table 5.

Table 5 : Method Precision of Manganese Sulphate

Preparation	% Assay
Oral solution	108.37
Tablets	110.75
Capsule	105.32

Ruggedness (Intermediate Precision):

Intermediate precision express's ability of method to produce reliable result under within laboratories variation, different days and different analysts.

Six samples were prepared as per the test method representing the same batch taken for precision. The % assay of these samples was determined and the precision of method was evaluated by computing the % RSD of the results.

The ruggedness of method was demonstrated by carrying out precision study in six replicates of a single batch sample by different analyst, on different day, by change in instrument illustrated in Table 3. Results obtained are given in Table 6

Table 6 : Intermediate Precision

Preparation	% Assay
Oral solution	100.71
Tablet	104.42
Capsule	98.10

Table 7 : Overall Precision results for Manganese Sulphate

Sample	% Assay	
	Intraday	Intermediate
Oral solution	106.57	101.52
Tablet	107.29	101.49
Capsule	105.32	100.42
Avg.	103.77	
SD	2.97	
% RSD	2.86	

Robustness:

Robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

In this study, Parameters like Change in wavelength was studied absorbance of each replicate standard are recorded and the results are reported. Also calculated the % Relative standard deviation of absorbance of five replicate standard solutions for the analyte.

Change in Wavelength ±2 nm:

Table 8 : Results of Change in Wavelength ±2 nm.

Sr. No.	Abs	
	523 nm	527nm
Standard	0.574	0.568
Oral solution	0.703	0.731
Tablet	0.736	0.759
Capsule	0.906	0.896

IV. CONCLUSION

The above summary and the validation data summarized in this document shows that the analytical method of Assay for Manganese Sulphate in a sample by UV-Spectrophotometer is found to be Suitable, Selective, Specific, Precise, Linear, Accurate and Robust.

{Refer to the validation results reported in Section. No. 7–Validation Results}.

Hence it is concluded that the Analytical Method is validated and can be used for Routine Analysis and for Stability Study. That type methods future research area to method development in analytical R&D. The optimization of developed method will lead to estimation of manganese from biological fluids

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