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New Method for Estimation Mebeverine Hydrochloride Drugs Preparation by a New Analyser: Ayah 6S.X1(WSLEDs)-T.- Two Solar Cells Complied with C.F.I.A

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Abstract:

A sensitivity-turbidimetric method at (0-180^{o}) was used for det^{n}. of mebeverine in drugs by two solar cell and six source with C.F.I.A.. The method was based on the formation of ion pair for the pinkish banana color precipitate by the reaction of Mebeverine hydrochloride with Phosphotungstic acid. Turbidity was measured via the reflection of incident light that collides on the surface particles of precipitated at 0-180^{o}. All variables were optimized. The linearity ranged of Mebeverine hydrochloride was 0.05-12.5mmol.L^{-1}, the L.D. (S/N= 3)(3S$_B$) was 521.92 ng/sample depending on dilution for the minimum concentration , with correlation coefficient r = 0.9966while was R.S.D% < 1% of 2,6 mmol.L^{-1} conc. of Mebeverine hydrochloride. The method is used successfully for three different of target drugs in three different pharmaceutical formulations. A comparison using t-test was studied. It was shown that there is no significant difference between two values.

Key words: Flow injection, Mebeverine hydrochloride, Turbidity.

Introduction

Mebeverine hydrochloride (MVH), 3,4-dimethoxybenzoic acid 4-[ethyl-2-(4-methoxyphenyl)- 1-aminobutylveratrate hydrochloride , Fig. 1 , is a nonspecific antispasmodic agent which acts directly on the smooth muscle of the gastrointestinal tract (1).

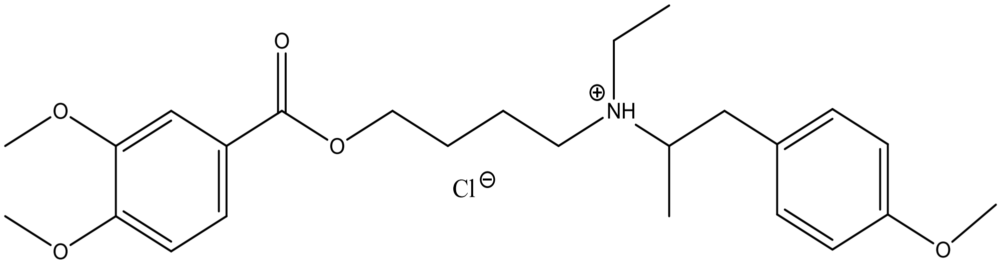


Figure 1.Chemical structure of Mebeverine hydrochloride

Turbidimetry is defined as the measurement of the degree of attenuation of a radiant beam incident on suspended particles in solution. Nephelometry is the scattered measurement of the light by suspended particles, usually carried out at 90^{o} (2). The earlier turbidimetry report using the FIA technique for estimating of $SO_4^{=}$ by monitoring the $BaSO_4$ suspended particles. Although the use of FIA system with coupled with turbidimetric detection for the determination of different inorganic species in water and plants (3),limited applications to pharmaceutical products were reported (4-6). Several analytical methods have been developed for the determination of Mebeverine Hydrochloride in lecturer review, Mebeverine Hydrochloride was determined by high performance liquid chromatography (HPLC) (7-10) , Spectrophotometric (11-14) .

This research used C.F.I.A with turbidimetric measurement for MVH determination using Ayah (6 source of W.S. LED the two solar cells) analyser. The measurements depends on (pinkish banana color) formation of precipitate particulate for M.V.H-P.T.A. system.

Martial and methods;

Chemicals

A standard solution (0.05 mol./L) of Mebeverine hydrochloride (466 g/mol.)was prepared by 5.825g/250 mL**.** 0.1 mol/L. of Phosphotungstic acid $H_3PW_{12}O_{40}$ 2880.2 g/mol. Hopkin & Willias) was prepared by 28.802 g /100 mL **(**a few drops of phosphoric acid were used for dissolving an amount of PTA, and then the solution was heated for completing the dissolution. Followed by completing the required volume and also kept overnight for use**)**. One mol/L of H_2SO_4 solution(96% of 1.84 g/ml, B.D.H) was prepared by 14 mL H_2SO_4 conc. / 250 mL. One M of HCl solution(35% of 1.19 g/ml, B.D.H) were prepared 21 mL of conc./250 mL flask. One mol/L of HNO_3 solution(70%, 1.42 $g.ml^{-1}$, B.D.H) was prepared by pipetting 16 mL of conc. /250 mL flask. One mol/L of H_3PO_4 solution (85% of 1.69 g/ml,BDH) was prepared by 17 mL of phosphoric acid conc. /250 ml. One mol/L acetic acid solution (99.5 % of 1.05 g/ml, B.D.H) was prepared by dilution of 15 ml acetic acid conc./250 mL.

Sample Preparation

Twenty tablets were weighted and ground. Each contains 135 mg of Mebeverine hydrochloride which weights (1.46412, 2. 07435, 1.92595) gm corresponding to 699 mg of active ingredient 15 mmol/L for Mebeverine hydrochloride (Mevir-Micro Labs, Meva-Jamjoom pharma, Duspalina- Asia) respectively. This powder was dissolved in D.W. and filtered to remove residue that might affect the measurement. The volume was completed with D.W to 100 mL.

Apparatus

Two channels – Peristaltic pump (GILSON, France) and 6-port injection were used for sample. The measurement was carried out by Ayah 6S.X1-T.-2D. Solar-C.F.I. analyser, depends on flow cell at 2mm path length. The collecting signals were detected by two solar cell (25 mm length X 14 mm width X 1.2 thickness). In addition of x-t. potentiometric recorder for the readout, or digital A.V.O-meter . Turbidometric readings of batch were made by HANNA company. The diagram is shown in Fig. 2 (15) for MVH

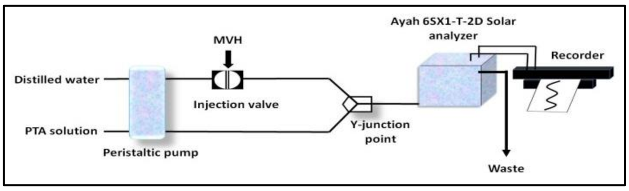
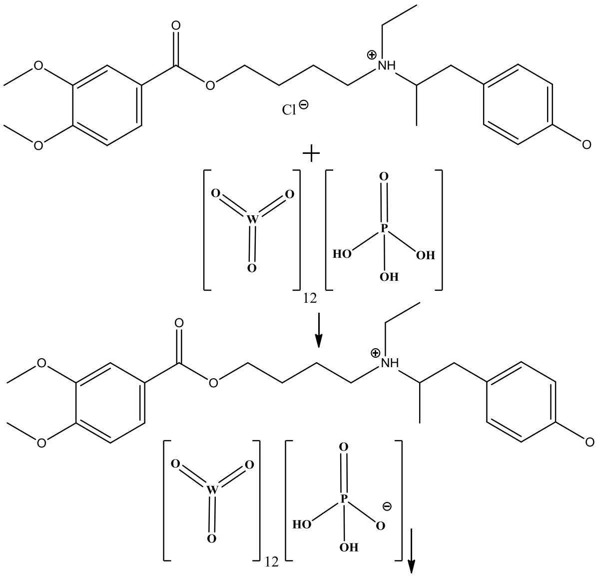


Figure 2. FIA manifold using MVH-PTA system.(16)

Methodology

FIA system for the reaction of MVH-PTA form pinkish banana color precipitate consists of two lines (Fig. 2). The carrier stream (1 line) was the D.W. at 1.8 mL/min that leads to the injection valve to carry Mebeverine hydrochloride as a sample, 140µl ; The second line is PTA solution (7.5 mmol/L) at 1.8 ml/min. Two lines combined at Y-junction, and then the reactant passes through a homemade for measurements (Ayah 6.S. X 1.T.2 D. as a solar cell). Each solution injected was assayed 3 times. The measurements of turbidity at 0-180°. Mechanism for system MVH-PTA in D.W. in is shown in scheme 1.



MVH-PTA Ion pair associate

Scheme 1. Possible reaction for MVH & PTA

Results and Discussion:

Optimum Parameters:

Using single variable optimization for the conduction of the measurements of MVH-PTA system. Two step study was used.

A: Effect of the chemical variables i.e. the concentration of reactants used, acidic media

B: Effect of physical variables i.e. flow rate, sample volume, purge time & light intensity (I_o).

Chemical Variables

PTA Concentration

Rang concentration (PTA) from (0.5-10 mmol/L) was 10 mmol/L of MVH and 140 µl sample was loaded through D.W a carrier stream. The results are tabulated in Table 1 in addition to Fig. 3.A.B. 7.5 mmol/L of PTA was the best for high response. More than 7.5 mmol/L causing accumulation of e particles in the flow cell and leading to restrict the flow, followed by increase of Δt_B of response.

Table 1. PTA concentration

[PTA] mmol / L	$\hat{Y}_{(mv)}$ (n=3)	R.S.D%	Confidence interval at (95%) $\bar{y} \pm t_{\frac{0.05}{2},n-1.}\ \sigma_{n-1}/\sqrt{n}$
0.5	336	0.179	336±1.492
2	551.33	0.278	551.33±3.799
3	576	0.174	576±4.303
5	656	0.403	656±6.681
7.5	1402	0.143	1402±4.974
10	1658.33	0.174	1658.33±7.180

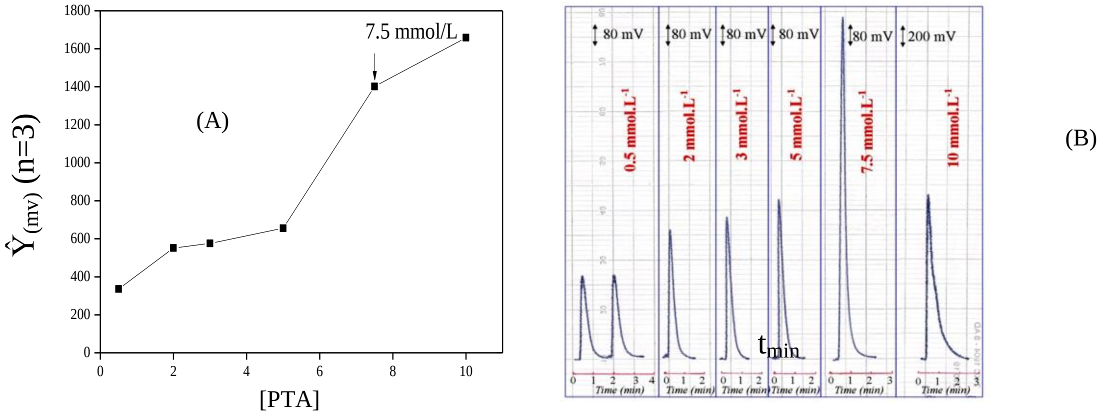


Figure 3. PTA concentration on:(A): height of peak (B): Response profile versus time

The Effect of Conducting the Reaction in Acidic Media

MVH(10 mmol/L)-PTA(7.5 mmol/L) was studied in several acids (H_2SO_4, HCl, HNO_3, H_3PO_4 and CH3COOH) in concentration of 50 mmol/L in addition to D.W. Results are shown in Table 2 and in Fig. 4.A.B. It was found that H_2SO_4 was the best as a carrier stream for maxima reflection of incident light compared with other used acids and distilled water. Probably, the present of H_2SO_4 might work as a catalyst for ion pair formation that attributed to the increase in the amount of precipitate.

Table 2. Water & acidic media effect

Type of medium	$\hat{Y}_{(mv)}$ (n=3)	R.S.D%	$\bar{y} \pm t_{\frac{0.05}{2},n-1}\ \sigma_{n-1}/\sqrt{n}$
H_2O	1408.67	0.217	1408.67±7.599
CH_3COOH	1409	0.256	1409±8.968
H_3po_4	1433	0. 209	1433±7.462
HCL	1481	0.270	1481±9.949
HNO_3	1495	0.354	1495±13.161
H_2SO_4	1647	0.210	1647±8.616

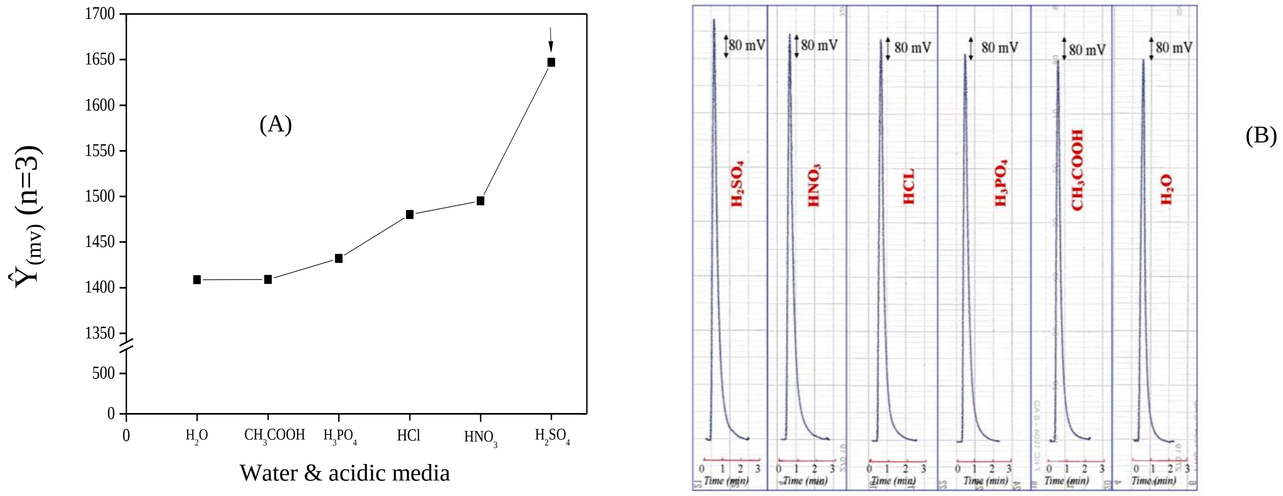


Figure 4. Water & acidic media (A): height of peak (B): Response profile versus time

The Effect of H_2SO_4 Concentration

The ion pair of MVH (10 mmol/L)-PTA (7.5 mmol/L) system was studied. A solutions H_2SO_4 (20-60 mmol/L) was prepared. The results obtained in Table 3 and Fig. 5 A and B explain the increase in the response with the increase of H_2SO_4 up to 50 mMol.L^{-1}, decrease in response at high concentration of H_2SO_4 (i.e > 50 mmol/L) which might be attributed to dissociation of some of the precipitate particles.

Table 3. (H_2SO_4) concentration

H_2SO_4 mmol / L	$\hat{Y}_{(mv)}$ (n=3)	R.S.D%	$\bar{y} \pm t_{\frac{0.05}{2},n-1.}\ \sigma_{n-1}/\sqrt{n}$
20	1520.33	0.324	1520.33± 12.436
30	1545	0.194	1545.00±7.599
40	1576.67	0.297	1576.67±11.216
50	1694	0.149	1694±6.2595
60	1504	0.277	1504±10.355

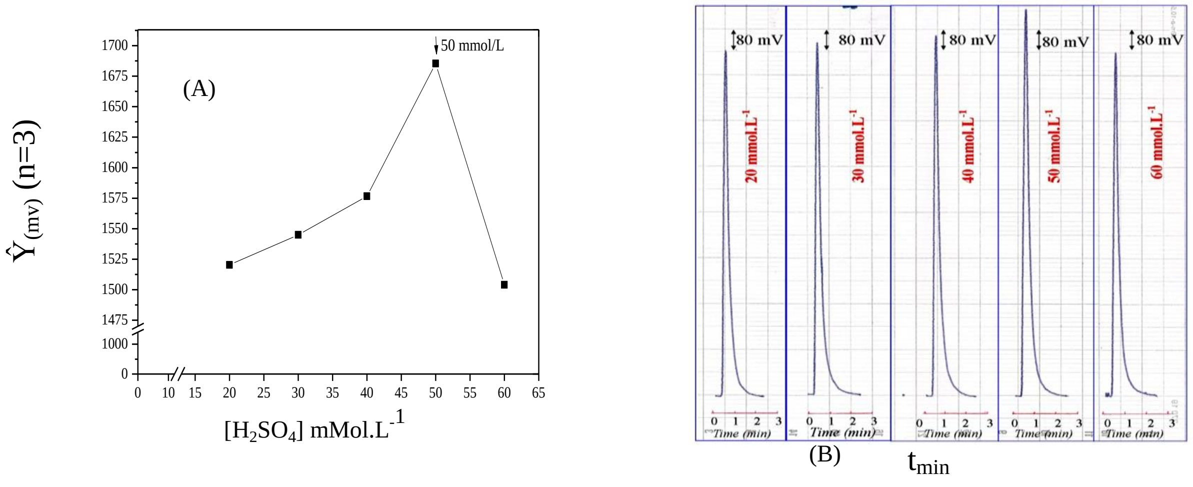


Figure 5: Variation of (H_2SO_4) on: (A): height of peak (B):Response versus time

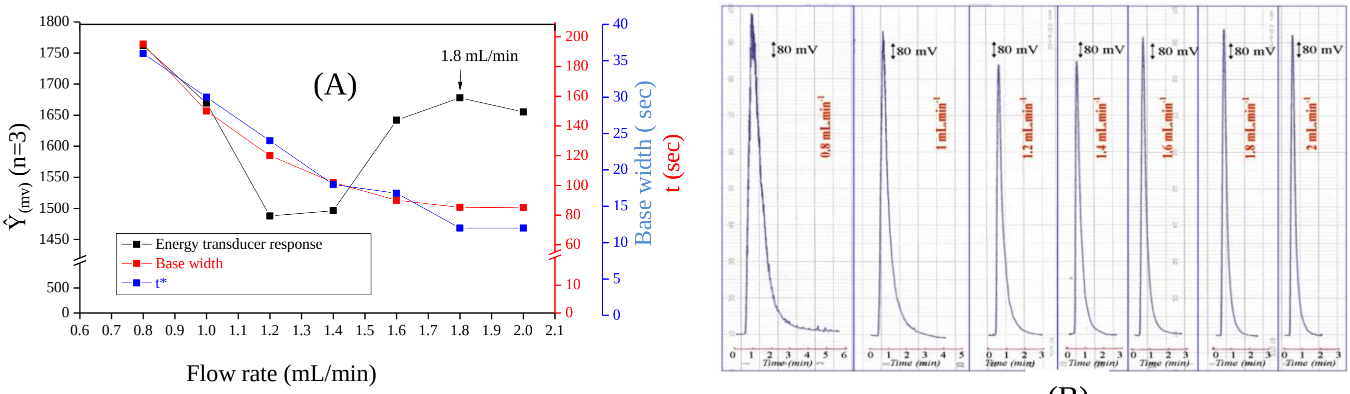
Physical Variables

Flow Rate

In this research, the optimized concentration was used MVH(10 mmol/L)-PTA(7.5 mmol/L)- H_3O^+ (50 mmo/L). Sample volume of 140 µl was used at a variable flow rate (0.8-2 mL.min^{-1}) .Results are summarized in Table 4. At slow flow rates, it was noticed that Δt_B of the response increased and the deformation of top maximum peak responses. This might be attributed to the dilution and dispersion factor. While at high flow rate i.e,> 1.8 mL.min^{-1}, it was noticed that there was a slight increase in peak height, this probably could be due to decrease in dilution and dispersion which affects precipitated particulates. Therefore; a 1.8 mL.min^{-1} for both line i.e: carrier stream & PTA line was used to obtain the best regular response, low Δt_B, minimize the reactions solution and to complete reaction of MVH as ion pair (Fig. 6.A and B)

Table 4. Effect of Flow Rate

Flow rate mL / min	$\hat{Y}_{(mv)}$ (n=3)	R.S.D%	$\bar{y} \pm t_{0.05/2,n-1}\, \sigma_{n-1}/\sqrt{n}$	Δt_B (S)	t^* (S)	DF
0.8	1762	0.227	1762±9.949	195	36	19.6
1	1669.33	0.270	1669.33±11.216	150	30	18.87
1.2	1487.67	0.169	1487.67±6.259	120	24	18.18
1.4	1496.33	0.102	1496.33±3.799	102	18	18.18
1.6	1642	0.244	1642±9.949	90	16.8	18.18
1.8	1678	0.119	1678±4.975	85.2	12	19.2
2	1655	0.302	1655±12.436	85	12	21.28



(B)

Figure 6. Flow rate (A): Height of peak (B): Response versus time

Sample Volume

Using the optimum parameters achieved in previous sections. Variable sample volumes (26, 45,100,140,200) µl were injected using open valve mode. Table 5 tabulates all the results for the variation of injected sample volume. An increase in the sample volume led to a significant increase in sensitivity perceptible than low volumes as shown in Fig. 6 A , which shows that the optimum sample volume was 140 µl which gave a regular response Fig 6 B.

Table 5. Effect of sample volume

Sample volume Ml DS 1mm	$\hat{Y}_{(mv)}$ (n=3)	R.S.D%	$\bar{y} \pm t_{0.05/2}\, \sigma_{n-1}/\sqrt{n}$	Δt_B (sec)	t^* (Sec)
26	920.67	0.332	920.67±7.599	54	12
45	1040	0.333	1040±8. 616	60	12.6
100	1424	0.140	1424±4.975	75	13.2
140	1679	0.215	1679±8.968	96	15
200	1740	0.2298	1740±9.949	108	18

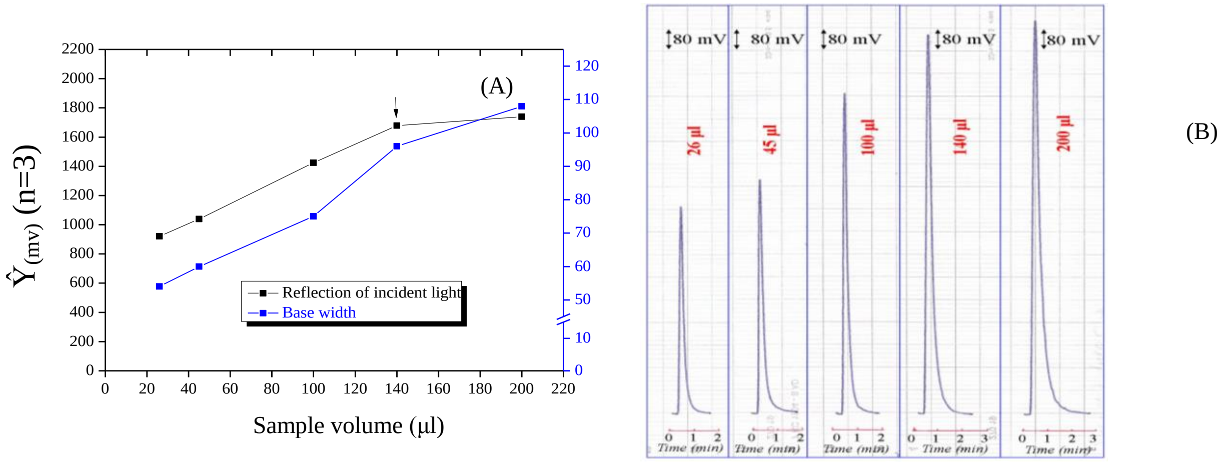


Figure 6. sample volume on : (A): height of peak (B): Response versus time

Purge Time

Using the optimum parameters that were achieved in previous section. A study was carried out to establish the optimum allowed permissible time for the sample segment to be injected from the injection valve; 3,5,7,9,7,9,11 and 13 sec. were used for this in addition to allowed the injection valve, Fig 7 A,B and Table 6 show the optimum purge time is 11 sec.

Table 6. Effect of Purge Time

Purge time (Sec)	$\hat{Y}_{(mv)}$ (n=3)	RSD%	$\bar{y} \pm t_{0.05/2}\,\sigma_{n-1}/\sqrt{n}$
3	648	0.309	648±4.975
5	1161	0.311	1161±8.968
7	1383	0.191	1383±6.581
9	1526	0.347	1526±13.161
11	1676	0.268	1676±11.398
13	1572	0.254	1572±9.949
Open valve	1543	0.171	1543±6.581

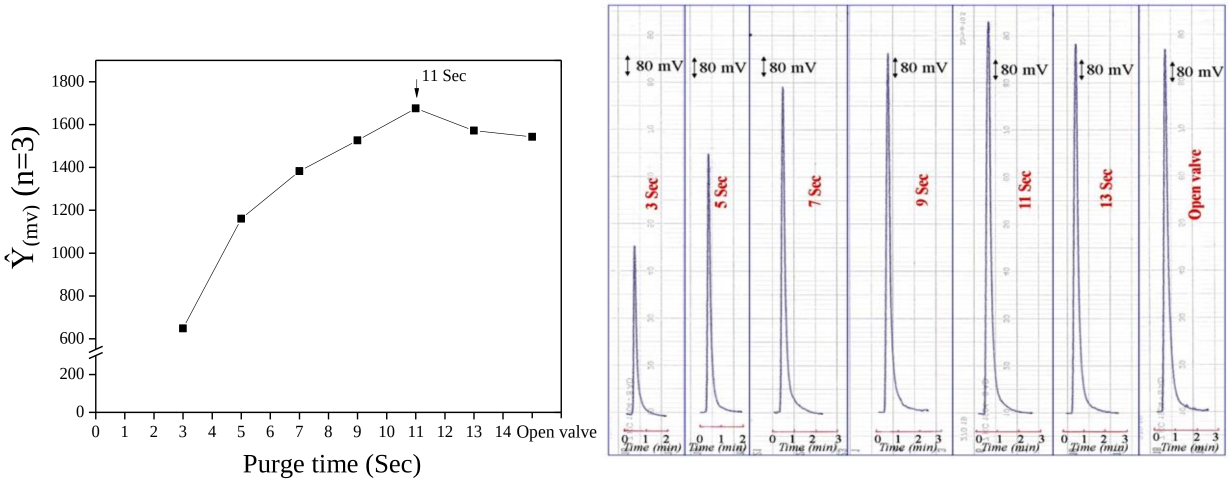


Figure 7. purge time on: (A): height of peak (B): Response versus time

Intensity of Light

By keeping all optimum variables fixed, the variation of light intensity on the efficiency for determination of MVH at 10 mMol/L was optimized by using AVO-meter. Variable intensity of light source was used (0.57-2.29) volt by variation of light intensity knob (in the front Ayah 6.S.X1-2.D. solar C.F.I. Analyser Fig. 1). The results were tabulated in Table 7 and Fig. 8 with optimum intensity (2.29 volt).

Table 7. Intensity of light on the height of peak

Intensity of light (Volt)	$\hat{Y}_{(mv)}$ (n=3)	R.S.D%	$\bar{y} \pm t_{0.05/2,n-1}\, \sigma_{n-1}/\sqrt{n}$
0.57	231.33	0.821	231.33±3.799
0.95	557.67	0.842	557.67±6.259
1.3	840	0.238	840±4.975
2	1505	0.304	1505±11.398
2.29	1674	0.119	1674±4.975

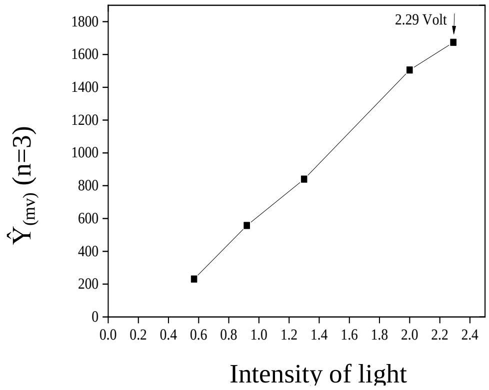
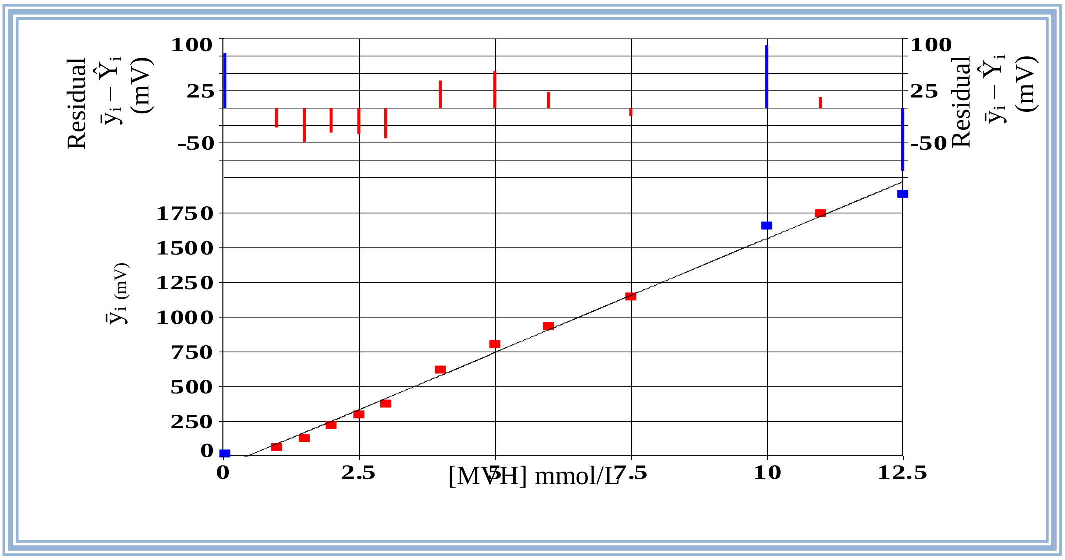


Figure 8. height of peak (intensity of light)

Calibration Curve of MVH

A series of MVH solutions 0.01-16 [mMol/L] were prepared. A sample volume 140 µl was used and all other parameters whether chemical or physical were used as it was fixed in previous sections. A diagram shows that a linear calibration graph range for the variation of the transducer energy response of Ayah 6.S.X.1-T-2.D. solar C.F.I. Analyser with [MVH] conc., Ranging 0.05-12.5 [mMol/L] as shown in Fig.9. Table 8 tabulates all the results that were obtained .



$\hat{Y}_{(mV)}$ **=-71.25±163.23+163.69±8.94[MVH]mMol.L^{-1} (16,17)**
r = 0.9966
r^{2}= 0.9933
% r^{2}= 99.33

Table 8. linear regression for the [MVH] using 1st equation $\hat{Y} = a+b.x$ at optimum conditions.

Recorded [MVH] [mmol/L]	Range of [MVH] [mMol/L] n=16	$\hat{Y}_{(mV)} = a \pm s_a t + b \pm s_b t[MTZ]$	r r^2%	$t_{.tab.}$	$t_{cal.}$ $\frac{/r/\sqrt{n-2}}{\sqrt{1-r_2}}$
0.01-16	0.05-12.5	$-71.25 \pm 163.23 + 163.69 \pm 8.94[MVH]mMol.L^{-1}$	0.9966 99.33	2.201<<40.31	

Limit of Detection

The limit of detection was studied at three methods as summed up in Table 9.

Table 9. L.D. for MVH.

Practically	TheoreticalBased on $X=3s_B$/slope	Based on the $\hat{Y}=Y_B+3s_B$
521.92 n.g./sample	11.96 n.g./sample	68.27 μ.g./ sample

Repeat Ability

It is a measurement of precision achieved by the whole assay process. Table 10 sums up measurement of two concentration of MVH each repeated for six successive measurements. Results show that the value of %RSD is less than 1 %

Table 10. Repeatability for MVH at optimum parameters.

[MVH] mmol/L (n=6)	Average response $\bar{y}_i$(mV)	RSD %	$\bar{y} \pm t_{0.05/2,n-1}\,\sigma_{n-1}/\sqrt{n}$
2	225.67	0.776	225.67±1.838
6	935.33	0.221	935.33±2.168

Analysis of the Drug

The established method was used for MVH in three kinds of 135 mg MVH from three manufactures (Mevir- Microlabs-India), (Meva- Jamjoom Pharma- Saudi Arabia), and (Duspalina- Asia- Syria) using Ayah 6.S.X1.-T.-2D.- Solar cell CFI Analysis which was compared with Quoted value [21]. Solutions were prepared of all drug (15 mmol/L) by 2.1 mL to all of the five V.F. (25 mL) and gradual of volumes MVH (0, 2.5, 5, 7.5, 10) mL of 10 [mmol/L] to obtain (0, 1, 2, 3, 4) mmol/L Flask no.1 is the sample. The measurement were conducted using Ayah 6.S.X1-T.-2.D. solar cell CFI Analyser method. Results were mathematically treated for the standard addition method. Results are shown in Table 11.

Table 11. Results of MVH in drugs by S.A.M

Sample no	Commerical name ,content ,country,company	$\bar{W}, \pm 1.96\,\sigma_{n-1}/\sqrt{n}$ at 95% (g)	Sample weight	Theoretical content for the active ingredient at 95%(mg)	Equation 95% for n-2 $\hat{Y}=a \pm s_b t$	r r^2%	Practical [conc.] and active ingredient (mg)	Pratical	(%Rec)
					AYAH 6.S.X1-T.-2.D. C.F.I.A.				
1	Mevir135 mg Micro Labs (india)	0.28277±0.00315	1.46412	135±0.64452	128±64.15+103±26.18 [x]	0.9906 98.12 %	14.798 689.57	133.18±8.95	98.65%
2	Meva135 mg Jamjoom pharma (Saudi Arabia)	0. 40063±0.00245	2. 07435	135±0.82693	179.8±141.72+141.8±57.858 [x]	0.9762 95.29 %	15.095 703.427	135.86±7.462	100.63 %
3	Duspalina135 mg Asia Syria	0.37197±0.00303	1.92595	135±1.10123	186.4±107.56+147.60±43.91 [x]	0.9871 97.44 %	15.04 700.66	135.32±6.47	100. 24%

Table 12 shows paired of t-test. T-test is used to compare the mean obtained for three manufacturers (Mevir- Micro labs- India) , (Meva-Jamjoom Pharma- Saudi Arabia), and (Duspalina-Asia- Syria). A MVH tablet of 135 mg dose was subjected to analysis. Table 12 tabulates Quoted value of active ingredient and the practically found values. Three successive tests were used, each for a single supplier, first for a supplier from Micro-labs-India.

The Quoted value 135 mg, found value = 133.18 mg

Null hypothesis H_o= The practically found value as good as the quoted value. i.e: $\mu_{Quo} = \mu_{Ayah\ 6SX1\text{-}T\text{-}2D\ solar}$ Alternative hypothesis H_1: The practically found value is not as good as the Quoted value

i.e: $\mu_{Quo} \neq \mu_{Ayah\ 6SX1\text{-}T\text{-}2D\ solar}$

Since all values obtained (t calc.) are < t tab (4.303) at confidence level 95 % therefore; Null hypothesis is accepted against alternative hypothesis; on this basis the newly developed method is good as the quoted value; and can be accepted as an alternative analytical determination method. The same approach can be used to evaluate the newly developed method of determination and assay. The product from Meva-jamjoom-saudi-arabia gave 135.86 mg

H_o: $\mu_{Quo} = \mu_{Ayah\ 6.S.X1.\ T.2.D.\ solar}$

H_1: $\mu_{Quo} \neq \mu_{Ayah\ 6.S.X1.T.2.D.\ solar}$

A value of calculated t_{value} of 0.496<< 4.303

There was no significant difference between the means of Quoted value and the analysed by Ayah 6.S.X1-T.-2.D. for the product of MVH form Saudi-Arabia.

While for the Syria manufacture, a value to beat is 4.303, a calculated t_{value}= 0.213.On the basis the MVH drug produced in Syria if it was compared with the analysis conducted by Ayah 6SX1-T.-2D. and shows no significant difference between the mean of the both Quoted and the one analysed by Ayah 6.S.X1.-T.-2D. Generally, it can be said that there were no significant differences between the three selected available drugs in the market and the analysis method carried out by Ayah 6.S.X1-T.-2.D. Therefore; the analysis carried out by Ayah 6S.X1.-T.-2.D. can be used as an alternative analytical method for whatever these three manufacture were to analyse their product.

Table 12. t-test for the compare (partical - Quoted)

(Sample)	Practical MVH $\bar{X}$ (m.g)	Quoted $\mu_{(m.g)}$	$(\bar{X}-\mu)\sqrt{n}/\sigma_{n-1}$ Ayah 6.S.X1-T.-2.D. with Quoted	
			t_{cal}	t_{tab}
1	133.18	135	$\lvert -0.875 \rvert << 4.303$	
2	135.86	135	$0.496 << 4.303$	
3	135.32	135	$0.213 << 4.303$	

μ: Quoted value, σ_{n-1} : Standard deviation, $t_{critical} = t_{tab} = t_{\alpha/2,n-1} = t_{0.025,2}$=4.303 , n= Three successive measurement (n=3)

Conclusion:

Simple sensitivity application of the proposed of methods to the analysis of Mebeverine hydrochloride in drugs .The method was based on the formation of ion pair for the pinkish banana color precipitate by the reaction of Mebeverine hydrochloride with Phosphotungstic acid. It was shown that there is a good result when compared with Quoted value. An alternative analytical method was found in this research work.

Authors' declaration:

- Conflicts of Interest: None.
- We hereby confirm that all the Figures and Tables in the manuscript are mine ours. Besides, the Figures and images, which are not mine ours, have been given the permission for re-publication attached with the manuscript.
- Ethical Clearance: The project was approved by the local ethical committee in Al-Essra University College.

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طريقة جديدة لتقدير المبفرين الهيدروكلورايد للادوية بواسطة محلل جديد Ayah 6S.X1(WSLEDs)-T.- two Solar cells complied with C.F.I.A

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الخلاصة:

تم استخدام طريقة تعكرية حساسة (0-180 درجة) لتقدير المبفرين الهيدروكلورايد في الادوية من قبل اثنين من الخلايا الشمسية وستة مصادر من Ayah 6.S.X1-T-2.D. تعمل هذه الطريقة الى تكوين مركب زوج للون الموزي الوردي يترسب بتفاعل مبفرين هيدروكلورايد مع حمض الفوسفوتونجستيك. تم قياس التعكرية عن طريق انعكاس الضوء الساقط الذي يصطدم بسطح دقائق الراسب بزواية 0-180 درجة. العلاقة الخطية لمنحني المعايرة للمبفرين هيدروكلورايد تمتد 12-0.5 مللي مول. لتر$^{-1}$ ، حدود الكشف (S/N = 3) ($521.92=S_B$ نانو غم/ انموذج من التخفيف التدريجي لاقل تركيز مع معامل الارتباط r = 0.9966 بينما كان RSD% اقل من 1% لتركيز 6 ,2 مللي مول/لتر من المبفرين هيدروكلورايد. تم تطبيق الطريقة بنجاح لتقدير الدواء المستهدف في ثلاث تركيبات دوائية مختلفة. تم دراسة مقارنة باستخدام اختبار t. كان يظهر أنه لا يوجد فرق كبير بين قيمتين.

الكلمات المفتاحية : التحليل بالحقن، المبفرين هيدروكلورايد، التعكرية.