

Fabrication of Ultrasensitive Aluminum Oxide Nanoparticle Sensors for Potentiometric Determination of Ondansetron Dihydrate Hydrochloride in Pure and Pharmaceutical Forms

Dheaa Shamikh Zgear¹, Muataz Ali^{*1}, Amina M. Abaas¹, Rami A. Abdel-Rahem²

¹ Higher Institute of Forensic Sciences, Al-Nahrain University, Jadiriya, Baghdad, Iraq.

² Department of Chemistry, Faculty of Arts and Sciences, University of Petra, Amman, Jordan.

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Abstract

A highly precise potentiometric method for trace determination of Ondansetron dihydrate hydrochloride (OND) has been developed and established. A highly sensitive sensor of coated wire modified with aluminum oxide (Al_2O_3) was developed by incorporating trace amounts of (OND) with the ion-pairing reagent phosphomolybdic acid (PMA). Under the test conditions, the sensor exhibited a near-Nernstian response towards the drug over a linear range of 1.0×10^{-10} to 1.0×10^{-2} mol L^{-1} with limit of detection of 5.0×10^{-11} mol L^{-1} and slope of $+59.30 \pm 0.05$ mV decade⁻¹ for (OND-PMA) coated wire sensor. The potentiometric sensor electrode showed stability up to 65 days and fast responsive time of 14 s. However, the developed potentiometric sensor for OND showed high selectivity to the mentioned drug in presence of various inorganic and some pharmaceutical species. The sensor response remained constant in a suitable potential at various pH from 2.5 to 9.0. Statistical analysis confirms that this potentiometric method is relatively very accurate and reproducible. The developed procedure was successfully applied to measure OND levels in both pure form and many commercial drug samples.

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*Corresponding author: Muataz.ali@nahrainuniv.edu.iq



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1. Introduction

Confirming that an analytical technique's performance metrics satisfy the required criteria for its intended laboratory use is the core of method validation. The basic objective of any chemical analysis is to ensure the collection of data appears to be consistent, accurate, and scientifically reliable. In order to ensure the quality of analytical results, method validation must assess linearity, calibration range, accuracy, precision (repeatability and intermediate precision), limit of detection (LOD), and limit of quantitation (LOQ) [1]. Chemically, Ondansetron dihydrate hydrochloride (OND), systematically designated as 9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-1,2,3,9-tetrahydro-4H-carbazol-4-one hydrochloride dihydrate [2,3], functions as a potent and selective 5-HT₃ receptor antagonist [4]. OND is indicated for the management of chemotherapy-induced emesis, as well as for nausea and vomiting associated with radiation therapy and surgery [5]. The molecular formula for

OND is $\text{C}_{18}\text{H}_{19}\text{N}_3\text{O} \cdot \text{HCl} \cdot 2\text{H}_2\text{O}$, with a molar mass of 365.86 g/mol [6]. Potentiometric detection was selected for this study because it provides a cost-effective, portable, and rapid analytical platform capable of direct analyte profiling with minimal sample preparation [7, 8].

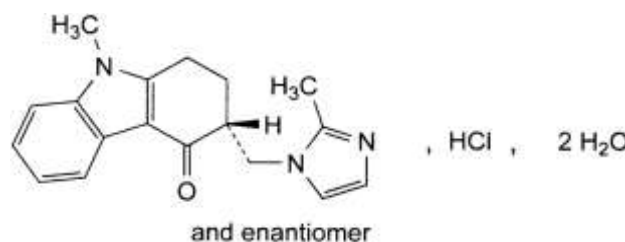


Figure 1: Chemical Structure of Ondansetron dihydrate hydrochloride Dihydrate (OND).

To construct an effective ion-selective membrane, phosphomolybdic acid (PMA) was selected as the inorganic ion-pairing reagent due to its high negative charge density and large ionic radius. PMA forms a highly stable, low-solubility hydrophobic ion-pair complex (OND-PMA) with the cationic Ondansetron species, ensuring efficient chemo-electrical signal transduction [9, 10]. Owing to their peculiar properties, metal oxide nanostructures have gained tremendous significance in various fields including biomedicine, optical sensors, and electrochemical applications [11, 12]. The high surface-area-to-volume ratio of these nanomaterials has successfully enhanced the performance of modern electrochemical sensors in terms of electrical conductivity, catalytic activity, and sensitivity [13, 14]. Electrochemical sensing platforms can be integrated with multiple forms of electroanalytical detection techniques [15]. Potentiometric Sensors are part of the larger family of electrochemical sensors. Potentiometric Sensors are very convenient due to their low cost and portability. Outstanding convenience for field applications is offered with minimal power consumption and disregard to specialized laboratory facilities. Smart pH sensors and electrodes for other relevant ions (e.g. F^- , CO_3^{2-} , NH_4^+ , NO_3^- , Cl^- , Br^- , I^- , SCN^-) are quickly advancing to a variety of applications because of their unique characteristics. These devices function by an interaction of "electricity" and "chemistry". The area where "chemistry" dominates the signal transduction process is confined to the receptor region that selectively reacts with target ions to form the ion-molecule combining sensor. Similarly the remaining portion of the sensor is dedicated to chemo-electrical signal transduction, commonly manifested as a change in current (i) or variation in potential (ΔV) [7]. The most commonly used types of electrochemical sensors are potentiometric sensors, which exist in numerous modified forms and adapted for ionic analyte profiling in matrices of widely different compositions ranging from purely aqueous samples through to complex food products. [14, 8]. The earliest ion-selective electrode (ISE) reported in a published work was the traditional configuration, which contained an interior electrolyte coupled with an ion-exchange matrix [9]. This approach is exemplified by a glass electrode containing a

potential producing element which is also the chemo-electrical transducer (an Ag/AgCl) and an interior solution with constant concentration, together with a silicate matrix [16–18]. While standard electrodes utilizing internal solutions offer good performance, they are often hindered by practical drawbacks, such as their delicate nature and bulkiness, which complicate the analysis of micro-volume samples, which renders the electrode susceptible to mechanical damage, along with their considerable surface area, which hampers low-volume sample as saying. Several techniques, such as UV spectrophotometry [19–20], RP-HPLC [21], and ion-pair potentiometric sensors [22], have been developed to quantify Ondansetron dihydrate hydrochloride. This work aims to design and evaluate a user-friendly, highly sensitive coated wire sensor based on Al_2O_3 nanoparticles for determining OND levels in both its pure form and in pharmaceutical formulations.

2. Experimental Work

2.1. Instrumentation

Electrochemical data was gathered using a HANNA pH 2110UK (Romania) and a Metrohm Model 744 for monitoring pH levels. A saturated calomel electrode (SCE) served as the external reference electrode.

2.2. Materials and reagents

Analytical-grade chemicals were used throughout the experiment. Pure OND was sourced from SDI, while solvents like methanol (99.9%) and THF (97.0%) were purchased from Fluka (Switzerland). Polyvinyl chloride (PVC) of high molecular weight and phosphomolybdic acid (PMA) 99.9% were acquired from Aldrich, Germany.

2.3. Synthesis of Al_2O_3 Nanoparticles

To synthesize Al_2O_3 nanoparticles, 10g of $Al_2O_3 \cdot 9H_2O$ was dissolved in 150 mL of deionized water under constant stirring. An ethanol-based nitrate solution was then added dropwise to the mixture. Subsequently, 14 mL of the ethanol solution was introduced dropwise, and the reaction mixture was progressively heated to 80 °C. A gradual transition into a clear sol-gel precursor (pH 2–3) was obtained. After stirring, the mixture was evaporated over a three-hour period and later allowed to cool to room temperature [23].

2.4. Standard drug solution and Preparation of Ondansetron dihydrate hydrochloride ion-pair

To prepare a 0.01M stock solution of OND, 0.3659g of the drug was dissolved in 100mL of deionized water; this solution was freshly made each day. Series of

working standards, with concentrations between 1.0×10^{-10} and 1.0×10^{-2} mol L⁻¹ were obtained through successive dilutions using purified water. The OND-PMA ion-pair was synthesized by blend equal volumes (50 mL) of 1.0×10^{-2} M OND and PMA solutions. After precipitation, the product was collected via filtration, rinsed extensively with deionized water, and allowed to air-dry at ambient temperature

2.5. Electrode construction

The OND-PMA-Al₂O₃ NP sensor was constructed in our lab using a copper wire substrate. Prior to use, the wire was degreased with acetone and then coated by multiple immersions into the membrane cocktail. The active sensing membrane was formulated by dissolving 5.0 mg of Al₂O₃ nanoparticles, 190.0 mg of PVC, 100.0 mg of the ion-pair, and 0.35 mL of DBPH plasticizer in 6 mL THF. By continuously swirling for 15 minutes, a uniformly mixed membrane solution was prepared at room temperature. A thin coating was developed on the sensors' surfaces from the membrane mixture. Following the drying process, the sensors were immersed multiple times in the membrane solution to create a thicker wire membrane coating [24].

2.6. Electrodes calibration

The sensor response was calibrated using reference samples of (OND) that spanned in the range 1.0×10^{-10} to 1.0×10^{-2} mol L⁻¹. The measurement sequence progressed from lower concentrations to elevated ones. The observed potential was graphed against the logarithmic scale of drug concentration. Between measurements, the sensor was rinsed with distilled water and dried with tissue paper.

2.7. Influence of pH

The influence of pH on the electromotive force (EMF) response of the modified electrodes were studied by varying the solution pH from 0.5 to 14.0 employing 1×10^{-3} mol. L⁻¹ OND. Appropriate amounts of 0.1 mol. L⁻¹ NaOH or HCl solutions were used for pH adjustment. Potential measurements at various pH standards were determined and plotted using the newly introduced electrode. The results show a stable performance of the electrode in the measured range 2.5-9.0 pH.

2.8. Electrode specificity

The potentiometric selectivity coefficients, K_{ij}^{pot} , for interfering ions and for some pharmacologically

important species, were determined by the Separate Solution Method (SSM), IUPAC recommended. [25].

2.9. Assessment of OND.HCl in Pharmaceutical Products

Validation of the developed OND sensor was performed on some real samples purchased from local market by applying both direct method and standard addition method.

3. Results and Discussion

3.1. Characterization of Nanoparticles

3.1.1. UV-Vis Spectrophotometry

The UV-Vis spectrophotometer were employed to measure UV-Vis response of the synthesized Al₂O₃ nanoparticles at room temperature. Figure 2 shows the UV-Vis absorption spectrum of Aluminum oxide nanoparticles. The absorbance peak at 244 nm was observed. This absorption peak is consistent with reported data for aluminum oxide nanostructures. [26].

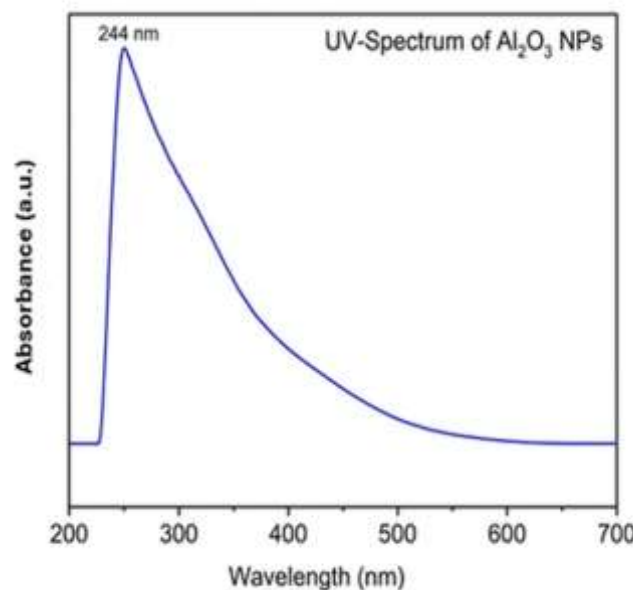


Figure 2: UV-VIS spectrophotometry of Al₂O₃ NPs

3.1.2 Fourier transform infrared spectroscopy

FTIR spectra of Al₂O₃ shown in Figure 3.

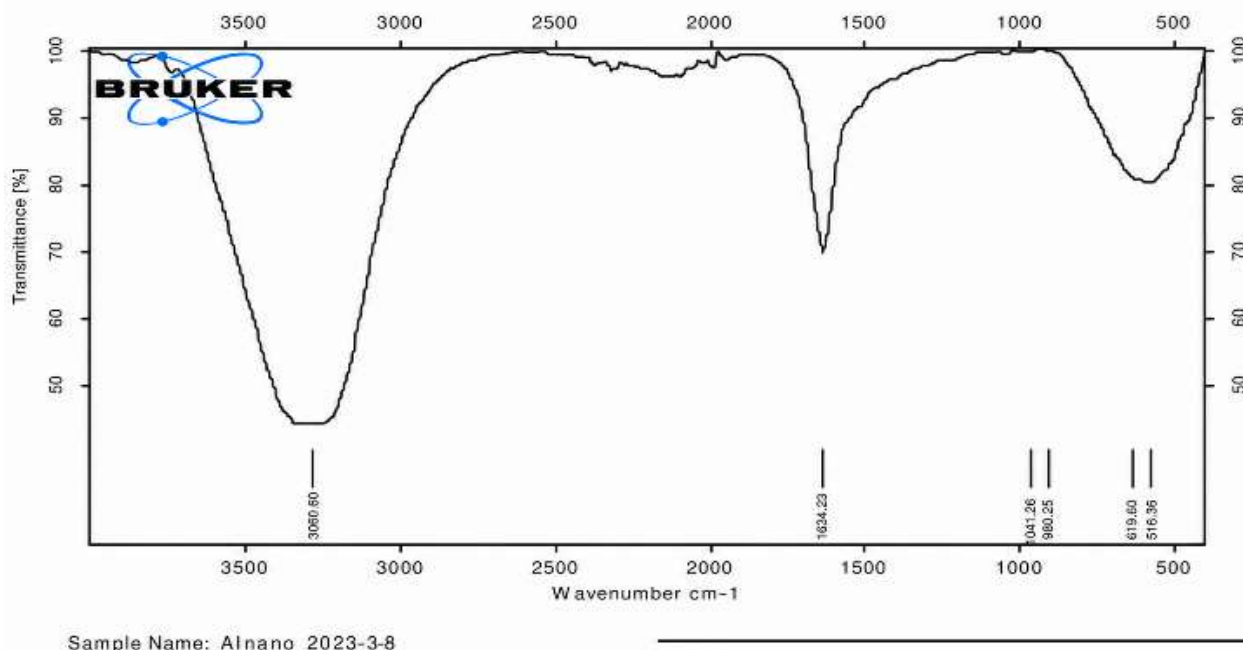


Figure 3: FTIR spectra of Al₂O₃ nanoparticles

A prominent, broad peak centered at 3236 cm⁻¹ corresponds to surface hydroxyl groups and adsorbed moisture, band at 1638.34 cm⁻¹ assigned to physisorbed water molecules. Bands assigned to γ -alumina in 500–1000 cm⁻¹ region with the band at 631.69 cm⁻¹ due to Al-O bond bending [27]. In the gamma phase, the transverse optical vibration at 578.92 cm⁻¹ is believed to arise from an Al-O-Al bond [27].

3.1.3. XRD measurement

The X-ray diffraction (XRD) patterns of the obtained Al₂O₃ nanoparticles were measured on a Rigaku D/MAX-RB X-ray diffractometer using Cu K α radiation with wavelength of 1.543 Å ($k = 1$). The XRD patterns of the Al₂O₃ nanoparticles are showed in Figure 4. The XRD pattern shows an amorphous or poorly crystalline phase of Al₂O₃, which consists of broad humps in the diffraction profiles and no sharp crystalline peaks were observed [28]. The broad line widths clearly point to very small nanocrystals with a size of approximately 2.5 to 5 nm and support the assumption of precipitation during the synthesis.

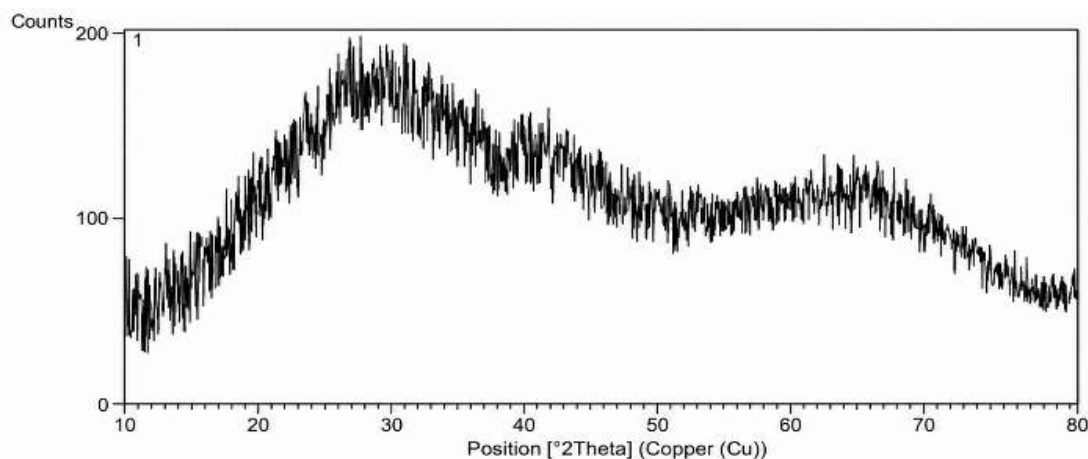


Figure 4: XRD patterns of the Al₂O₃ nanoparticles

3.1.4. FE-SEM and TEM Results

Figure 5 FE-SEM image of Al_2O_3 nanoparticles. The FE-SEM image shows that the obtained Al_2O_3 nanoparticles have largely spherical shape with mean diameter of around 25.78 nm. Notably, the average crystallite size (2.5–5 nm) derived from XRD profiles was smaller than that of the particle size determined by FE-SEM and TEM (approximately 25 nm). The XRD line widths are contributed by the size

of coherent scattering domains, and thus, represent the crystallite size, which is different from the particles dimension observable by FE-SEM in addition to the TEM images. The larger size observed in SEM suggests that the Al_2O_3 nanoparticles are polycrystalline in nature, where each observed particle consists of an aggregate of several smaller crystallites [29].

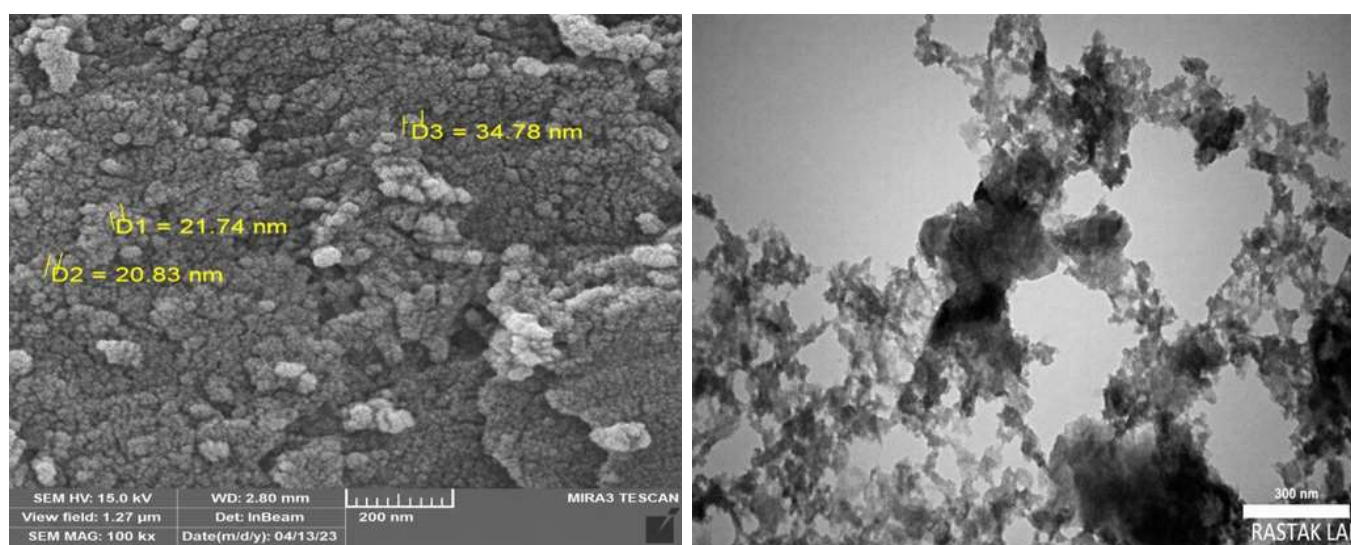


Figure 5: (a) FE-SEM and (b) TEM images of Al_2O_3 nanoparticles.

3.1.5. Atomic force microscopy (AFM)

AFM was used to investigate the surface topography and grain size of the Al_2O_3 nanostructures. Software-

assisted analysis of the AFM images determined an average grain size of roughly 38.74 nm [30].

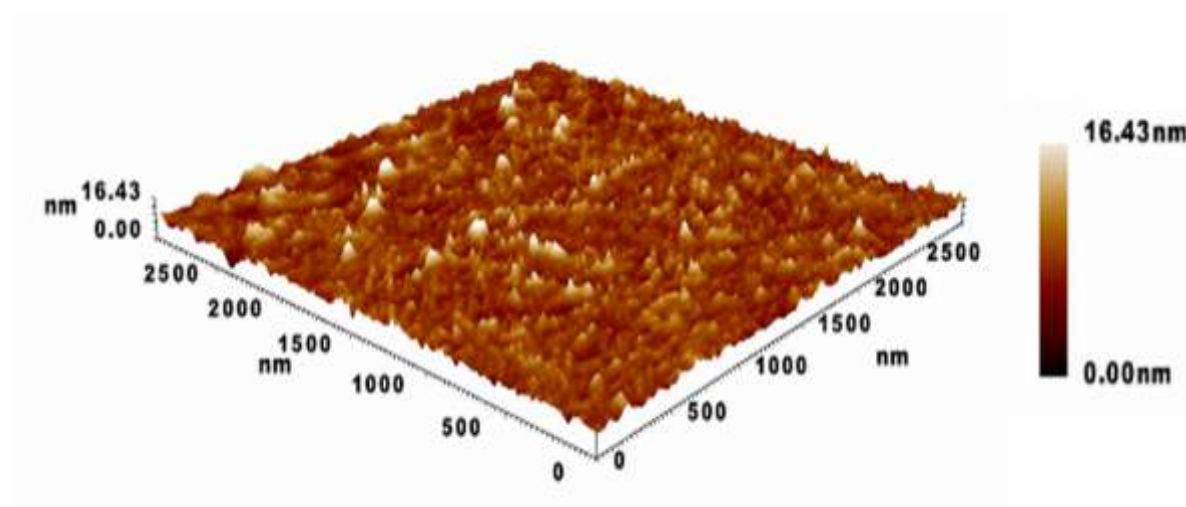


Figure 6: AFM images of Al_2O_3 nanoparticles.

3.2. Performance of the Proposed Sensor

3.2.1. Calibration and Sensitivity:

The analytical detection range of the potentiometric device corresponds to the quantitative linear range of the calibration plot illustrated in Figure 7. The key performance characteristics of the coated-wire electrode were assessed, while the findings are presented in Table 1. Analytical data confirmed a near-Nernstian response for the target drug, spanning a broad concentration range from 1.0×10^{-10} to 1.0×10^{-2} mol L⁻¹ for the drug examined. This ultra-wide linear range and sub-nanomolar detection limit are attributed to the incorporation of Al₂O₃ nanoparticles, which enhance surface area and charge-transduction efficiency, allowing

quantification from trace levels up to high-concentration pharmaceutical assays without sample dilution. The slope of the calibration graph for the coated wire sensor is $+59.30 \pm 0.05$ mV per decade for the (OND-PMA) coated wire sensor. This positive slope confirms the selective Nernstian response toward the cationic Ondansetron (OND⁺) species, where a near-Nernstian slope indicates ideal theoretical charge-transfer behavior per decade concentration according to the Nernst equation. The developed sensor maintained relatively high performance for 65 days, consistently delivering a fast response time of just 14 seconds, which provides a significant practical advantage for rapid, high-throughput quality control testing.

Table 1: The parameters of OND-PMA-Al₂O₃NPs coated wire electrodes.

Parameter	OND-PMA-Al ₂ O ₃ NPs Sensor
Slope (mV decade ⁻¹)	59.30±0.05
Intercept	79.055
Correlation coefficient, (r)	0.9988
Linear range (mol L ⁻¹)	1.0×10^{-10} - 1.0×10^{-2}
LOD (mol L ⁻¹)	5.0×10^{-11}
Response time for 10 ⁻³ M OND/s	14
Lifetime/day	65
Working pH range	2.0-9.5
Robustness a	99.74±0.37
Ruggedness b	99.43±0.06

^a The experimental parameters were slightly modified, such as the pH of the borate buffer(pH 7.5±1).

^b the analytical performance was benchmarked against measurements recorded using a commercial Jenway 3510 pH meter

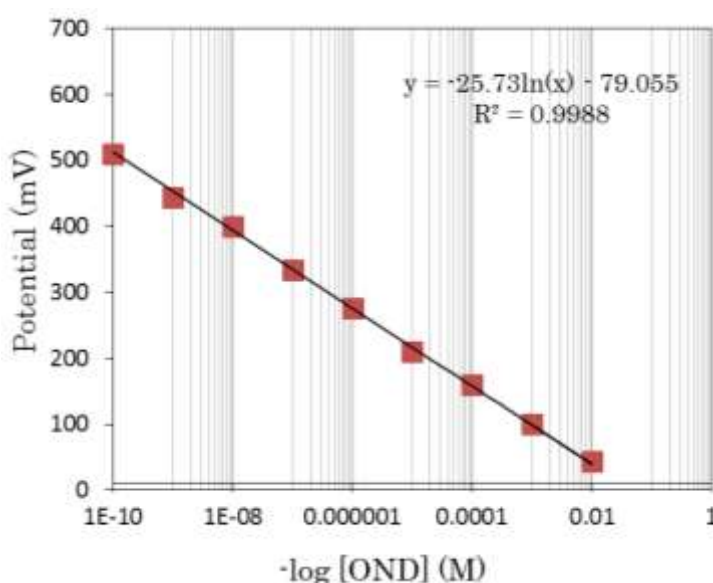


Figure 7: Typical calibration graph of the OND-PMA-Al₂O₃NPs coated wire electrode.

3.2.2. pH Effect Results:

To investigate how pH influences the response of the OND-PMA-Al₂O₃NPs sensor, the response was recorded at a constant concentration of OND (1.0×10^{-3} mol L⁻¹ across a pH spectrum of 2 to 12 (adjustments were made using 0.1 mol L⁻¹ NaOH or 0.1 mol L⁻¹ HCl solutions). Potential remained constant across a wide pH range (2.5–9.0) demonstrating the suitability of the sensor within this range (Figure 8). This stable plateau indicates

that Ondansetron remains fully protonated as a monovalent cation (OND⁺) without precipitating, while H⁺ or OH⁻ ions do not interfere with the membrane recognition sites in this region. Below pH 2.5, the electrode potential shifted positively as a function of acidity as the membrane absorbed excess H⁺ ions. Above pH 9.0, the response of the electrode diminished as the concentration of OH⁻ increased, due to the deprotonation of OND into its insoluble neutral base form.

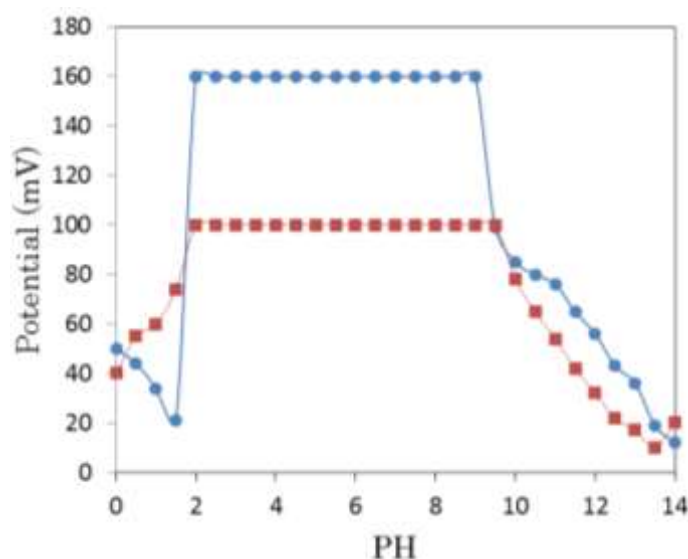


Figure 8: pH dependence of the potentiometric response of the OND-PMA-Al₂O₃NPs coated wire electrode.

3.3 Selectivity of the electrode

The selectivity of the sensor, was evaluated against common inorganic cations and structurally related, pharmacological compounds, using the Separate Solution Method (SSM) according to IUPAC

guidelines [31]. Anionic species NO₃⁻ and CO₃²⁻ were excluded from the final selectivity evaluation as they are electrochemically irrelevant to cationic potentiometric sensors, which respond exclusively to competing positively charged species.

Table 2: The Values of selectivity coefficient for OND-PMA-Al₂O₃NPs coated wire electrode

Interfering Species	Selectivity Coefficient ($K_{\text{OND}, J^{\text{pot}}}$)
Li ⁺	9.47×10^{-3}
Na ⁺	7.50×10^{-3}
Ca ²⁺	2.31×10^{-4}
Ba ²⁺	5.20×10^{-4}
Cr ³⁺	2.87×10^{-8}
Fe ³⁺	8.85×10^{-8}
Glucose	8.73×10^{-8}
Starch	4.02×10^{-8}

Recent literature also highlights the continuing development of potentiometric ion-selective electrodes, including advances in nanoscale metal-

oxide materials and modern ion-selective electrode architectures [32, 33]. As summarized in Table 2, the experimental results underscore the exceptional

selectivity of the proposed electrode for the OND⁺ cation over other materials. The high selectivity was confirmed by obtaining extremely small selectivity coefficient values $K_{OND,J} \ll 10^{-2}$, demonstrating that signal response remains unaffected by high concentrations of interfering substances. Our measured selectivity process is largely driven by electrostatic interactions and stereospecificity, depending on how well the competing ions align with the hydrophobic domains of the OND-PMA ion-pair

receptor. As shown in Table 2, the electrodes displayed high tolerance to interference from inorganic cations and common pharmaceutical excipients.

3.4. Analytical Applications:

The proposed sensor proved us a precise determination of OND concentrations in pure solutions through both the standard addition and calibration curve method. The results obtained were listed in Table 3 and Table 4.

Table 3: Statistical Data Evaluation for OND Determination in Pure and Pharmaceutical Formulations via Direct Potentiometry Using an OND-PMA-Al₂O₃-NPs Coated-Wire Electrode.

Sample No.	Taken ($\times 10^{-3}$ mol L ⁻¹)	Found ($\times 10^{-3}$ mol L ⁻¹)	Recovery (%)	Found ($\times 10^{-3}$ mol L ⁻¹)	Recovery (%)
		Pure Drug		Pharmaceutical Form	
1	10	9.93	99.3	9.91	99.1
2	9	8.98	99.77	8.89	98.77
3	8	7.94	99.25	7.75	96.87
4	8.5	8.45	99.41	8.41	98.94
5	7	6.96	99.42	6.95	99.28
6	6	5.95	99.16	5.94	99
7	5	5.03	100.6	5.11	102.2
8	4	3.98	99.5	3.97	99.25
9	3.4	3.44	101.17	3.45	99.14
10	2	1.97	98.5	1.97	98.5
Statistical Analysis					
Mean $\pm$ SD	99.60 $\pm$ 1.3			99.10 $\pm$ 0.7	
S (Std Dev)	0.75			1.29	
%RSD	0.76			1.3	
%RE	-0.4			-0.9	

Table 4: The Statistical treatment of data for the determination of OND in bulk preparations by standard addition method for OND-PMA-Al₂O₃-NPs coated wire electrode

Sample No.	Taken ($\times 10^{-3}$ mol L ⁻¹)	OND-PMA-Al ₂ O ₃ -NPs Coated Wire Electrode (Pure Drug)		OND-PMA-Al ₂ O ₃ -NPs Coated Wire Electrode (Pharmaceutical Form)	
		Found ($\times 10^{-3}$ mol L ⁻¹)	Recovery (%)	Found ($\times 10^{-3}$ mol L ⁻¹)	Recovery (%)
1	4	3.98	99.5	3.97	99.25
2	5	5.03	100.6	5.11	102.2
3	7	6.96	99.42	6.95	99.28
4	8	7.94	99.25	7.75	96.87
5	9	8.98	99.77	8.89	98.77
Statistical Analysis					
Mean	99.71		99.27		
S (Std Dev)	0.53		1.91		
%RSD	0.53		1.92		
%RE	-0.29		-0.73		

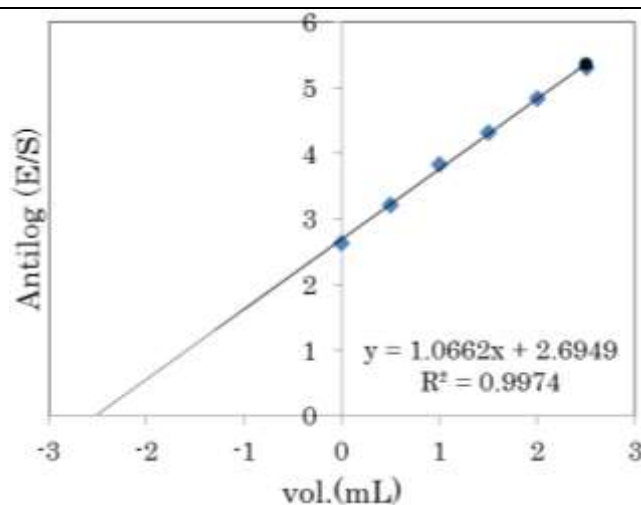


Figure 9: Standard addition method for OND-PMA- Al_2O_3 NPs coated wire electrode for pure form.

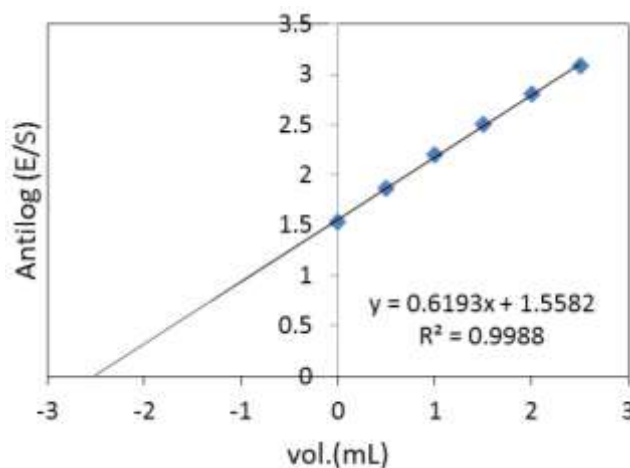


Figure 10: Standard addition method for OND-PMA- Al_2O_3 NPs coated wire electrode for pharmaceutical form.

3.5. The sensor response in pharmaceutical formulation

The analytical capability of the sensor was further evaluated by measuring OND levels in tablet formulations. The results demonstrated high agreement with existing standards, showing no statistically significant differences between the methods.

4. Conclusions

The potentiometric method developed in this study offers a simple, accurate, and economical way to measure OND. Its highly precision and ease of use make them an excellent candidate for routine quality control testing in pharmaceutical environments. Additionally, the sensor enables relatively rapid

analyses of OND in drug products without being affected by common additives or excipients. Therefore, the suggested methodologies hold high potential for the routine quality control of OND in industrial pharmaceutical, clinical, and academic settings.

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Conflict of Interest: The authors declare that there is no conflict of interest regarding this work.

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