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Mesoporous Silica MCM-41 as a Carriers Material for Nystatine Drug in Delivery System

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Abstract

In the present study, MCM-41 was synthesis as a carrier for poorly drugs soluble in water, by the sol-gel technique. Textural and chemical characterizations of MCM-41 were carried out by X-ray diffraction (XRD), Fourier transform infrared (FTIR), scanning electron microscope (SEM), and thermal gravimetric analysis (TGA). The experimental results were analyzed mesoporous carriers MCM-41. With maximum drug loading efficiency in MCM-41 determined to be 90.74%. The NYS released was prudently studied in simulated body fluid (SBF) pH 7.4 and the results proved that the release of NYS from MCM-41 was (87.79%) after 18 hr. The data of NYS released was found to be submitted a Weibull model with a correlation coefficient of (0.995). The Historical data experimental design facilitated the formulation and optimization of sustained discover the optimal formulation to loading drug, combine process variables, mixture components and categorical factors in one design.

Keywords: *MCM-41 silica, Nystatine, adsorption, drug delivery, release systems.*

1. Introduction

Oral delivery is the favored route of medication management, but is often hampered by some challenges such as inadequate physical, biopharmaceuticals, many existing pharmaceuticals suffer from poor water solubility and/or physiological properties, resulting in inadequate solubility and bioavailability by oral [1-2]. During the past decades, porous silica has been used with many attractive properties widely in biomedical applications and drug delivery scale materials for effective oral delivery of poorly soluble drugs [3]. In addition to widely studied organic and inorganic polymers,micro-and nano-porous material have attracted considerable attention recently because they are widely used as controlled delivery systems for controlled drugs and lowering the drug concentrations to be transported by employing nanostructure based on drug delivery vehicles with enhanced adsorption capability and controlled drug release properties can improve the drug's efficiency [4-5]. The applications of mesoporous silica nanoparticles (MSNs) in pharmaceuticals are increasing day by day and are receiving careful attention (Since the discovery of mesoporous silica materials in the 1990s, the synthesis and applications of (MSNs) have received substantial attention because their highly porosity, high surface area, tunable pores, non-cytotoxic properties, and well-ordered structure, well-defined surface properties and high loading and easy control of release, mesoporous materials seem ideal carrier's drugs[6]. The mesoporous has a uniform and adjustable pore size of (2–50) nm, In covenant with (IUPAC) "the International Union of Pure and Applied Chemistry commendation"[7]. Among these mesoporous silica "Mobil Composition of Matter number 41 (MCM-41)" that pore diameter (2 nm < d_{ap}< 6 nm) [8] and "Santa Barbara Amorphous number 15 (SBA-15)" with pore diameter (4 nm <

d_{ap}< 13 nm) [9] with a two-dimensional hexagonal arrangement of cylindrical pores of a uniform size are amongst the most common investigated mesoporous materials. MCM-41 is a widely researched type of MSNs for drug delivery [10-11]. MCM-41, it has unidirectional and very uniform channel structures from Medium hexagonal pores with pore size distributions are very narrow with cylindrical ordered hexagonal mesopores structure, was firstly synthesized in a highly acidic media using amphiphilic tri-block co-polymer of "Cetyl-Trimethyl-Ammonium-Bromide (CTAB)" as template in 1992 [9-12]. The loading and releasing of drugs by the (MSNs) is dependent on factors such as the surface chemical nature, size of pore, specific surface area and morphology of mesoporous silica [13-14].

Experimental design has been used for several decades in science that provides specific information experiments, The factors really influencing was determined and see whether the effects of certain factors depend on other factors. The effect factors were taking into account possible interaction between factors. Use this program to help optimize process, achieve optimal performance, discover the optimal formulation, combine process variables, mixture components and categorical factors in one design. The two parameters that studied (concentration and time) and the response was insert as group and decide the optimal parameter theoretical and experimental and studied the more effect parameter [15].

In this work preparation and characterization of MCM-41 and used for the loading of Nystatine (NYS), and select the best operating conditions for the different studied parameters of loading (concentration of drug and contact time) and the release of (NYS) in simulated body fluid (SBF) pH 7.4. Nystatin (NYS) chemically "tetraene diene polyene macrolide" ($C_{47}H_{75}NO_{17}$) shown in Fig.1. It's possesses different hydrophilic and lipophilic moieties: the hydrophilic area is composed of alcohols, carboxylic acid, and sugar whereas the lipophilic one consists of a chromophore of six conjugated double bonds [16]. Nystatin (NYS) is commonly employed to treat fungal infections in HIV-infected, it's used orally, but a disadvantage of these formulations is the limited residence time of it's in the affected areas [17]. The dosage form needs to reside at the site of infection for a prolonged period. These limitations can be overcome by a drug delivery system because of portability, convenient application, long retention time, easy storage and handling and improved stability [18].

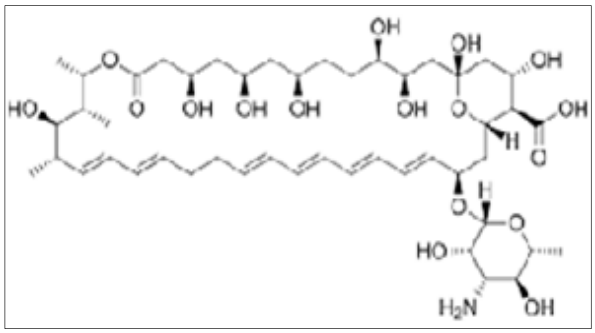

Fig. 1. The 2D structure of NYS.

2. Experimental

2.1 Chemicals

Nystatine was purchased from Al KINDI Company for Pharmaceutical Industries in Iraq. Cetyl Trimethy Ammonium Bromide $CH_3(CH_2)_{15}N(Br)$ $(CH_3)_3$, (CTAB, 99%) with Mwt. 364.45 g/mol and Tetra-Ethyl-Ortho-Silicate (TEOS, 98%) were obtained from Sigma Chemicals. Hydrochloric acid, potassium dihydrogen phosphate (KH_2PO_4, 99.5%, Mwt 136.2) and potassium hydrogen phosphate (K_2HPO_4, 98%, Mwt 178.3) were purchased from CDH India.

2.2 Preparation of Mesoporous MCM-41

The mesoporous MCM-41 was purely synthesized according to the literature using SiO_2 under basic conditions and CTAB, Aldrich as a structural directing agent [9-12] and (TEOS) was used as silica precursor**.** First, prepare a mixture containing NaOH with a weight of 0.35 g and 30 mL of distillate water, dissolve 1.01 g of CTAB in solution. Then, added 5.78 g of TOES to the mixture drop by drop, under 1h of stirring at room ambient temperature. The homogeneous mixture output was crystallized under constant hydrothermal temperature (110 ° C) in the 96 hour in in autoclave device. The solid product obtained by filtration was washed using distill water to remove the micro-surface agent. The solid material obtained at 40 ° C was then dried overnight and the calcination was performed at 550 ° C for 6 hours to remove the surface agent, mold, and MCM-41 was obtained as show in Fig. 2. [20].

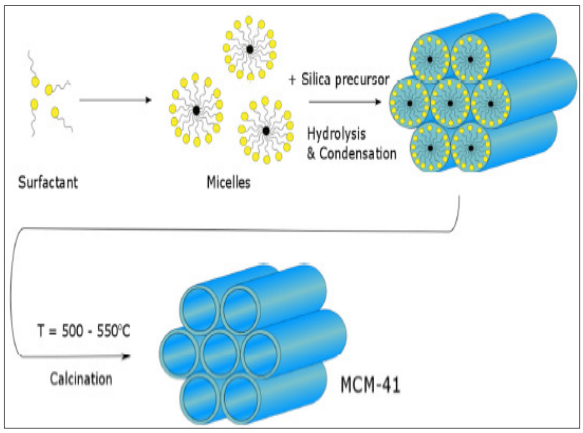

Fig. 2. Scheme of synthesis the MCM-41.

2.3 Characterization

The X-ray diffraction patterns for the mesoporous sample were used to show the crystalline structure and collected using an x-ray diffractometer (Type: Shimadzu-6000, Origin: Japan) with a Cu Kα radiation (λ 1.154 A), with 2θ in the range 0° to 10° with scan rate 2(deg/min). The unit cell and d-spacing factors were obtained by using the equations nλ=2dsinθ and ao=2d_{100}/√3. The SEM analysis (Scanning Electron Microscopy) show the morphology of MCM-41 was performed using SEM instrument [Type: VEGA 3 LM, Origin: Germany]. The FT-IR instrument was used to analyze the chemical bonds of MCM-41. The scanning range was 400–4000 cm^{-1} and the resolution was 4 cm^{-1} and the analysis was carried out using FT-IR [Type: Bruker –Tensor 27, Origin: Germany]. Thermogravimetric analysis (TGA) for MCM-41 and NYS@MCM-41 was performed using thermogravimetric analyzer [Type: STA PT1000, origin: USA], the sample was heated from room temperature to 600 ^{O}C with rate of heating 10 ^{O}C min^{-1} to obtain information concerning thermal stability.

2.4 Nystatine Loading

The loading experiment was conducted by contacting 50 mL of known concentration of NYS with a 0.14 g of MCM-41 in 50 mL of conical flasks which were closed and placed in a shaker at the constant agitation speed at room temperature. The amount of NYS loaded was calculated using the absorbance values obtained at 305nm. The NYS drug loading was estimated according to the Eq.1 [21].

$$Drug\ loading\% = \frac{M2-M1}{M3} * 100\% \quad \ldots (1)$$

2.5 Nystatine Release

The release of the NYS from MCM-41 have done in laboratory equipment at given time intervals. The suspension was withdrawn by syringe into a quartz cuvette. The UV–Vis spectrophotometer was used to measure the amount of the released drugs NYS at 305 nm, according to Equation (2)[22].

$$\%Release = \frac{\text{Weight of Drug in solution}}{\text{Weight of Drug in MSMs}} * 100\% \quad \ldots (2)$$

2.6 Experimental Design

Response surface methodology (RSM) is a statistical method used for experiment design and optimization where experimental responses are fitted with quadratic functions. The objective function of the current study was chosen to maximize the drug loading (DL%) though minimizing the dose of mesoporous carriers and concentration of drugs. Historical data design was used to statistically optimize the formulation parameter and estimate the chief parameters effects, interactions effect and quadratic effect of the formulations ingredient on the % drug loading a nano- carrier systems [23].

3. Results and Discussion

3.1 X-Ray Diffraction Pattern

The different supports were characterized by standard technique. The X-ray patterns of the solid MCM-41 as produced. Fig. (3) shows the presence of reflections at 2θ° angle of 2.86°, 4.4° and 5°, corresponding to planes (100), (110) and (200), reflections related through p6 mm hexagonal symmetry characteristic for MCM-41 material [24]. The position of the first peak, (1 0 0) that presented in Fig. (3) allows direct determination of the center-center distance (The lattice parameters) between adjacent tubes using $a_0 = (2*d_{100}/\sqrt{3})$ [25]. The calculated d_{100} and a_o values are given in Table (1).

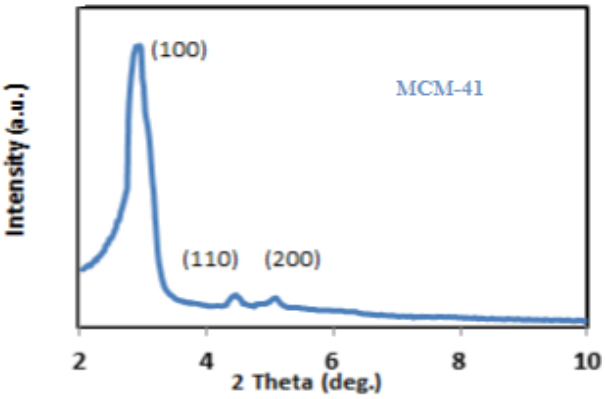

Fig. 3. XRD pattern for MCM-41.

3.2 Scanning Electron Microscopy (SEM)

The morphology of mesoporous materials was analyzed by SEM. Fig. (4) shows image of MCM-41. The SEM image obviously presented that MCM-41, indicate the presences of agglomerate sphere particles shapes and taking smooth surfaces. [26].

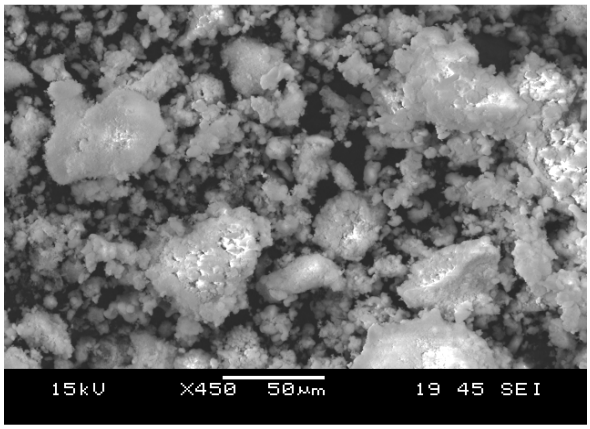

Fig. 4. Typical SEM image for MCM-41.

3.3 FT.IR Spectra

Fig. 5 shows FT-IR spectra of MCM-41. A broad band around 3442-3440 cm^{-1} is given to the stretching type vibration of surface silanol group (Si–O–H) for MCM-41, which is associated with bending at a range 1687 and 1630 cm^{-1} and stretching type vibration of (H-O-H) hydrogen bonded water adsorbed on the surface for SBA-15. Characteristic mesoporous silica Si–O–Si stretching mode vibration is observed at 1336 cm^{-1} and 1084 $cm^{-1}$for MCM-41, which are assigned to symmetric and asymmetric stretching mode respectively. Another peak at 467 cm^{-1} is the Si–O–Si bending type vibration [25].

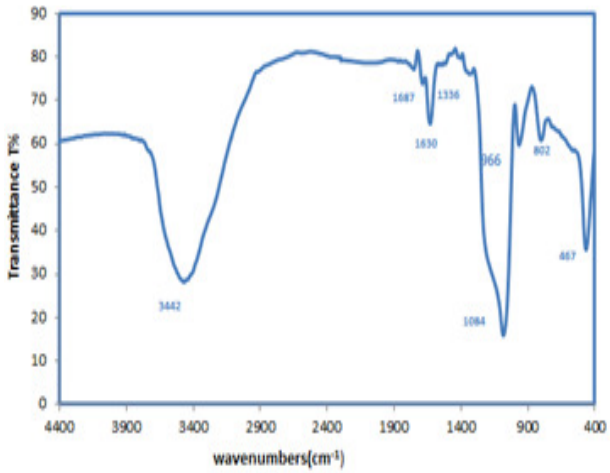

Fig. 5. FT-IR spectra of MCM-41.

3.4 Thermal Gravimetric Analyses (TGA)

TGA measures the losses in mass that is related to the total drug content in the sample. The TGA curves for MCM-41, NYS@MCM-41 are shown in Fig.6. Samples are heating to 600 ºC, at heating rate of 10 ºC/min. The thermal gravimetric curves presented weight loss of NYS loading by MCM-41 (9.52%) and no weight loses of pure MCM-41.

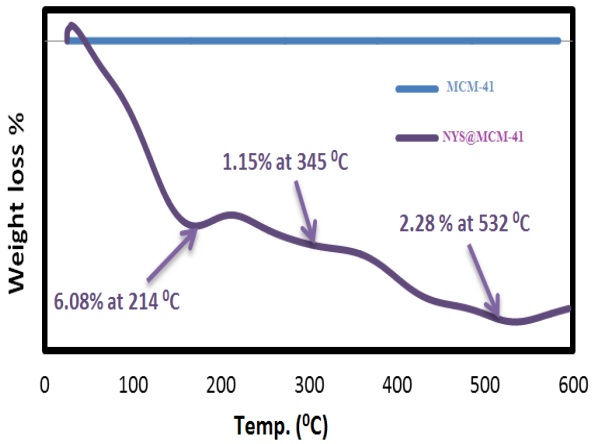

Fig. 6. Thermal gravimetric analysis for MCM-41 & NYS@MCM-41.

3.5 Response Surface Analysis for NYS Drug

Figs. 7 shows the effects of two factors in response (DL%), the effact of time and concentration in drug loading (DL%), when the pH =2 and dose. =0.14gm, observed that at intermediate concentration of NYS drug at

30mg/l, the drug loading efficiency of mesoporous increases when contact time at 24 h and at high concentration of NYS drug stemmed in the formation of aggregate rather than mesoporous, which is extremely undesire so, the maximum DL% show in time=24h, conce. =30mg/l, pH =2 and dose. =0.14gm.

Table 1,
The properties of MCM-41 Structure.

Mesoporous	d_{100} (nm)	a_o (nm)	D_p (nm)	Wt (nm)	Vp (cm^3/g)	S_{BET}(m^2/g)
MCM-41	3.34	3.861	2.32	1.541	0.69	1394

- d-Spacing of (100) reflection. Unit cell constant, $a_o=2d100/\sqrt{3}$. The thickness of the pore wall calculated by the difference (a_o _ Dp). At $p/p_0=0.982$ of N_2 volume adsorbed the total pore volume was taken.

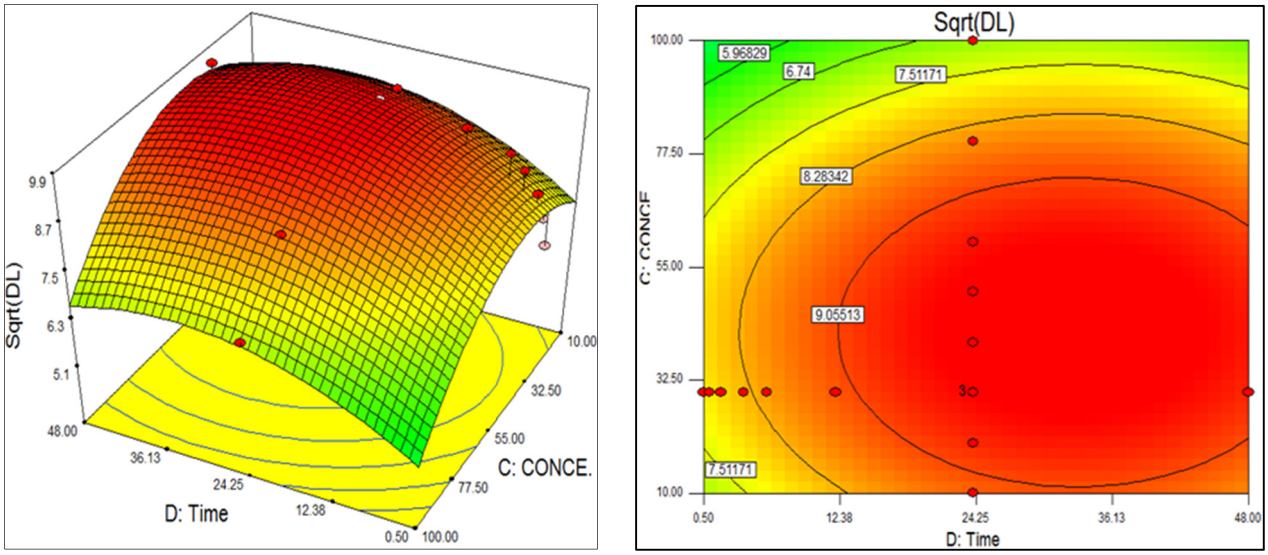

Fig. 7. 3D surface plot & 2D contour plot for effect of Time and Conce. on DL%.

3.6 Nystatine Loading

3.6.1 Effect of Initial Drug Concentration

The effect of initial NYS concentration was studied by changing concentration from 10 mg/L to 100 mg/L as shown in Fig.8

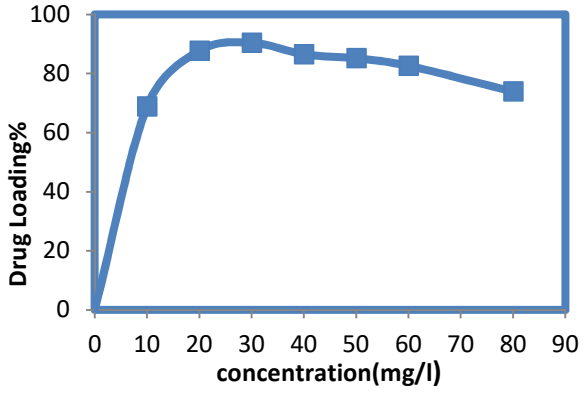

Fig. 8. Effect of the initial NYS concentration on the DL% at: (pH=2, dosage=0.14g/50ml, contact time=24h).

Drug loading efficiency (DL%) decreased with increasing concentration of NYS drug from 30mg/l to 80mg/L. The higher (DL%) were 90.47% at 30 mg/L, the lower (DL%) are 73.98% at concentration drug 80mg/l. The decrease of the drug loading of NYS was due to, the MCM-41 had limited number of active sites which have become saturated above a certain concentration. Conversely, in the case of a lower concentration of NYS that more mesoporous sites were available for NYS molecules, this is agreement with Shah & Rajput (2017) [27].

3.6.2 Effect of Contact Time

The effect of contact time for loading NYS drug by the mesoporous MCM-41 at C_0 = 30 mg/L, pH =2 and dose = 0.14 g is shown in Fig. 9. The rate of the drug loading is rapid in the first 30 min (48.64%) and, thereafter, the loading increased gradually and the it's reached equilibrium at 24hr (90.74%). Large numbers of

devoid surface sites are obtainable for drug sorption through the initial stages, and after a period of time, the residual devoid surface sites are hard to be occupied because repulsive forces among the solute molecules on the solid and bulk phases [28], so we noted after 48hr the drug loading decrease to 89.11%.

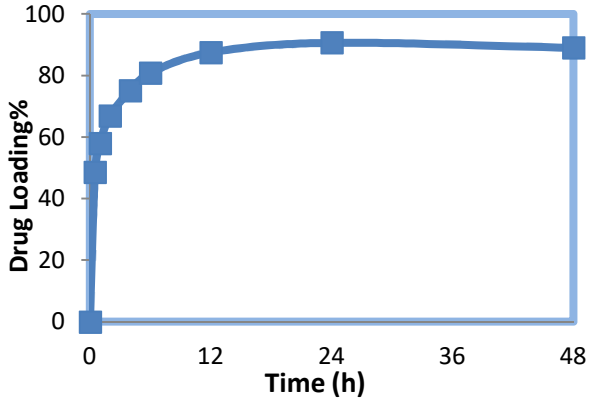

Fig. 9. Effect contact time on the drug loading at: (pH=2, dosage=0.14 g/50ml, conce. of drug=30 mg/l).

3.7 Nystatine Release

The in vitro release of NYS from MCM-41 mesoporous was carried out at pH 7.4 (the physiological pH in the human blood is around 7.4), and showed drug release behaviour **Fig. 10**. At pH 7.4 and body temperature (37 °C), An UV vis spectrometer at 305 nm, was used to measure the NYS release, after the initial release of NYS is about 20% in first hour when the concentration gradient between surfaces of the MCM-41 in the bulk media (SBF, pH =7.4, T =37°C) was large, leading to large percent of NYS released, the drug release rate was relatively slow and was further reduced after 18 h (equilibrium was reached). The cumulated release amount about 87.97% after 18 h and mechanism of the electrostatic repulsion, as experiential in MCM-41 mesoporous silica in which silanol group are deprotonate in pH 7.4 forcing the loading drug to be released and this phenomenon can be explained as follows the PBS is a negative charge inducer and have negatively zeta potential charge. So, it's possible to interaction with positively charged of NYS drug. [29-30].

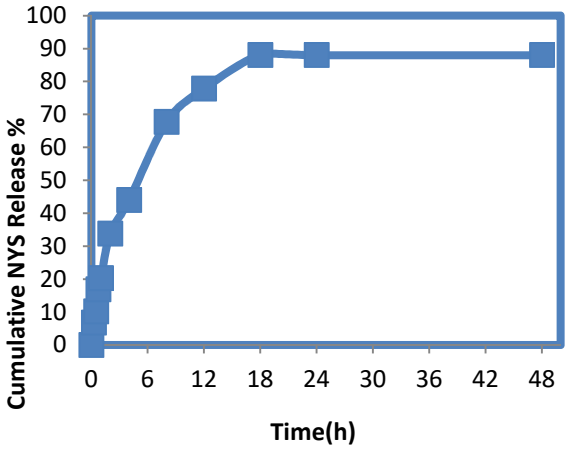

Fig.10. Release of NYS from MCM-41 in SBF at: (pH =7.4, T =37°C).

3.8 kinetic Release of Nystatine

The kinetic of drug release on MCM-41 was studied by using First order, Higuchi, Korsmeyer-Peppas, and Weibull kinetics models, by Eq. (3, 4, 5 and 6).

First order

$$\text{Log}\,(100 - W) = \text{Log}100 - K1\,t \qquad \ldots (3)$$

Higuchi

$$Q = K_H\, t^{1/2} \qquad \ldots (4)$$

Korsmeyer-Peppas

$$\frac{Mt}{M\infty} = Kt^n \qquad \ldots (5)$$

Weibull kinetics models

$$\text{Log}\left[\text{Ln}\left(\frac{1}{1-f}\right)\right] = m\text{Log}\,t - \text{Ln}\,t_0 \qquad \ldots (6)$$

It's used to estimate the mechanism of the drug release. The obtained results from the linearized of models for release of drugs (constants & correlation coefficient) are listed in Table 2.

Table 2,
Release kinetic parameters of drugs in SBF (pH =7.4)

Drug	First order		Higuchi		Korsmeyer-peppos			Weibull	
	R^2	K_1 (h^{-1})	R^2	K_H ($\%h^{1/2}$)	R^2	n	K (h^{-n})	R^2	m
NYS@MCM-41	0.993	0.049	0.983	21.87	0.978	0.6089	17.9	0.995	0.796

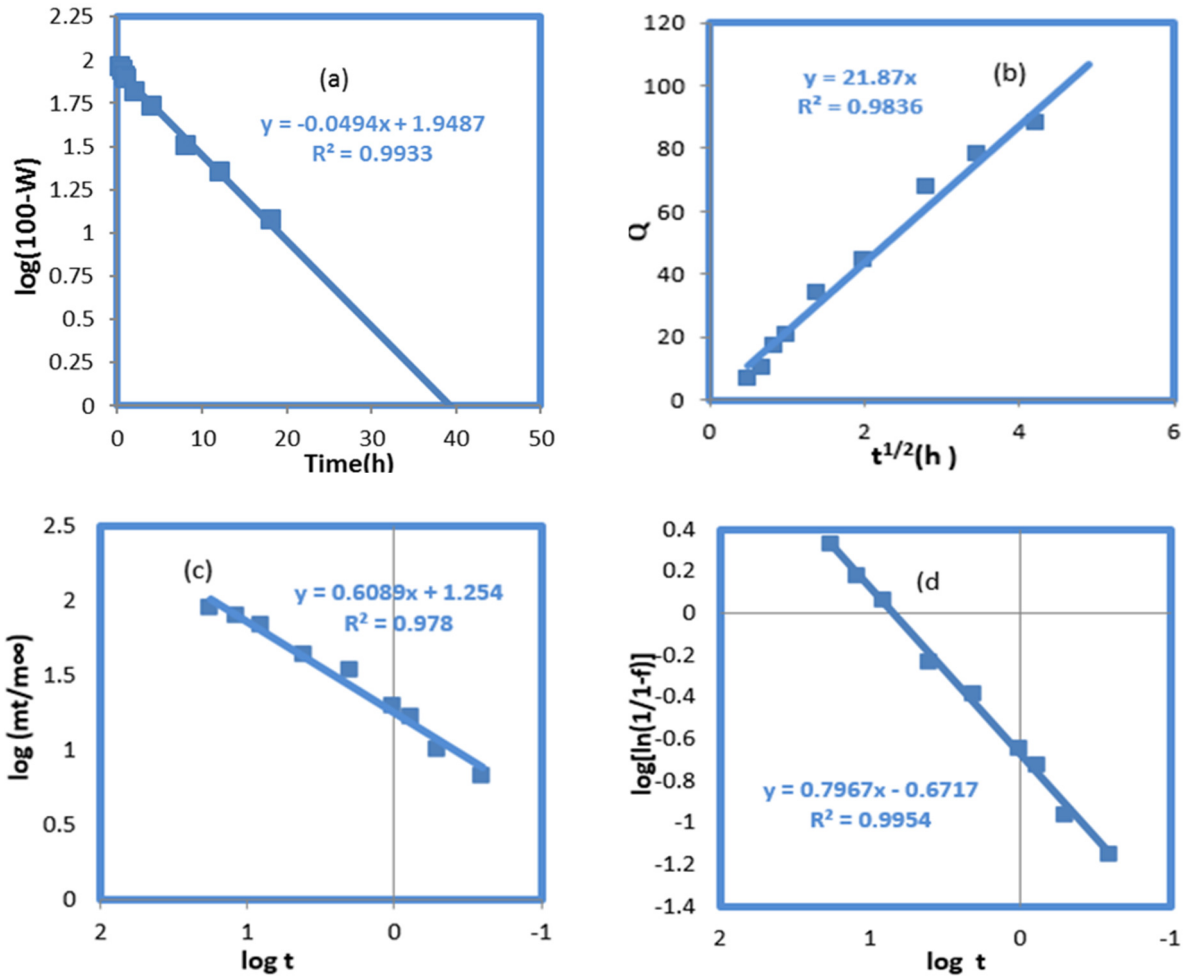

Fig. 11. Kinetic release of NYS for (a) first order, (b) Higuchi model, (c) Korsmeyers Peppas, and (d) Weibull models.

4. Conclusions

Mesoporous silica MCM-41 with high surface area was synthesis by sol-gel technic and used as naocarrier in drug delivery system. NYS was loading by MCM-41 and the maximum loading percentage was 90.74%. The NYS release was studied at SBF media with pH (7.4). The time of NYS release was (87.79%) after 18 hr. The kinetics of release of NYS drug from MCM-41 is fully fit by a weibull model with a correlation coefficient of (0.995).

Abbreviations

BET	Brunauer – Emmett – Teller
CTAB	CetylTrimethyl Ammonium Bromide
D_p	Pore Diameter
IUPAC	International Pure and Applied Chemistry
MCM	Mobil Composition of Matter
MSNs	Mesoporous Silica Nanoparticles
NYS	Nystatine
RSM	Response surface methodology
SBA	Santa Barbara Amorphous
SBF	Simulated Body Fluid
TEOS	TetraEthyl OrthoSilicate

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السليكا المساميَة MCM-41 مادة ناقلة لعلاج النستاتين لنظام تسليم الدواء

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الخلاصة

في هذه الدراسة ، حضرت المادة النانوية المسامية MCM-41 وصفها ناقلات للأدوية صديئة للذوبان في الماء ، من خلال تقنية sol-gel. أجريت التوصيفات التركيبية والكيميائية لـ MCM-41 وباطة حيود أشعة السينية (XRD)، وجهاز فورير الأشعة تحت الحمراء (FTIR) ، ومسح المجهر الإلكتروني (SEM) ، والتحليل الوزني الحراري (TGA). تم تحليل النتائج التجريبية للناقل MCM-41 مع الحد الأقصى لفعالية تحميل دواء النستاتين في MCM-41 وتبين ان كفاءة التحميل ٩٠,٧٤ ٪. وتم دراسة اطلاق علاج النستاتين المحمل شكل حذر في سائل يحاكي جسم الانسان (SBF) عند الاس الهيدروجيني ذو القيمة ٧,٤ وأثبتت النتائج أن اطلاق العلاج من MCM-41 كان (٨٧,٧٩٪) بعد ١٨ ساعة. بيانات تحرر NYS وجدت انها تخضع لمعادلة weibull وكان معامل التصحيح (٠,٩٩٥). هل التصميم التجريبي للبيانات صياغة وتحسين الصيغة المثلى لتحميل الدواء ، وجمع المتغيرات