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Research Article

PREPARATION AND CHARACTERIZATION OF MESOPOROUS SILICA NANOPARTICLES OF POORLY WATER SOLUBLE DRUG CANDIDATE IRBESARTAN AND FORMULATION OF IMMEDIATE RELEASE TABLETS

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ABSTRACT

Objectives: The present study aimed to prepared mesoporous silica nanoparticle (MSN)-loaded immediate release tablet of drug candidate irbesartan. This approach initiates immediate dissolution of poorly water soluble drug and increases solubility, respectively.

Methods: According to this study, mesoporous nanoparticles could be used to assess a mesoporous carrier's effectiveness for a drug candidate that is not poorly water soluble. To deliver a drug candidate with low water solubility, mesoporous nanoparticles were chosen. MSNs were prepared by sol-gel process. To describe the characteristics of mesoporous nanoparticles, we used scanning electron microscopy, infrared, differential scanning calorimetry, and powder X-ray diffraction. The percentage of drug release was observed by *in vitro* dissolution. Direct compression method was employed to formulation of immediate release tablets of mesoporous silica nanoparticle's loaded irbesartan.

Results: The particle size of MSN's was found to be 98.3 nm. Brunauer-Emmett-Teller isotherm gives the idea about mesoporous nature with pore diameter 3.17 nm. The entrapment efficiency of drug into nanoparticles found to be 82%. Drug loaded MSNs then subjected to formulation of tablet by direct compression method. Irbesartan MSNs tablet was prepared successfully. The prepared tablet is white rounded in shape. The hardness of tablet is 3.21±0.117–4.32±0.620 range. The friability study showed that there is very little dusting of prepared that after 30 min of study. The disintegration time found to be in range of 117±0.330–135±0.00 s. The dissolution study drug is range of 65–80% in 45 min in acidic buffer pH 1.2. The Batch F1 showed lower release 68% and Batch F11 showed highest release of drug 81%.

Conclusion: The MSNs loaded irbesartan immediate release tablet offers a sure alternative for immediate delivery of antihypertensive drug irbesartan. The MSNs enhance dissolution rate of drug and hence improved solubility which may give better therapeutic outcomes.

Keywords: Irbesartan, Mesoporous silica nanoparticles, Particle size, Entrapment efficiency, Immediate release tablet, Bioavailability, Hypertension.

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INTRODUCTION

Irbesartan is an antihypertensive drug candidate which is angiotensin II receptor antagonists used in management of hypertension [1]. The irbesartan drug is having low aqueous solubility. It has 90% plasma binding and 60–70% bioavailability hence required large therapeutic doses 75–300 mg are required for the required therapeutic effect [2]. Mesoporous silica nanoparticles (MSNs) play an important role in delivering poorly water soluble drug in immediate way by increasing dissolution rate of drug candidate [3]. The MSNs are having new technology that attracting researchers due to its structural properties. Mesoporous silica nanoparticles are chemically stable and biocompatible, making them excellent carriers to help poorly soluble drug candidate to improve dissolution rate which improves their effectiveness [4]. Due to high compatibility MSNs, greater chemical stability it arising as a perfect carrier to increase dissolution of drug candidate [5]. The nanosize of MSNs initiates amorphisation and immediate release pattern of drug [6]. The preparation of MSNs is simple in nature and porous nature of particles enhances ability to retain drugs during loading and release [7]. MSNs play a key role in maintaining the stability of drugs by preventing their detoriaion by means of various reactions such as oxidation and reduction [8]. This study made MSNs with nanoscale particle sizes using a method called sol-gel [9]. The goal of this study was to find a way to load MSNs into an immediate tablet so that they could be used to make a unique formulation and due to their unique properties, such as a highly mesoporous structure, significant pore volume, adjustable pore size, superior biocompatibility, and thermal stability, mesoporous materials are useful as a drug carriers [10].

MATERIALS AND METHODS

Materials

Irbesartan was used as active pharmaceutical ingredient. Tetra-Ethyl-Ortho Silicate (TEOS) and cetyltrimethylammonium bromide (CTAB) were purchased from Chempure Pvt Ltd and Hychem laboratories. Diethanolamine, purified water and ethanol were procured from school of pharmacy.

Method (preparation of mesoporous nanoparticles)

The sol-gel process is used to prepare MSNs 5.2 g of CTAB be taken, 32 mL of water and 9 mL of ethanol have been combined to make a solution. To the solution, add 0.1 g of dimethylamine. Put it in a water bath and heat until reaches 30°C. A careful drop-by-drop administration of 3.65 mL of TEOS was then given. For a further 2 h, keep stirring the mixture until it turns white. After being cleaned with water and the procedure is repeated frequently. The white precipitate then filtered out. The material is first calcined at 823 k for 6 h at 550°C, and then, it is dried for 72 h at 318 k.

Drug loading

The solvent evaporation method is used to load drug. The drug is dissolved in ethanol. Furthermore, the solution was supplemented with MSNs. The solution was stirred for 2 h. The product dried as the

solvent evaporated while it was being stirred. MSN was kept in airtight containers for future study [11,16].

Preparation of fast dissolving tablet

Direct compression method

The each ingredient was measured accurately. After going through sieve number 60, the irbesartan, sodium starch glycolate, and crospovidone were mixed together and keep aside in a container for 15 min. Both talc and magnesium stearate were sieving through screen number 60 at the same time. After that, it was added to the previous mixture and mixed for 20 min to get it ready to be compressed. After that, the mixture was pressed on tablet punching machine to make 350 mg round tablets. The compression force is kept constant so that tablets with a hardness of 3–5 kg/cm^2 can be made (Table 1).

Characterization of MSNs

1. Particle size: The Zetasizer is used to characterize the size of MSN particles. Water served as the dispersion medium for the study, which was carried out at 25°C [12].
2. Entrapment efficiency: An ultraviolet (UV) spectrophotometer was used to measure the amount of irbesartan contained in MSNs. To help the organic solvent evaporate, 10 mg of precisely weighed MSNs were dissolved in 10 mL of ethanol, extracted in a phosphate buffer with a pH of 1.2, and continuously stirred for half an hour. A UV spectrophotometer is used to examine the solution at 243 nm after it has been filtered through Whatman filter paper. The following formula is used to calculate the entrapment efficiency percentage.

Entrapment efficiency=Actual drug loaded/Practical drug loaded × 100

The formula was applied for calculation of entrapment efficiency.

3. Fourier transform infrared spectroscopy (FTIR) analysis: Using a Bruker FTIR spectrophotometer, the FTIR spectra of irbesartan and irbesartan MSNs were acquired at room temperature. Infrared spectra were analyzed using the KBr pellet technique at a resolution of 4 cm^{-1} over the 4000–400 cm^{-1} range [13].
4. X-ray diffraction (XRD): The XRD patterns were examined using a X-ray diffractometer [14].
5. Differential scanning colorimetry (DSC): DSC was performed using the DSC. Using hermetically sealed aluminum crucibles, temperature and enthalpy were measured. Using a nitrogen gas purge at a flow rate of 50 mL/min, additional analysis of the medication and MSN was carried out.
6. Solubility study: After being dissolved in a solvent for a full day, measured amounts of MSN were filtered through Whatman filter paper. A UV spectrophotometer was used to measure the solution's absorption at 243 nm.
7. Transmission electron microscope (TEM) study: TEM studies of MSNs involve preparing samples, imaging them using a TEM instrument, and analyzing the resulting images to determine their size, morphology, and pore structure. Typically, MSNs are first dispersed or deposited on a TEM grid, then imaged at various magnifications, including high-resolution TEM [15].

Characterization of immediate release tablet

Tablet appearance

Assessing the tablet's appearance by visual inspection, verification of its shape, and identification of any defects, such as capping or chipping.

Uniformity of tablet

Twenty tablets were randomly selected from each formulation and weighed individually using an electrically sensitive balance to assess weight consistency. The standard deviation and mean weight were calculated.

Hardness test

A hardness tester was employed to quantify the breaking force to determine the hardness and friability. The uniform hardness throughout the manufacturing process, testing was conducted before, during, and subsequent to tablet production.

Friability test

A friability tester was employed to assess the friability of the tablets. Initially, 20 tablets were weighed (Weight) before their placement in the friabilator. The friabilator was operated at 100 rpm for 30 min. A subsequent weighing of the tablets was conducted.

Disintegration study

The disintegration time was evaluated in accordance with United States Pharmacopeia (USP) criteria using the disintegration apparatus. The disintegration time was measured in second for each of the six tablets, with each tablet placed in an own vessel.

Dissolution study

The USP dissolution testing apparatus, which is a paddle-type apparatus, to find out drug release pattern of immediate release tablet. To maintain sink conditions in dissolution test the dissolution volume kept as 900 mL and pH 1.2 is maintained. The dissolving process took place at 37°C±0.5°C with a rotation speed of 50 rpm. The 50 rpm speed is generally used for immediate release formulation due to it assume similar condition and movement of gastro intestinal tract. The greater speed can excessively increase dissolution. We took 5 mL samples of the solution from the dissolution device at 5, 10, 15, 30, and 45 minutes and replaced them with new dissolution medium to keep the sink condition. Sample was filtered with a membrane filter and used a UV-visible double-beam spectrophotometer to measure and calculate the absorbance of the irbesartan at 243 nm, linear equation was used based on a standard curve to find the cumulative percentage of drug release.

RESULTS AND DISCUSSION

Particle size

The diameters of MSN particles are measured using the Zetasizer. The MSN's particle size was determined to be 98.3 nm after the particle size analysis (Fig. 1).

FTIR

The MSNs particles' FT-IR spectra fell between 4000 and 500 cm^{-1}. The rocking vibration and bond stretching of the surface Si-OH groups are seen at 460 cm^{-1}. The unique H-OH water bending band at 1640 cm^{-1} was accompanied by a prominent hydrogen-bonded hydroxyl stretching band for both silanol Si-O-H and water hydroxyls, clearly observed at 3500 cm^{-1}. The symmetric band is located at 800 cm^{-1}, but internal Si-O-Si stretching vibration of the SiO_4 asymmetric band is observed as 1100 cm^{-1}. It is suggested that the silicate network consists

Table 1: Composition of immediate release silica mesoporous irbesartan tablets

Ingridint	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13
Irbesartan MSNs (mg)	150	150	150	150	150	150	150	150	150	150	150	150	150
Lactose (mg)	112.5	106.9	111.25	107.75	111.25	111.25	77.70	110	112.92	115	144.80	111.25	111.25
MCC (mg)	70	72.5	72.5	75	72.5	72.5	106.05	75	72.5	70	38.95	72.5	72.5
Sod. Starch glycolate (mg)	7.5	10.60	6.25	7.5	6.25	6.25	6.25	5	4.58	5	6.25	6.25	6.25
Magnesium Stearate (mg)	2	2	2	2	2	2	2	2	2	2	2	2	2
Talc (mg)	6	6	6	6	6	6	6	6	6	6	6	6	6
Aspartame (mg)	2	2	2	2	2	2	2	2	2	2	2	2	2

MSNs: Mesoporous silica nanoparticle

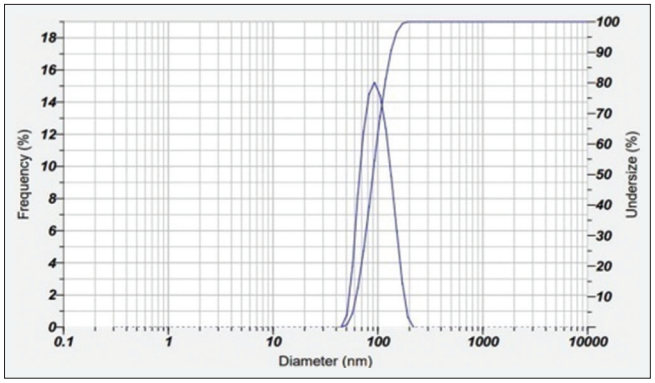

Fig. 1: Particle of mesoporous silica nanoparticles

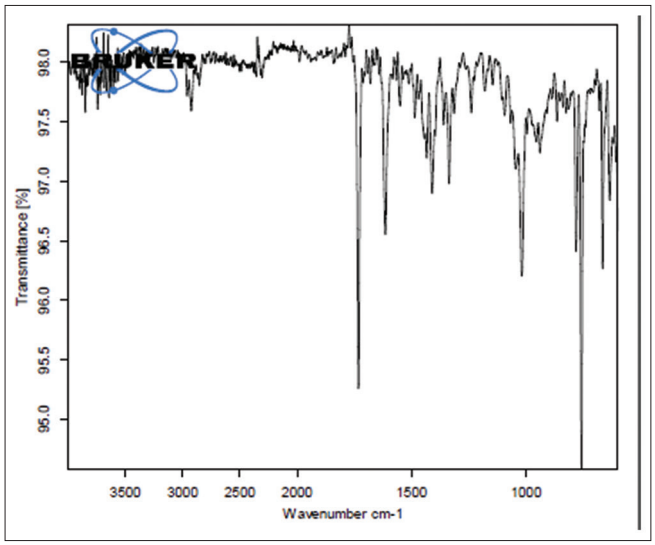

Fig. 2: Fourier-transform infrared spectroscopy of irbesartan

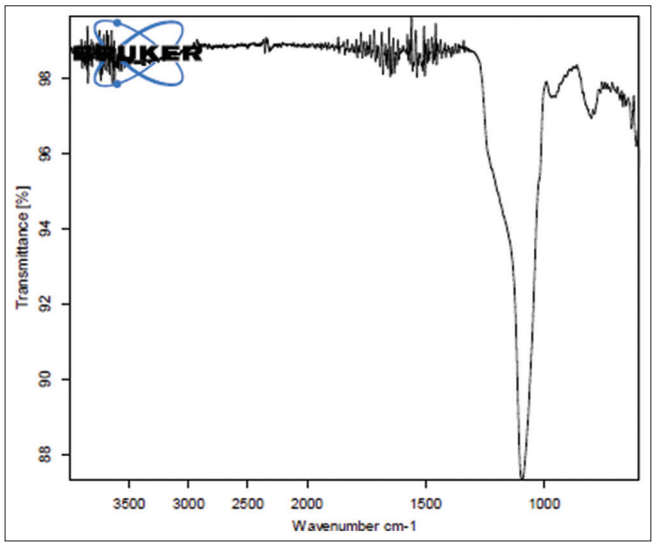

Fig. 3: Fourier-transform infrared spectroscopy of mesoporous silica nanoparticles

of Si-O-Si connections and various silanol Si-OH groups, both external and internal, displaying a range of shapes. FTIR of irbesartan shows N-H stretching at 3608 cm^{-1}, C-H stretching at 2961 cm^{-1}, and C=C at 1550 cm^{-1}. Stretching at MSNs did not change the distinctive peaks of Irbesartan (Figs. 2-4).

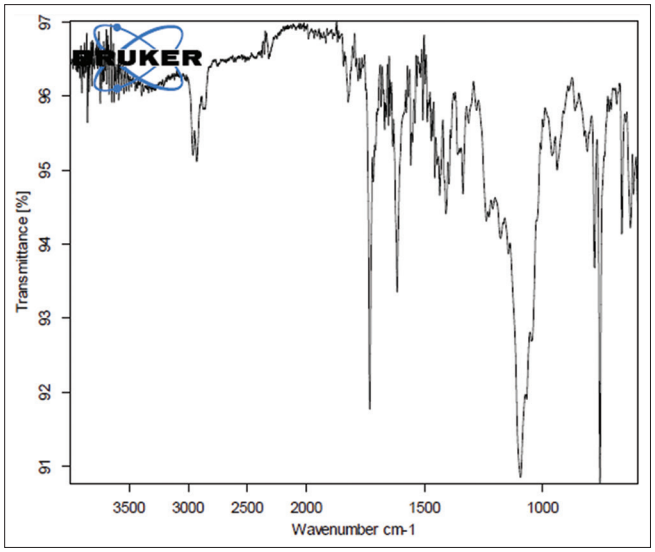

Fig. 4: Fourier-transform infrared spectroscopy of mesoporous silica nanoparticles irbesartan tablet

Table 2: Solubility study of pure irbesartan and MSNs loaded Irbesartan

Solvent	Irbesartan solubility (mg/mL)	MSNs loaded irbesartan solubility (mg/mL)
Water	0.040±0.021***	0.242±0.001***
Phosphate buffer pH 6.8	0.087±0.013*	0.500±0.015**
Phosphate buffer pH 1.2	0.098±0.044**	0.627±0.014**

Values are expressed as mean±S.D. follows t-test (n=3) ***p<0.01, *p<0.1, **p<0.05 shows significant difference

Entrapment efficiency

An UV spectrophotometer was used to measure the amount of medication contained in MSN. After precisely measuring ten milligrams of MSNs, they were dissolved in 10 mL of methanol and extracted in a phosphate buffer with a pH of 1.2 while being constantly stirred for half an hour. A UV spectrophotometer is used to measure the solution's wavelength in nanometers after it has been filtered through Whatman filter paper. The following formula is used to determine the percentage of entrapment efficiency. Irbesartan's encapsulation percentage in MSNs was 82%.

XRD

Pure irbesartan has a prominent peak at 1000 along with a number of smaller peaks, according to XRD research. The peaks of lower intensity in the irbesartan-loaded MSNs indicate that the crystalline drug is encapsulated within the MSNs, causing amorphization at the mesopores and, consequently, producing smaller peaks.

DSC

Irbesartan's DSC thermogram shows an endothermic event that takes place between 181°C and 190°C. Pure irbesartan has a melting point of 181°C and a boiling point of 190°C (Fig. 5 and 6).

Saturated solubility

Irbesartan's saturated solubility was investigated in a variety of dissolving media. After being measured, ten milligrams of irbesartan were put into individual conical flasks with ten milliliters of various dissolution media (water, pH 6.8 phosphate buffer, and pH 1.2), and the flasks were properly sealed. For 24 h, all conical flasks were kept at 37±1°C on a magnetic shaker set to 50 rpm. After taking the conical flasks out of the incubator shaker, Whatman filter paper was used to filter the samples. Using the corresponding dissolution media as a blank, absorbance measurements were made at 243 nm after the

Table 3: Characterization of immediate release silica mesoporous irbesartan tablet

Formulation code	% drug release	Disintegration time (s)	Weight variation (mg)	Friability (%)	Hardness (kg/cm^2)
IRB F1	68±0.50	121±0.00	347±0.02	0.21±0.12	3.65±0.22
IRB F2	72±0.65	117±0.33	351±0.12	0.24±0.17	3.21±0.11
IRB F3	74±0.19	132±0.16	349±0.18	0.27±0.12	3.80±0.51
IRB F4	77±0.62	130±0.11	349±0.72	0.30±0.13	4.00±0.15
IRB F5	74±0.40	121±0.00	350±0.55	0.31±0.13	4.12±0.02
IRB F6	75±0.59	134±0.00	351±0.22	0.25±0.13	3.22±0.22
IRB F7	76±0.18	135±0.00	353±0.20	0.26±0.15	3.24±0.75
IRB F8	75±0.69	119±0.00	347±0.02	0.26±0.97	3.23±0.51
IRB F9	79±0.88	127±0.00	353±0.50	0.33±0.09	4.32±0.62
IRB F10	77±0.11	124±0.33	351±0.50	0.34±0.11	3.40±0.71
IRB F11	81±0.08	118±0.00	351±0.50	0.30±0.78	3.94±0.30
IRB F12	76±0.03	125±0.00	354±0.50	0.27±0.11	3.74±0.17
IRB F13	74±0.25	130±0.00	352±0.77	0.22±0.57	3.70±0.52

n=3, mean±standard deviation, various characterization parameters of immediate release tablet of irbesartan

Table 4: *In vitro* study of immediate release silica mesoporous irbesartan tablets

Formulation	0 min	05 min	10 min	15 min	20 min	25 min	30 min	35 min	40 min	45 min
IRB F1	0	12±0.62	22±0.40	27±0.14	37±0.34	51±0.22	53±0.74	59±0.62	63±0.14	68±0.50
IRB F2	0	14±0.14	19±0.13	28±0.22	40±0.13	43±0.28	51±0.10	60±0.34	67±0.46	72±0.65
IRB F3	0	10±0.24	20±0.84	31±0.56	41±0.24	50±0.64	60±0.31	64±0.18	67±0.48	74±0.19
IRB F4	0	11±0.60	17±0.20	27±0.12	39±0.36	47±0.33	57±0.65	64±0.74	70±0.50	77±0.62
IRB F5	0	13±0.200	19±0.56	31±0.36	40±0.50	51±0.36	57±0.50	63±0.62	69±0.14	74±0.30
IRB F6	0	14±0.320	22±0.02	33±0.19	43±0.24	54±0.72	61±0.28	67±0.44	71±0.02	75±0.22
IRB F7	0	12±0.12	23±0.32	36±0.16	43±0.73	51±0.18	59±0.14	66±0.58	70±0.18	76±0.18
IRB F8	0	14±0.74	24±0.00	34±0.28	41±0.02	53±0.00	60±0.12	64±0.38	69±0.42	75±0.69
IRB F9	0	13±0.50	18±0.18	35±0.68	45±0.28	57±0.33	63±0.11	67±0.17	71±0.46	79±0.88
IRB F10	0	15±0.10	24±0.21	31±0.27	41±0.14	51±0.28	60±0.34	64±0.50	69±0.22	77±0.11
IRB F11	0	13±0.26	25±0.30	31±0.20	46±0.64	58±0.37	65±0.14	69±0.32	75±0.20	81±0.08
IRB F12	0	12±0.04	21±0.88	32±0.20	42±0.10	53±0.43	61±0.34	65±0.74	71±0.66	76±0.03
IRB F13	0	11±0.12	22±0.40	31±0.50	40±0.31	49±0.14	59±0.24	64±0.28	70±0.27	74±0.25

n=3, mean±standard deviation, % drug release of immediate release tablet of Irbesartan from 0 min to 45 min

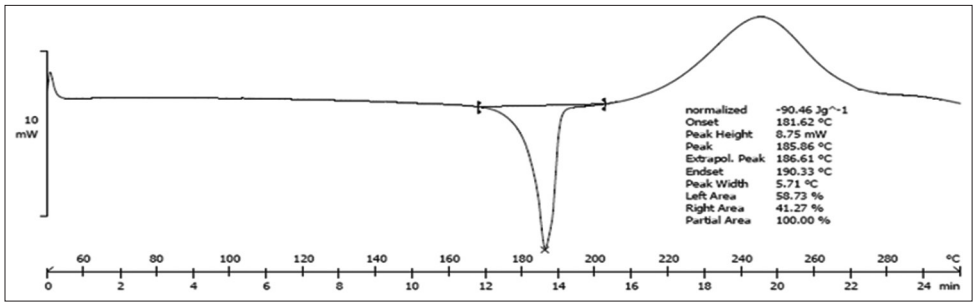

Fig. 5: Differential scanning colorimetry of irbesartan

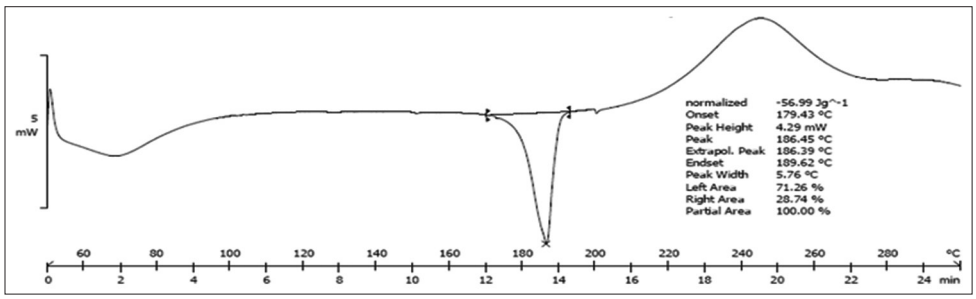

Fig. 6: Differential scanning colorimetry of irbesartan+mesoporous silica nanoparticles

filtrate had been appropriately diluted with the appropriate dissolution media. The result found that in Water pure irbesartan solubility was 0.040 mg/mL MSNs loaded irbesartan was 0.242 mg/mL same phosphate buffer pH 6.8, 0.087 mg/mL and 0.500 mg/mL, respectively. In phosphate buffer pH 1.2, solubility was 0. 098 mg/mL and in MSNs loaded irbesartan was found that 0.627 mg/mL (Table 2).

TEM

TEM study shows honeycomb like porous structure of MSNs. The hexagonal straight channels are shown extending along the spherical particles. The particles have straight one dimensional cylindrical pores. TEM image shows the pores as well organized channels forming a honeycomb like structure (Fig. 7).

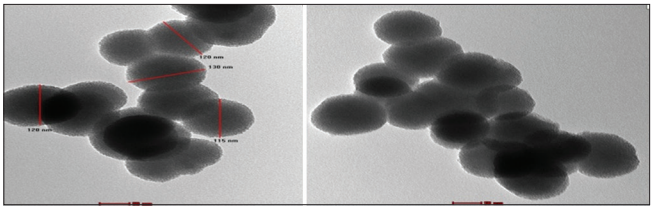

Fig. 7: Transmission electron microscope study of mesoporous silica nanoparticles

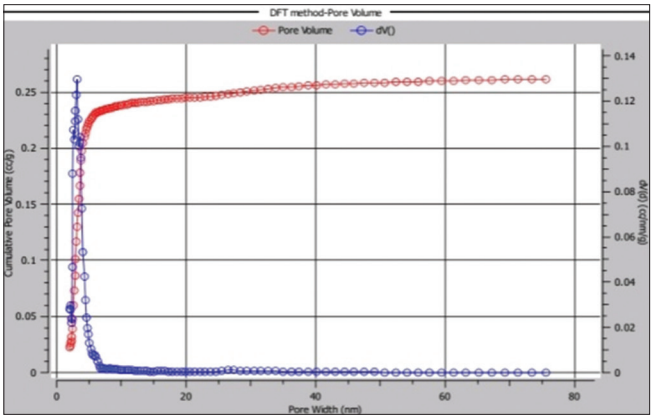

Fig. 8: Brunauer-Emmett-Teller isotherm of mesoporous silica nanoparticles

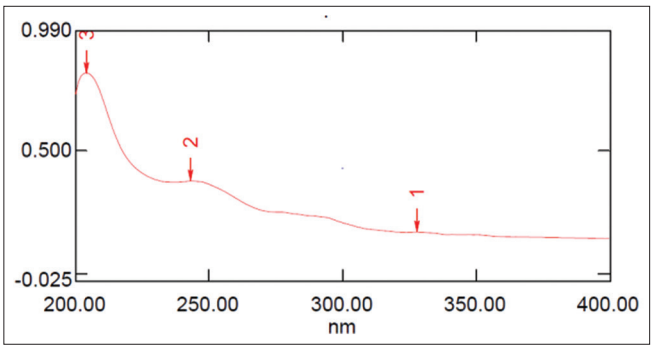

Fig. 9: Ultraviolet spectra for irbesartan at 243 nm

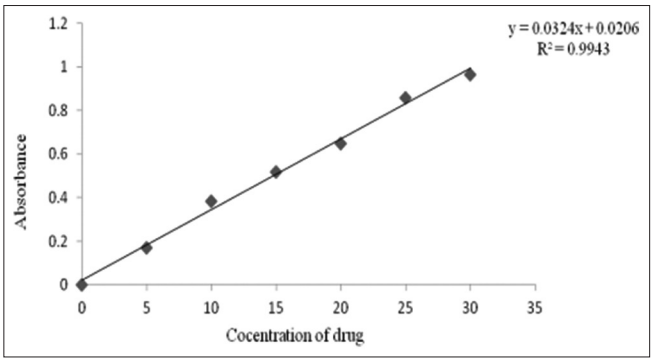

Fig. 10: Calibration linear curve of irbesartan

Brunauer-Emmett-Teller (BET) surface area

MSNs exhibit high surface area. The surface area found to be 322.182 m^2/g. The pore volume was 0.2612 cc/g. The pore width was found to be 3.1790 nm (Fig. 8).

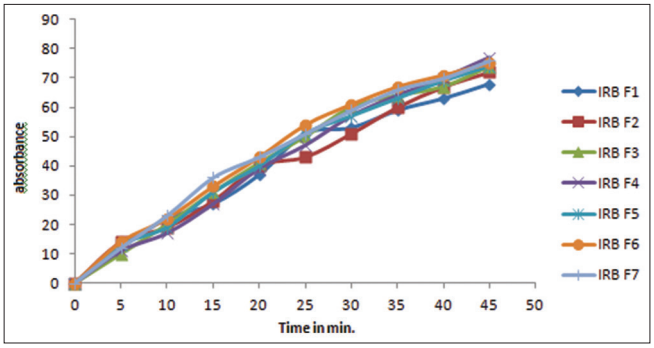

Fig. 11: Cumulative drug release of Batch F1 to F7

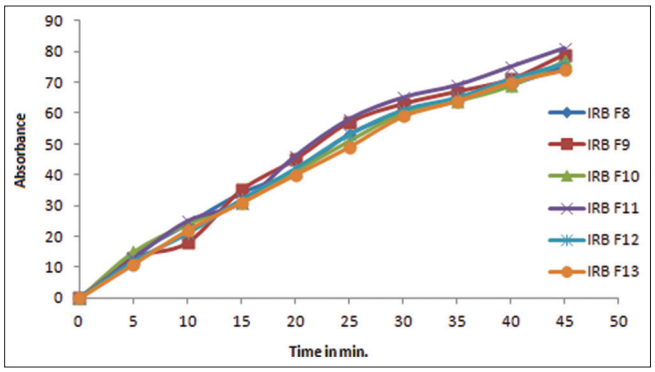

Fig. 12: Cumulative drug release of Batch F8 to F13

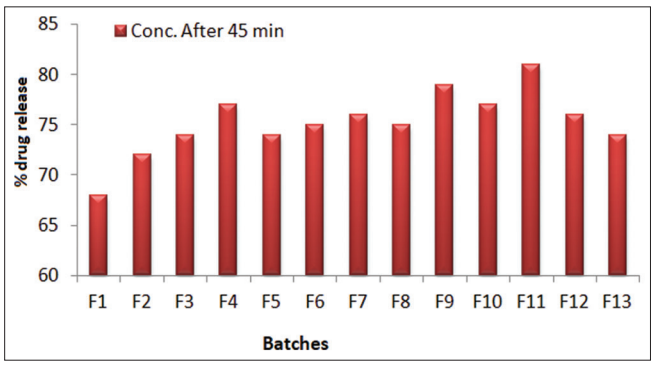

Fig. 13: Drug release at 45 min

Tablet appearance

White colored round-shaped uncoated tablet was prepared.

Hardness test

The hardness was uniformly sustained and it was found to be within 3.21±0.117–4.32±0.620 range (Table 3).

Friability test

A friability tester was employed to assess the friability of the tablets. Initially, 20 tablets were weighed (Weight) before their placement in the friabilator. The friabilator was operated at 100 rpm for four minutes. A subsequent weighing of the tablets was conducted. The range of friability of tablet was found to be 0.21±0.125 to 0.34±0.119 (Table 3).

Disintegration study

The disintegration time was evaluated in accordance with USP criteria using the disintegration apparatus. The disintegration time was measured in second for each of the six tablets, with each tablet

placed in an own vessel. The disintegration time found to be in range of 117±0.330–135±0.00 s (Table 3).

Dissolution study

In dissolution study, all batches F1 to F13 show increase in drug release rate as in crease in time. The drug release from formulation shows the immediate release pattern. At 45 min. immediate release tablets of irbesartan having drug loaded into MSNs show that drug release was more than 68%. The range of drug release was 68% in F1 batch and 81% in F11 batch (Figs. 9-13 and Tables 3 and 4).

CONCLUSION

The MSNs were successfully prepared by sol gel method. FTIR and DSC study shows compatibility of irbesartan with MSNs. XRD study assure that the MSNs loaded irbesartan is in there amorphous forms. Solubility study gives idea about increase in dissolution rate of MSNs loaded Irbesartan as compared to pure drug Irbesartan. BET isotherm showed that the mesoporous nature with pore is 3.17 nm with high pore volume. After characterization of MSNs, irbesartan is successfully loaded into the MSNs. Drug-loaded MSNs then subjected to formulation of tablet by direct compression method. Irbesartan MSNs tablet was prepared successfully. The prepared tablet is white rounded in shape. The hardness of tablet is 3.21±0.117–4.32±0.620 range. The friability study showed that there is very little dusting of prepared that after 30 min of study. The disintegration time found to be in range of 117±0.330 to 135±0.00 s. The dissolution study drug is range of 65–80% in 45 min. The Batch F1 showed lower release 68% and Batch F11 showed highest release of drug 81%.

AUTHORS' CONTRIBUTIONS

MSP-made research work with methodology, conceptualization, and writing original draft. SJW-Formal analysis and data interpretation. TMK- Data interpretation.

CONFLICTS OF INTEREST

The authors do not have any conflicts of interest.

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