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**Research Article**

# Development, optimization and Evaluation of Solid Dispersion Formulation of *Portulaca Grandiflora* Hook Hydro Alcoholic Leaf Extract

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## ABSTRACT

Portulaca grandiflora Hook. is an annual herb whose leaves have historically been used to treat the prevention of hepatitis, asthma, depurative (helps in purification), and rheumatism, among other ailments. The poor solubility and limited dissolution properties of Portulaca grandiflora hydroalcoholic extract act as one of the major limits in making an effective commercial oral formulation. The objective of the study was to prepare solid dispersion of hydro-alcoholic extract of Portulaca grandiflora leaves to enhance its dissolution properties. The water-soluble polymer (Polyethylene glycol 4000) was used to prepare solid dispersion. The solid dispersions were prepared by the kneading method using plant extract, polyethylene glycol 4000, and time (min) in different concentrations by using a central composite design followed by a response surface design in 20 batches of solid dispersions and the formulation (SD15) shown higher drug content. The prepared formulations were evaluated for interaction study by Fourier-transformed infrared spectroscopy, percentage of practical yield, drug content, differential scanning calorimetry, particle size characterization, and in-vitro drug release studies. The results showed no interaction between the drug and the polymer, a percentage yield of 70±0.21 to 95.19±0.42%, drug content of 69.1±0.31 to 95.7±0.16%, no thermal change in solid dispersion formulation, the particle size of 1411 nm and a significant increase in the dissolution rate.

## INTRODUCTION

The management of human health is greatly influenced by medicinal plants. Around 80% of people worldwide rely on traditional medicine,

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which is largely composed of plant-based ingredients. Ayurveda, Siddha, Unani, and folk/tribal medicine are just a few of the many historic natural health care philosophies included in traditional medicine (Kumar, S. V *et.al*., 2012) These medical practices go literally from the beginning of time and have steadily evolved via practical experience, largely without substantial references to modern scientific ideas (Jain, D., & Janmeda, P 2023)

Herbal remedies work well to cure a variety of illnesses; however, they are frequently misused or abused without sufficient research. Therefore, given advancements in science, these plant-based medications need thorough research (Shakya, A. K. 2016)

Though there are several routes of drug administration, Oral medication administration is the most recommended due to the convenience of formulation flexibility, and administration. However, the oral route has several bottlenecks, including lower gastrointestinal absorption of weakly water-soluble medications, which leads to low bioavailability and inferior pharmacological response (Sareen, S *et.al*., 2012). Most novel chemical compounds being developed today are meant to be used as solid dosage forms that produce an efficient because of the various benefits of this path, such as higher stability, smaller bulk, precise dosage, and simple manufacture, there is repeatable *in-vivo* plasma concentration following oral administration (Singh, S., & Baghel, R. 2011 & Jung, J. Y. *et al*., 1999) Due to high lipophilic nature a significant part of drug remains poorly absorbed after administration of the drug by oral route. This causes various issues like low bioavailability of active constituents and absorption of insufficient dosage (Lewis, D. *et.al*., 2009) Solid dispersion (SD) technology is one such formulation strategy that has considerably improved such medications' solubility/dissolution (Kaushik, R., *et al*., 2020).

The Biopharmaceutical classification system (BCS) system of classification classifies flavonoids and phenols into the Class II category due to their lower solubility and higher permeability. Therefore, everything that can improve in vivo dissolution will likewise improve product absorption. High-fat foods, which increase biliary solubilization and gastrointestinal secretions and are less soluble than Class II medicines, frequently aid in drug absorption. This is especially true for bases and acids with low pKa values that are weak. However, when meals cause the pH of the GI contents to rise, the small intestine and the stomach may tend to precipitate weak bases with low pKa values (Martinez, M. N. *et al.,* 2002), (Shah, V. P. & Amidon, G. L. 2014).

*Portulaca grandiflora* Hook. Commonly known as 'Moss rose' is an erect, succulent flowering plant belonging to the family Portulacaceae which had a wide variety of therapeutic properties. The plant has played an important role in tribal and rural medicine. The entire plant of *Portulaca grandiflora* Hook. Is used as a depurative (helps in purification) and also used in the prevention of hepatitis. This plant leaves is employed in the treatment of liver cirrhosis accompanied by pharyngeal swelling and pain (Anghel, A. I. *et al.,*2013). Additionally, the fresh juice extracted from its leaves and roots is applied topically as a lotion to alleviate symptoms associated with snake and insect bites, burns, scalds, and eczema. Chemical constituents of *Portulaca grandiflora* such as Quercetin, Kaempferin, and Myricetin, and Caffic acid, β- sitosterol. The leaves extract have a huge amount of alkaloids, flavonoids, saponins, tannins, and phenolic substances (Aisyah Si, *et al.,* 2023). The plant *Portulaca grandiflora* Hook. have been proved for various

medicinal activities like antioxidant, anti-diabetic, antimicrobial, cytotoxic, enzyme inhibiting, hepatoprotective, anticancer, and anti-inflammatory. (F. Dert *et al.,* 2019).

The present investigation aimed to development, optimization and evaluation of solid dispersion of *Portulaca grandiflora* Hook. hydroalcoholic leaves extract to improve its dissolution properties.

## MATERIAL AND METHODS

The leaves of the *Portulaca grandiflora* were collected from the medicinal herbal garden of Maharshi Dayanand University, Rohtak, India. Polyethylene glycol was procured from Loba chemie Pvt. Ltd, India. Rutin standard was purchased from CDH, New Delhi.

### Preparation of hydro alcoholic extract

The leaves of *P.grandiflora* were authenticated by Dr. S.S Yadav, Associate Professor in the Department of Botany, Maharshi Dayanand University, Rohtak. Fresh leaves of *P.grandiflora* were washed with tap water and clean to remove the dust particles. Then leaves were shade dried for two weeks and coarse powdered by a mortar pestle. The powder was separately defatted with n-hexane (40 -60$^0$C) by soxhlet apparatus for 5hrs. The defatted leaves were dried and extracted with hydro alcohol (50:50 v/v) using the soxhlet apparatus for 8 hrs. until the solvent appears transparent. Then extract which remains in the flask is concentrated in water bath and stored at room temperature in desiccators for further use (Devi M. *et al*., 2019).

### Preparation of solid dispersion

The formulation of solid dispersion was prepared by the kneading method. Accurate quantities of polymer were weighed in a mortar and a little amount of ethanol was added and triturated to obtain a homogeneous slurry-like consistency. After that, slowly the drug was incorporated into the slurry, and triturate was continued for 30 minutes. Then dried at 25ºC for 24 hours and then pulverized, sieve through mesh no. 100. and stored in a desiccator until further use (Yadav, A. V., Yadav, V. B. 2008).

### Evaluation parameters

### Percentage Practical Yield

The prepared solid dispersions were collected and weighed practical yield of solid dispersion prepared by the kneading method was determined by using the following equation (Narkhede, K. B. *et al.,* 2012).

$$\% \text{ Practical yield} = \frac{\text{Practical Mass (Solid dispersion )}}{\text{Theoretical Mass (Drug + Polymer )}} \times 100$$

### Drug content determination

### Preparation of calibration curve

The ultraviolet spectrophotometric method (Shimadzu UV-3600 Plus Spectrophotometer) was selected in the estimation of rutin. The drug solution in various concentrations was scanned in between the wavelength of 200 – 400 nm. The wavelength of 266 nm was selected and a calibration curve was plotted. The slope, regression coefficient, and equation for the line were determined (Li, B., Konecke, *et al.,* 2013).

### Drug Content

Accurately weighed various batches of solid dispersions, each containing 10 mg of the drug, were dissolved in 100 ml of a phosphate buffer solution with a pH of 7.4 in a conical flask. The resulting solution was then filtered using Whatman filter paper. The filtrate was appropriately diluted, and the drug content was analysed using a UV

spectrometer at the wavelength of maximum absorption (lambda max) which was determined to be 266 nm. The actual amount of drug in the solid dispersion was calculated using the following equation:

$$\% \text{ Drug Content} = \frac{\text{Actual amount of drug in solid dispersion}}{\text{Theoretical amount of drug in solid dispersion}} \times 100$$

This calculation allowed for the determinatiomn of the percentage of drug content in the solid dispersion (Adibkia, K. *et al.,* 2013).

**Particle Size Characterization**

The mean particle size of the optimized formulation of solid dispersion was determined by the dynamic light scattering technique. The optimized formulation was dispersed in deionized water and analysed at 60 °C with a detection angle of 90 °. The particle size was later estimated using a zeta sizer (Ming-Thau *et al.,* 1994).

**Thermal Analysis by Differential Scanning Calorimetry**

Differential Scanning Calorimetry (DSC) analysis is conducted to check the purity of the drug if there are any impurities separate peak will be absorbed in the DSC thermogram. The methodology for DSC is mentioned below. DSC analysis was conducted using a Shimadzu-Thermal Analyzer DT 40 instrument from Kyoto, Japan. For the analysis, approximately 5 mg of the optimized solid dispersion formulation was placed in an open aluminium pan. The temperature was then increased at a rate of 10°C per minute, covering a range from 30°C to 300°C. A nitrogen flow of 40 mL/min was maintained throughout the analysis (Modi, A., & Tayade, P. 2006).

**Fourier Transform Infra-Red Spectroscopy**

FTIR spectra were obtained using an Alpha Bruker ATR FTIR-5300 spectrophotometer from Tokyo, Japan. The hydro-alcoholic leaf extract of *P. grandiflora*, PEG 4000, and the optimized solid dispersion were thoroughly mixed with dry KBr. The mixture was then pressed into KBr disks using a hydrostatic press to prepare the samples. The spectra were recorded in the scanning range of 400 to 4000 cm–1, with a resolution of 4 cm–1 (Chan, K. A., & Kazarian, S. G. 2004).

***In-vitro* Dissolution study of solid dispersion**

The *in-vitro* dissolution studies of solid dispersions were conducted using the USP dissolution test type II apparatus, as per the guidelines of the United States Pharmacopeia (USP). A dissolution vessel containing 900 ml of pH 7.4 Phosphate Buffer Solution (PBS) at a temperature of 37°C±5°C was utilized to disperse samples equivalent to 10 mg of the drug. The mixture was stirred at a speed of 50 rpm. At regular time intervals (15 min, 30 min, 45 min, 1 hr, 2 hrs, 3 hrs, 4 hrs, 5 hrs, 6 hrs, and 7 hrs), a 10 ml aliquot was withdrawn from the dissolution medium. To ensure the maintenance of a sink condition, an equivalent amount of fresh dissolution medium was added. The withdrawn samples were filtered through a 0.45 µm microfilter and analysed using spectrophotometry at the wavelength of lambda max 266 nm. The process was repeated with a new, identically sized dissolving medium for each time point. The percent drug release was calculated and plotted against time to study the dissolution behavior of the solid dispersions (Ugandhar, C. 2012)

## RESULT AND DISCUSSION

**Results of various evaluation parameter**

Optimization of the formulation was done by central composite response surface design and the

responses are shown in **Table 1.** The % Drug content for all the 20 formulations varied from 69.1±0.12 to 95.7±0.16 %. The higher drug content was seen in formulations (SD15) containing higher percentage of drug content hence it is the optimized batch and Figure 1 (a) demonstrates graph showing 3D Surface factor coding actual design. Between A: Drug (mg) and B: PEG 4000 (mg) (b) demonstrates graph showing Standard Error of Design between A: Drug (mg) and B: PEG 4000(mg).

**Table 1 Responses of various batches of formulation**

| Std. | Run. | A. Drug (mg) | B. Peg 4000 (mg) | C. Time (min.) | Response Drug Content %±SD |
|---|---|---|---|---|---|
| 19 | 1 | 65 | 225 | 35 | 90.3±0.12 |
| 1 | 2 | 30 | 150 | 30 | 86.4±0.34 |
| 6 | 3 | 100 | 150 | 40 | 92.4±0.16 |
| 2 | 4 | 100 | 150 | 30 | 91.2±0.26 |
| 14 | 5 | 65 | 225 | 43.409 | 89.4±0.31 |
| 16 | 6 | 65 | 225 | 35 | 90.6±0.22 |
| 4 | 7 | 100 | 300 | 30 | 93.2±0.14 |
| 3 | 8 | 30 | 300 | 30 | 82.4±0.17 |
| 7 | 9 | 30 | 300 | 40 | 81.2±0.46 |
| 10 | 10 | 123.863 | 225 | 35 | 90.6±0.37 |
| 8 | 11 | 100 | 300 | 40 | 90.4±0.25 |
| 9 | 12 | 6.13725 | 225 | 35 | 69.1±0.12 |
| 15 | 13 | 65 | 225 | 35 | 91.6±0.15 |
| 13 | 14 | 65 | 225 | 26.591 | 91.03±0.23 |
| 11 | 15 | 65 | 98.8655 | 35 | 95.7±0.16 |
| 12 | 16 | 65 | 351.134 | 35 | 86.2±0.42 |
| 18 | 17 | 65 | 225 | 35 | 91.4±0.42 |
| 20 | 18 | 65 | 225 | 35 | 88.4±0.27 |
| 17 | 19 | 65 | 225 | 35 | 92.7±0.26 |
| 5 | 20 | 30 | 150 | 40 | 87.5±0.14 |

**SD implies to standard deviation (n=3)**

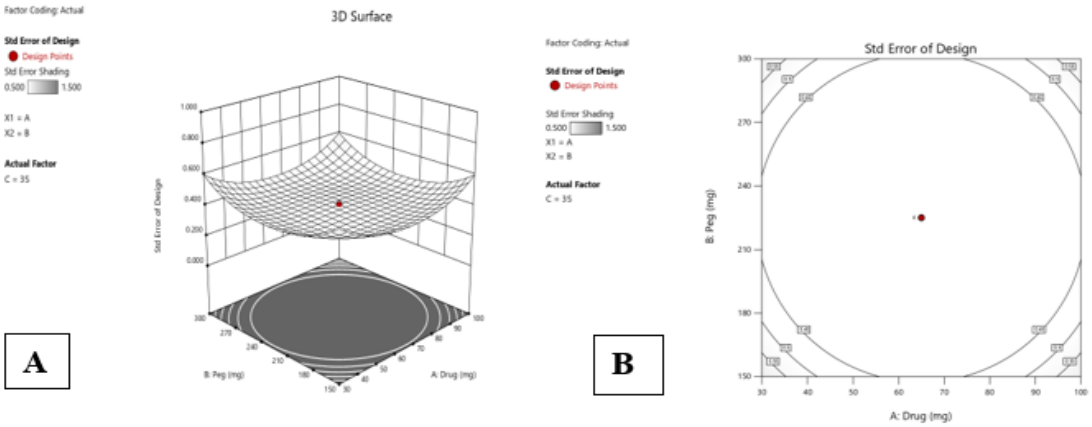



**Figure 1 (a) Graph showing 3D Surface factor coding actual design between A: Drug (mg) and B: PEG 4000 (mg)**

**(b)Graph showing Standard Error of Design between A: Drug (mg) and B: PEG 4000(mg)**

**Evaluation of optimized formulation**

**Percentage yield**

The percentage yield of optimized formulation was found to be 95.19±0.42 % (w/w). The result of the percentage yield of optimized batch of SD formulation are shown in Table 2.

**Standard calibration curve of rutin**

To evaluate drug release and in vitro dissolution studies, the standard plot of rutin in the phosphate buffer pH 7.4 was prepared. 10 µg/ml, 20 µg/ml, 30 µg/ml, 40 µg/ml & 50 µg/ml concentrations were scanned at 266 nm to get the absorption v/s concentration plot. Fig. 2 shows the standard calibration curve of pure drug rutin at pH 7.4.

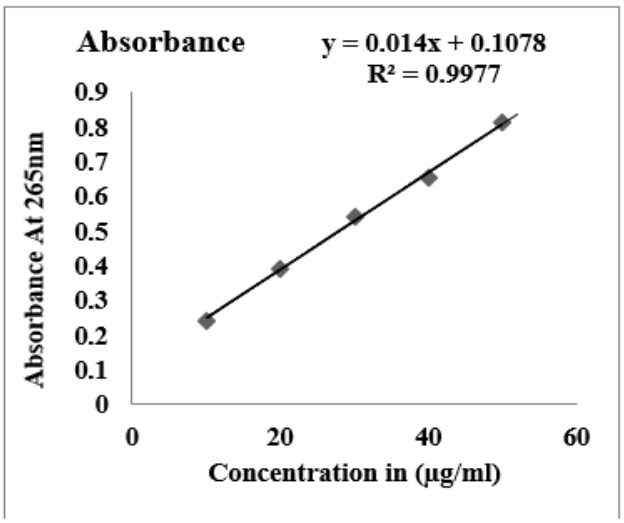



**Figure 2 Standard calibration curve of pure drug rutin in pH 7.4 phosphate buffer**

**Drug content of the optimized formulation**

The percentage drug content of optimized solid dispersion of hydro alcoholic extract of dried leaves of *P. grandiflora* is shown in **Table 2.**

**Table 2 Optimized formulation SD15 drug content**

| Sr.no. | Optimized formulation of SD15 | Drug content % ± SD | Percentage yield (%) ± SD |
|---|---|---|---|
| **1.** | **SD15** | **95.7±1.6** | 95.19±0.42 |

**Particle size analysis**

The particle size analysis of optimized solid dispersion is showed in Fig 3. The particle size was analyzed by zeta sizer and found to be 1411 nm.

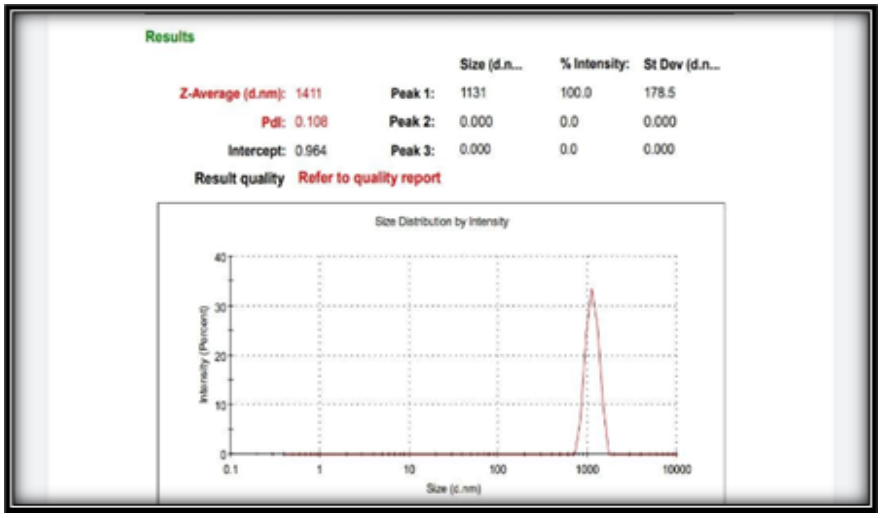



**Figure 3 Particle size analysis of optimized formulation SD15**

## DSC

In the analysis conducted using DSC, the samples were examined under atmospheric conditions with an empty pan as the reference. The PEG 4000, pure hydroalcoholic extract of dried leaves of *P.grandiflora,* and the optimized solid dispersion formulation was analyzed by DSC to study the thermal behavior. DSC thermogram of the PEG 4000, pure extract, and optimized SD formulation are shown in **Fig 4**. Additional proof of the formation of solid dispersions was supplied by the DSC study. DSC thermogram of PEG 4000 and pure plant extract shows endothermic peaks at 69.921°C and 201.287°C which is similar to the melting point of pure polymer and plant extract. The DSC thermogram of optimized solid dispersion was melted at 66.301°C and 210.631°C, which is similar to pure extract so, there is no thermal change in the final formulation.

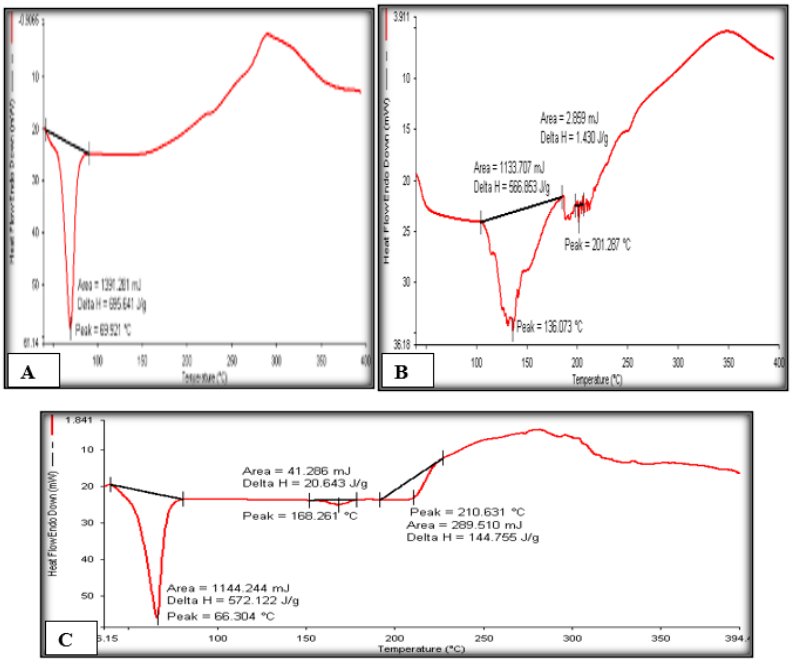



**Figure 4 (a) DSC thermogram of PEG 4000 (b) DSC thermogram of plant extract (c) DSC thermogram of optimized formulation SD15**

## FTIR

The IR spectrum of PEG 4000, pure hydroalcoholic leaves extract of P.grandiflora, and optimized solid dispersion formulation is shown in Fig 5, There was no disappearance of any characteristic peaks. These figures show that there is no chemical interaction between the polymer, plant extract, and prepared solid dispersion formulation. The presence of characteristic peaks confirmed that the polymer and plant extract used were compatible. Additionally, it demonstrated that the process utilized to make the solid dispersion had no negative effects on the chemical stability of the phytoconstituents.

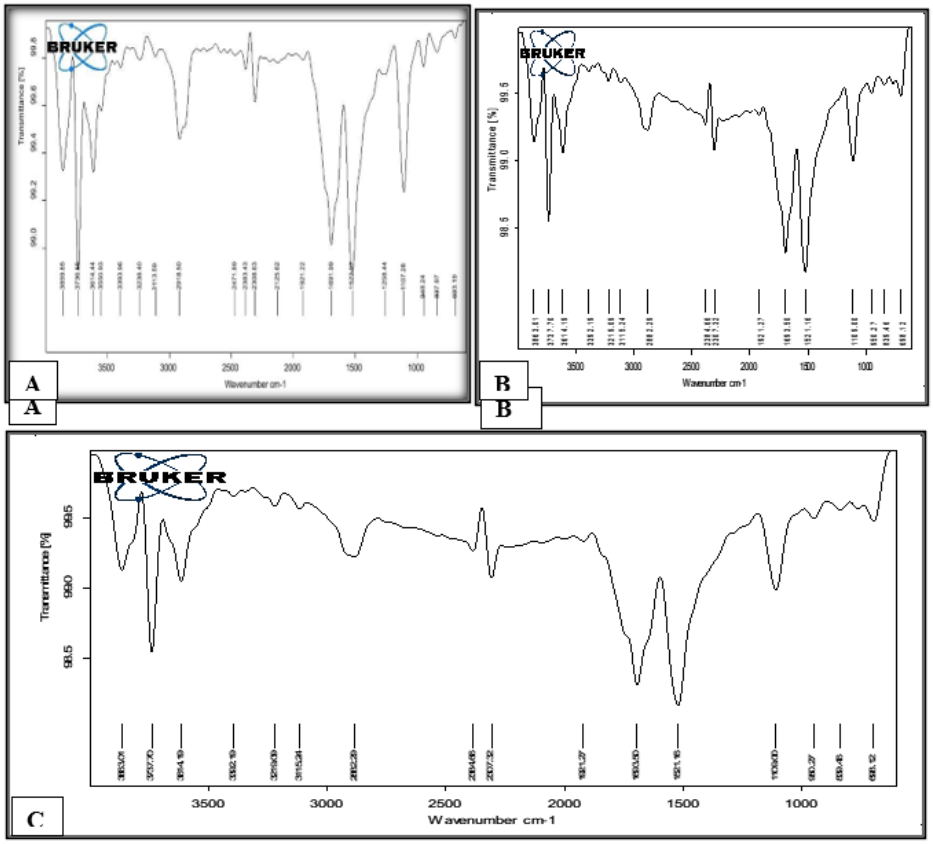



**Figure 6 (a) FTIR spectra of PEG 4000, (b) FTIR spectra of pure hydro alcoholic dried leaf extract of *P.grandiflora*, (c) FTIR spectra of optimized formulation SD 15**

## *In-vitro* dissolution study

*The in-vitro* dissolution study of optimized solid dispersion formulation drug release is shown in **Fig 7.** It shows the cumulative percent drug release as a function of time for optimized formulation. The cumulative percent drug release after 480 min is 91.21%.

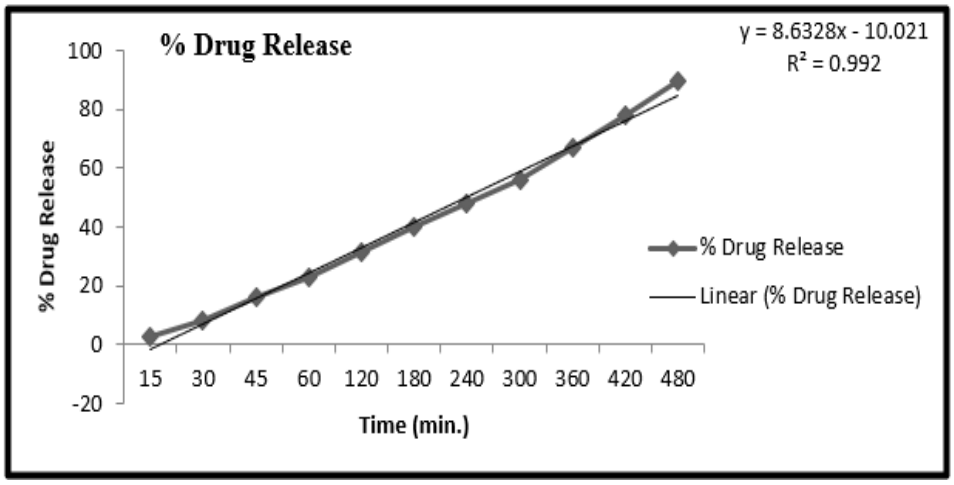



**Figure 7 *In vitro* dissolution of SD15 at the end of 8 hrs.**

## CONCLUSION

For the development and optimization of solid dispersion formulation as design expert software version 10 was used by central composite response surface design taking one response as % drug content of the optimized batch (SD15) has found to be 95.7±1.6. The ANOVA of response drug content implies the model is significant. The determination of drug content was performed using a UV-visible spectrophotometer, which measured the absorbance of the supernatant containing rutin at 266 nm. The measurements were conducted in a pH 7.4 buffer solution. The optimum values are 65 mg hydro alcoholic plant extract, 225 mg PEG 4000 and 35 min time which gives 95.7±1.6% drug content. The particle size analysis of optimized solid dispersion was analysed by zeta seizer and found 1411 nm. In DSC thermogram of optimized solid dispersion was melted at 66.301°C and 210.631°C, which is similar to pure extract So, there is no thermal change in the final formulation. FTIR of optimized solid dispersion shows that there is no chemical interaction between the polymer, plant extract and prepared solid dispersion formulation. The presence of characteristics peaks confirmed that the polymer and plant extract used was compatible. *In vitro* drug release of the optimized solid dispersion (SD15) of hydro alcoholic extract of dried leaf of P. grandiflora was found to be 91.21 % at the end of 8hrs.

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### Conflict of interest

We declare that we have no conflict of interest.

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