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Research Article

Formulation and evaluation of Deflazacort liquisolid tablets

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ABSTRACT

In the present investigation, liquisolid compact technique is investigated as a tool for enhancement of dissolution of poorly water-soluble drug, Deflazacort. Deflazacort liquisolid tablets were prepared using propylene glycol as non-volatile liquid vehicle, microcrystalline cellulose (Avicel PH 102) as carrier material, colloidal silicon dioxide (Aerosil 200) as coating material and sodium starch glycolate as super disintegrant. The prepared liquisolid compacts were evaluated for bulk density, tapped density, angle of repose, Carr's index, Hausner's ratio, thickness, hardness, friability, weight variation, disintegration, drug content estimation and in-vitro dissolution studies. The formulated liquisolid system of Deflazacort exhibited acceptable flowability and compressibility. FTIR studies revealed that there is no significant interaction between the drug and excipients. The XRD analysis confirmed formation of a solid solution inside the compact matrix. Among all formulations, Deflazacort liquisolid compacts containing 10% drug solution and carrier to coating material ratio of 10:1 (LS2) showed significant higher dissolution rate of 96.46% in 45 min compared to 32.80% in 45 min of conventional tablet. From this study it can be concluded that the liquisolid technique is a promising alternative for improvement of dissolution property of water-insoluble drugs.

Key words: *Deflazacort, Liquisolid tablets, Dissolution property*

INTRODUCTION

The oral route of drug administration still remains as the preferred route of drug administration due to its convenience, good patient compliance and low production costs. In order for a drug to be absorbed into the systemic circulation following oral administration, the drug must be dissolved into the gastric fluids.[1,2] Solubility of drugs is a major factor in the design of pharmaceutical formulations which lead to variable oral bioavailability. Dissolution is an important factor for absorption of drugs especially in case of water insoluble or poorly water soluble drugs. The rate limiting step for most of the pharmaceutical formulations is dissolution. The various properties of drug like solubility, particle size, polymorphism, salt form, complexation, wettability affect drug dissolution and its rate and can be targeted to enhance dissolution of poorly water soluble drugs.[3,4] Deflazacort (DEF) is an anti-inflammatory drug and is used for the treatment of rheumatoid arthritis and asthma. Chemically it is known as (11β, 21-Dihydroxy-2'-methyl-5'βH-pregna-1, 4-dieno [17, 16-d] oxazole-3, 20 dione 21-acetate) is an oxazoline derivative of prednisolone. It is practically insoluble in water with an oral bioavailability of about 70%, which exhibits low mineral corticoid activity.[5,6] Over the years, various techniques have been employed to enhance the dissolution profile and, in turn, the absorption efficiency and bioavailability of water insoluble drugs and/or liquid lipophilic medications such as micronization, use of surfactants, salt forms, metastable polymorphs, solvent deposition, molecular encapsulation with cyclodextrins, solid solutions and pro drug approach.[7] However, among them, the technique of 'liquisolid compacts' is one of the most promising technique. Low cost, simple formulation technique and capability of industrial production serve to be advantageous of this technique. The liquisolid compacts are acceptably flowing and compressible powdered forms of liquid medications. The term '*liquid medication*' refers to water-insoluble solid drugs dissolved in suitable water-miscible non-volatile solvent systems termed as the liquid vehicle. Such liquid medication may be converted into a dry, non-adherent, free flowing and readily compressible powders by a simple admixture with selected powder excipients referred to as the "carrier and coating materials". Various grades of cellulose, starch and lactose may be used as the carriers, whereas very fine particle sized silica

powders like colloidal silicon dioxide (aerosil and cab o sil) may be used as the coating (or covering) materials. The enhanced dissolution from liquisolid compacts are due to an increase in wetting properties and increased surface area available for dissolution.[8] Besides drug release enhancement, the liquisolid approach is a promising technique, because of the simple manufacturing process, low production costs and the feasibility for large scale manufacturing due to its enhanced flow and compaction properties. The aim of present work is to improve the dissolution of a poorly water soluble drug Deflazacort by preparing a liquisolid system containing Avicel PH 102, Aerosil 200 and Propylene glycol as carrier, coating material and liquid vehicle respectively.

MATERIALS AND METHODS

Materials

The following gift samples were received: Deflazacort (Eugia, Hyderabad), Aerosil 200 and sodium starch glycolate (Marksans Pharma, Goa). All reagents used were of analytical grade.

Standard curve of Deflazacort in deaerated water

10 mg of drug was dissolved in deaerated water and volume made upto 100 ml to produce a stock solution of 100 µg/ml. From this 10 ml of the above solution was taken and further diluted to 100 ml with deaerated water to produce a stock solution of 10 µg/ml solution. From this aliquots of 0, 2, 4, 6, 8 and 10 ml were taken to produce concentrations of 0, 2, 4, 6, 8 and 10 µg/ml. The absorbance was measured by using UV-visible spectrophotometer at 246 nm. Beer-Lambert's law was obeyed in the concentration range of 2-10 µg/ml.

Solubility studies

The solubility of Deflazacort was carried out in propylene glycol, polyethylene glycol 400 and water. Saturated solutions in respective solvents were prepared by adding an excess amount of drug and rotated for 48 h at 25°C using a mechanical shaker. The filtered supernatants were further diluted and analyzed with an UV/visible spectrophotometer at 246 nm. The solubility of Deflazacort in the respective liquid vehicle was calculated using calibration curve. Each experiment was carried out in triplicate.

Application of the mathematical model for designing the liquisolid systems[9]

A powder can retain only limited amounts of liquid while maintaining acceptable flow and compression properties. To calculate the required amounts of powder excipients a mathematical approach for the formulation of liquisolid systems has been developed by Spireas. This approach is based on the flowable and compressible liquid retention potential introducing constants for each powder/liquid combination. The liquid load factor that ensures acceptable flowability (ΦLf) can be determined by:

$$\Phi Lf = \Phi + \varphi \cdot (1/R) \quad (1)$$

where Φ and φ are the Φ- values of the carrier and coating material, respectively.

Similarly, the liquid load factor for production of liquisolid systems with acceptable compactability (ΨLf) can be determined by:

$$\Psi Lf = \Psi + \psi \cdot (1/R) \quad (2)$$

where Ψ and ψ are the Ψ-numbers of the carrier and coating material, respectively.

Therefore, the optimum liquid load factor (Lo) required to obtain acceptably flowing and compressible liquisolid systems are equal to either ΦLf or ΨLf, whichever represents the lower value. Depending on the excipient ratio (R) of the powder substrate, an acceptably flowing and compressible liquisolid system can be obtained only if a maximum liquid load on the carrier material is not exceeded.

$$R = Q/q \quad (3)$$

R represents the ratio between the weights of the carrier (Q) and the coating (q) material present in the formulation.

As soon as the optimum liquid load factor is determined, the appropriate quantities of carrier (Q_0) and coating (q_0) material required to convert a given amount of liquid formulation (W) into an acceptably flowing and compressible liquisolid system may be calculated as follows:

$$Q_0 = W/L_0 \quad (4)$$

and

$$q_0 = Q_0/R \quad (5)$$

where W is the weight of the liquid medication (the drug + non-volatile liquid vehicle)

Preparation of directly compressed tablet and liquisolid compact

Directly compressible tablets (DCT) of Deflazacort (DEF) were prepared by direct compression using tablet punch machine, each containing 6 mg drug with Avicel PH 102, Aerosil 200 and sodium starch glycolate (SSG). Various liquisolid compacts containing 6 mg of Deflazacort were prepared by dispersing in propylene glycol (PG) in a glass beaker and then heated to 80°C. The resulting hot medication was incorporated into calculated quantities of carrier and coating materials. The mixing process was carried out in three steps.

1. In the first stage, the system was blended at an approximate mixing rate of 60 rpm for one min in order to evenly distribute liquid medication in the powder.
2. In the second stage, the liquid-powder admixture was evenly spread as a uniform layer on the surfaces of the mortar and left standing for approximately 5 m to allow the drug solution to be absorbed in the interior of powder particles.
3. In the third stage, powder was scraped off the mortar surface by means of an aluminum spatula and then blended with sodium starch glycolate for 30 s. This yielded a final formulation of liquisolid compacts.
4. Lubricant was added and the liquisolid formulations thus prepared were compressed.

Pre-compression parameters

Flow properties of liquisolid systems were estimated by Angle of repose, Bulk density, Tapped density, Carr's index and Hausner's ratio. These properties were determined by using the following equations:

Angle of repose $\Theta = \tan^{-1} h/r$

Bulk density, ρ_b = weight of the powder / bulk volume of the sample

Tapped density, ρ_t = weight of the powder / minimum volume occupied in cylinder

% compressibility = $\frac{\rho t - \rho b}{\rho t}$ x 100

Hausner's ratio = $\frac{\rho t}{\rho b}$

Fourier Transform Infrared spectroscopy (FTIR)

FTIR spectral analysis of pure drug and liquisolid formulation were carried out. The samples were placed in FT-IR window after mixing and triturating with potassium bromide.

X-ray powder diffraction analysis

Crystallinity of the drug and the samples was determined using the Philips Analytical XRD with copper target. The conditions were as follows: Voltage: 40 kV, Current: 35 mA. The samples were loaded onto the diffractometer and scanned over a range of 5° to 70° 2θ angle with a scan rate of 10° /m.

Evaluation of liquisolid tablets

Tablet Thickness

Thickness of the tablets was determined using Vernier callipers.

Weight Variation Test[11]

Weight variation test was determined as per test mentioned in IP.

Hardness Test

10 tablets were selected and the hardness was tested using Monsanto tester. "Hardness factor", the average of six determinations, was determined.

Friability Test[10, 11]

Roche friabilator was used to measure the friability of the tablets.

Disintegration test[11]

Disintegration time for liquisolid tablets were determined using USP tablet disintegration apparatus with water. The volume of medium was 900 ml and temperature was 37±2°C. The time in seconds taken for complete disintegration of the tablets with no palatable mass remaining in the apparatus is measured.

Drug content determination

Five randomly selected tablets were weighed and powdered in a glass mortar. From this, the powder equivalent to 6 mg Deflazacort was accurately weighed and dissolved in small volume of methanol and further diluted with deaerated water to make up the volume to 100 ml. The absorbance was spectrophotometrically determined at 246 nm using uv-visible spectrophotometer. The drug in each tablet is calculated using standard calibration curve.

In-vitro drug release study[11]

In-vitro dissolution studies were carried out using USP apparatus Type II at 50 rpm. Dissolution medium consisted of 500 ml deaerated water maintained at 37°C ± 0.5°C. Drug sample (5 ml) was withdrawn at 0, 5, 10, 15, 20, 30, 45, 60 and 90 m time intervals and diluted to a suitable concentration and absorbance was measured by UV-visible spectrophotometer at 246 nm. The samples were replaced with fresh dissolution media.

STABILITY STUDIES

Stability studies were carried out on optimized formulation according to International Conference of Harmonization (ICH) guidelines. The optimized formulations were stored at 40±2°C/ 75±5% RH for one month. After the stability period, samples were removed and analyzed for the friability, hardness, disintegration, % drug content and in-vitro drug release study.

RESULTS AND DISCUSSION

Solubility studies

Solubility of Deflazacort was performed in various solvents like propylene glycol, polyethylene glycol 400 and water. Solubility study revealed that propylene glycol is a better solvent and hence the same has been selected as solvent for all further trials.

Table 1: Solubility of DEF in various solvents

Solvent	Solubility (mg/ml)
Water	0.108 ± 0.23
Propylene glycol	7.92 ± 0.17
Polyethylene glycol 400	6.08 ± 0.33

Application of the mathematical model for designing the liquisolid systems

To calculate the required ingredient quantities, the flowable liquid-retention potentials (Φ-values) of powder excipients were used. In propylene glycol, the Φ-value was 0.16 for Avicel PH 102 and 3.31 for Aerosil 200 and the Ψ-value was 0.224 for Avicel PH102 and 0.560 for Aerosil 200. The liquid load factor was computed from the flowable liquid-retention potential in accordance with equation 1 and 2 using a different R value (excipient ratio). The most suitable quantities of carrier (Q) were calculated using equation 3. The optimum quantities of carrier (Q_0) and coating material (q_0) were obtained from equation 4 and 5 respectively.

Table 2: Formulation of DEF liquisolid system

Formulation	Drug conc. in vehicle (%w/v)	Carrier: Coating ratio	Loading factor (LF)	Vehicle (mg) PG	Active ingredient (mg) DEF	Carrier Q (mg) Avicel PH102	Coating q (mg) Aerosil 200	SSG (mg)
LS1	10	5	0.336	54.00	6.00	178.57	35.71	13.71
LS2	10	10	0.280	54.00	6.00	214.29	21.48	14.79
LS3	10	20	0.252	54.00	6.00	238.10	11.91	15.50
LS4	10	25	0.246	54.00	6.00	243.90	9.76	15.68
LS5	20	5	0.336	24.00	6.00	89.29	17.86	6.86
LS6	20	10	0.280	24.00	6.00	107.14	10.71	7.39
LS7	20	20	0.252	24.00	6.00	119.05	5.95	7.75
LS8	20	25	0.246	24.00	6.00	121.95	4.88	7.84
LS9	30	5	0.336	14.00	6.00	59.52	11.91	4.57
LS10	30	10	0.280	14.00	6.00	71.43	7.14	4.93
LS11	30	20	0.252	14.00	6.00	79.37	3.97	5.17
LS12	30	25	0.246	14.00	6.00	81.30	3.25	5.23

Table 3: Formulation design of Deflazacort directly compressed tablet

Ingredients	Directly Compressed Tablet (DCT) (mg)
Deflazacort	6.0
MCC	268.29
Aerosil	21.48
SSG	14.80
Magnesium stearate	3.10
Unit weight	313.67

Precompression studies

Flow properties

The flow properties were estimated by bulk density, tapped density, angle of repose, Carr's index, Hausner's ratio and are given in Table No.4.

Table 4: Precompression parameters of liquisolid compacts

Formulation code	Bulk density (g/cc)	Tapped density (g/cc)	Carr's index	Hausner's ratio	Angle of repose (θ)
LS1	0.315 ± 0.021	0.382 ± 0.031	19.03 ± 0.080	1.212 ± 0.025	24.58 ± 0.23
LS2	0.326 ± 0.033	0.365 ± 0.045	10.68 ± 0.035	1.120 ± 0.042	23.20 ± 0.25
LS3	0.335 ± 0.012	0.415 ± 0.062	19.28 ± 0.026	1.239 ± 0.032	26.49 ± 0.72
LS4	0.345 ± 0.038	0.405 ± 0.014	14.81 ± 0.018	1.174 ± 0.049	26.98 ± 0.33
LS5	0.366 ± 0.024	0.435 ± 0.016	15.86 ± 0.024	1.189 ± 0.042	27.12 ± 0.19
LS6	0.365 ± 0.033	0.412 ± 0.021	11.41 ± 0.030	1.129 ± 0.035	24.31 ± 0.28
LS7	0.388 ± 0.010	0.460 ± 0.024	15.65 ± 0.036	1.180 ± 0.028	27.56 ± 0.17
LS8	0.414 ± 0.080	0.480 ± 0.027	13.75 ± 0.042	1.159 ± 0.016	26.28 ± 0.13
LS9	0.450 ± 0.035	0.523 ± 0.030	13.96 ± 0.048	1.162 ± 0.032	27.14 ± 0.23
LS10	0.355 ± 0.028	0.398 ± 0.015	10.80 ± 0.054	1.121 ± 0.027	25.25 ± 0.60
LS11	0.380 ± 0.040	0.434 ± 0.020	12.44 ± 0.060	1.142 ± 0.036	29.02 ± 0.12
LS12	0.387 ± 0.068	0.456 ± 0.030	15.13 ± 0.063	1.178 ± 0.039	28.26 ± 0.10
DCT	0.386 ± 0.012	0.545 ± 0.012	29.11 ± 0.056	1.412 ± 0.046	29.76 ± 0.14

Each value represents mean ± SD (n=3)

The pre-compression characteristics for all batches were found to be satisfactory. Based on the data, it can be concluded that liquisolid compacts possessed good flow and compressibility properties. If we compare between the batches, LS2 possessed the best granule characteristics and ensured good flow and compressibility.

Fourier Transform Infrared spectroscopy (FTIR)

FT-IR spectrum of pure Deflazacort in Fig 1 showed characteristic peaks at 1658.67 cm^{-1} (C=O) stretching, 2931.60 cm^{-1} (aliphatic CH_3 C-H stretching), 1442.66 cm^{-1} (C=N stretching) and 2871.81 cm^{-1} (aliphatic CH_2 C-H stretching). Disappearance of the characteristic absorption band of deflazacort (1658.67 cm^{-1}) was observed in liquisolid formulation in Fig 2, which might be attributed to the formation of hydrogen bonding between the drug and liquid vehicle; this resulted in drug dissolution enhancement as shown by dissolution data.

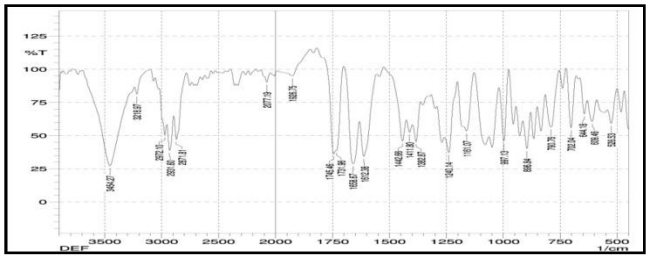

Figure 1: FT-IR spectrum of Deflazacort

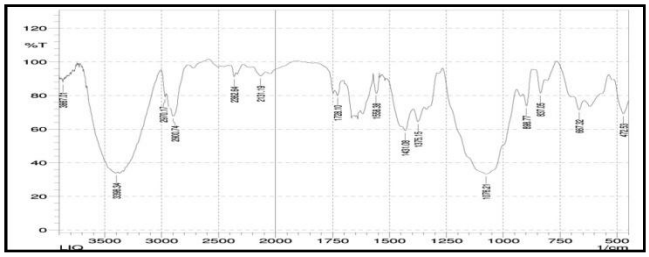

Figure 2: FT-IR spectrum of Liquisolid formulation

X-ray powder diffraction analysis

The X-ray diffraction pattern of pure Deflazacort given in Fig 3 showed characteristic high intensity diffraction peaks at a diffraction angle (2θ) of 11.87°, 15.83°, 16.852°, 17.29°, 23.025° and 17.716° which indicated that the drug is in crystalline form. The same Deflazacort characteristic peaks were observed in physical mixture given in Fig 4 demonstrating that its crystalline structure remained unchanged during the physical mixing The liquisolid powder diffraction pattern in Fig 5 showed only one sharp diffraction peak at 2θ angle of 22.5 belonging to Avicel PH 102 indicating that only Avicel PH 102 maintained its crystalline state. Thus the absence of characteristic peaks of Deflazacort in liquisolid compacts indicated that Deflazacort is entirely converted into amorphous form or solubilized as powdered drug solution in liquisolid compacts. This amorphization or solubilization of

Deflazacort in the liquisolid system must have contributed to the improvement in the dissolution rate of Deflazacort.

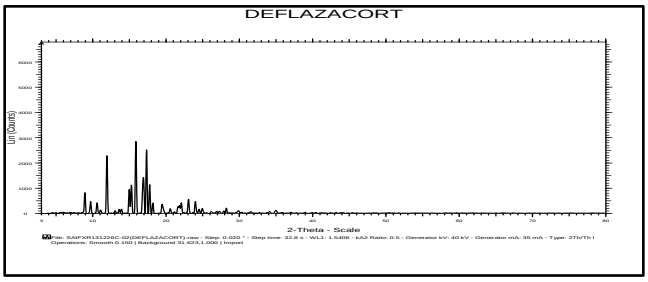

Figure 3: XRD of Deflazacort

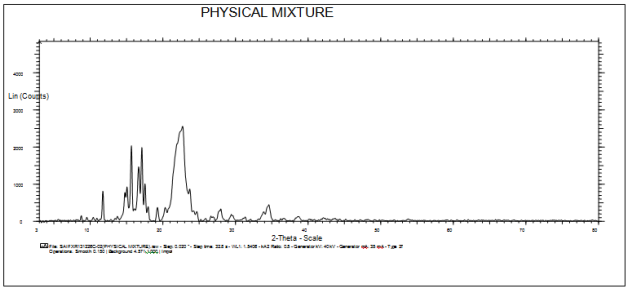

Figure 4: XRD of Physical mixture

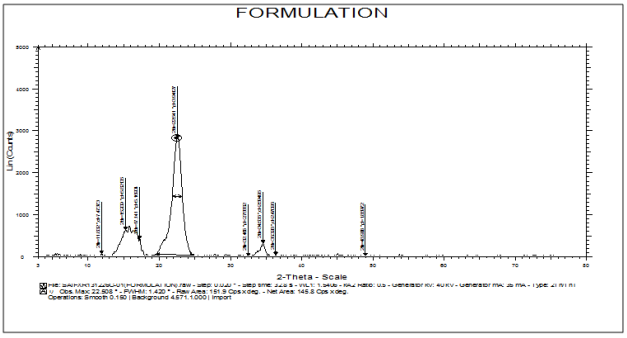

Figure 5: XRD of Liquisolid formulation

Evaluation of liquisolid tablets

Thickness, hardness, friability, weight variation and disintegration

The thickness of all the formulated liquisolid tablets of Deflazacort is given in Table 5 and was found to be between 2.4 - 3.8 mm which was satisfactory. The hardness of the batch was found to be in the range 3.0-6.7 kg/cm^2 and thus the tablets were having good mechanical strength. At the same hardness range, disintegration time of 20-64 sec was observed, except of DCT batch (112 sec), which was satisfactory to provide a rapid dissolution. The friability of all the formulated liquisolid tablets of Deflazacort is given in Table 5 and was found to be between 0.126 - 0.432%. All the formulated tablets showed the percentage friability within the official limit of NMT 1.0% w/w.

The prepared tablets were evaluated for weight variation and percentage deviation from the average weight are reported in Table 5 and was found to be within the prescribed official limits as per IP.

The disintegration test revealed that all the liquisolid tablets disintegrated in less than 5 min and ranged from 20-64 seconds. The DCT batch showed a slow disintegration time of 112 sec, which may be the reason for slow initial drug release of 6.25% at 5 min. The disintegration time is also reflected in-vitro dissolution testing, which showed an increased drug release at initial time points where disintegration was rapid.

Table 5: Results of thickness, hardness, friability, and disintegration time and weight variation of Deflazacort liquisolid tablets

Formulation code	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Disintegration time (sec)	Weight variation (%)
LS1	3.4 ± 0.054	6.7 ± 0.10	0.395	40 ± 2.6	1.9 ± 0.34
LS2	3.5 ± 0.070	6.6 ± 0.37	0.126	20 ± 3.0	1.1 ± 0.72
LS3	3.7 ± 0.054	6.3 ± 0.05	0.355	24 ± 1.5	1.6 ± 0.45
LS4	3.8 ± 0.070	4.2 ± 0.15	0.331	34 ± 1.8	2.1 ± 0.67
LS5	3.0 ± 0.044	3.8 ± 0.17	0.302	52 ± 3.6	1.3 ± 0.12
LS6	3.1 ± 0.026	3.7 ± 0.25	0.250	34 ± 2.0	1.0 ± 0.98
LS7	3.2 ± 0.055	3.5 ± 0.42	0.346	38 ± 1.7	2.0 ± 0.57
LS8	3.3 ± 0.017	3.4 ± 0.20	0.265	42 ± 2.8	1.7 ± 0.73
LS9	2.4 ± 0.044	3.3 ± 0.29	0.432	64 ± 1.4	1.5 ± 0.59
LS10	2.5 ± 0.070	3.2 ± 0.11	0.256	48 ± 1.2	1.3 ± 0.41
LS11	2.6 ± 0.039	3.1 ± 0.38	0.278	52 ± 0.4	1.4 ± 0.43
LS12	2.7 ± 0.012	3.0 ± 0.34	0.267	55 ± 0.6	1.6 ± 0.55
DCT	3.6 ± 0.065	2.1 ± 0.28	0.622	112 ± 1.7	2.1 ± 0.35

Drug content determination

The drug content for tablets of all the formulations ranges from 96.6-99.6%. The results indicate that the contents for tablets of all the formulations were uniform and contains therapeutic dose of the active ingredients.

In-vitro drug release study

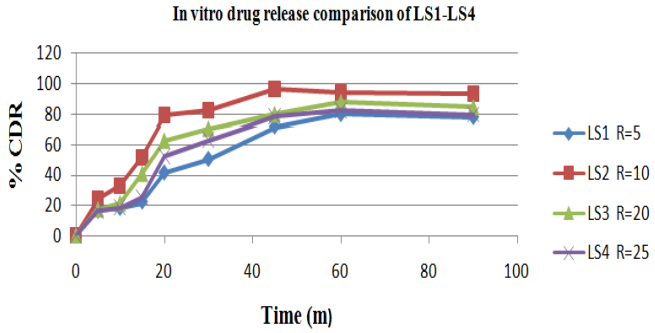

Figure 6: In-vitro drug release profile of Deflazacort Liquisolid tablets containing 10% drug solution

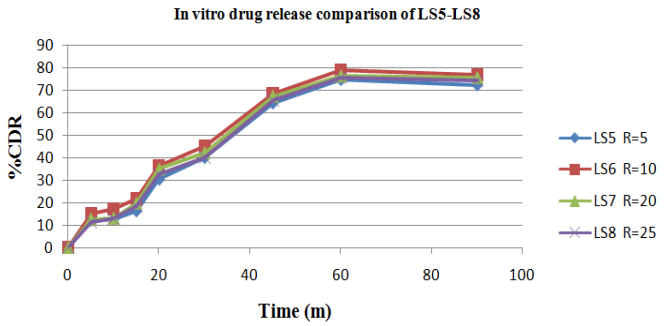

Figure 7: In-vitro drug release profile of Deflazacort Liquisolid tablets containing 20% drug solution

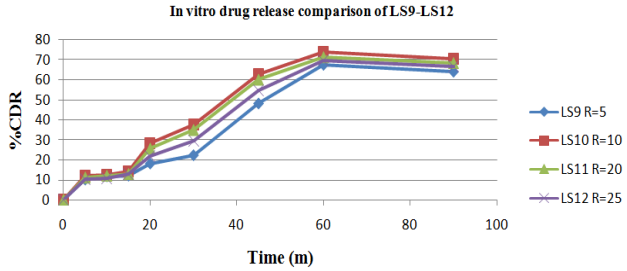

Figure 8: In-vitro drug release profile of Deflazacort Liquisolid tablets containing 30% drug solution

Liquisolid formulations (F9, F10, F11 and F12) containing 30% drug solution exhibited drug release of 48.24%, 62.77%, 59.96%, 54.73% in 45 m. Liquisolid formulations (F5, F6, F7 and F8) containing 20% drug solution exhibited drug release of 64.48%, 68.35%, 67.42% and 65.82% in 45 m. Liquisolid formulations (F1, F2, F3 and F4) containing 10% drug solution exhibited drug release of 71.98%, 96.46%, 80.22% and 78.67% in 45 m. From the above dissolution study, it can be concluded that, as the drug concentration in vehicle increased, dissolution rate decreased. The improvement in dissolution for lower drug concentration batches may be due to the presence of increased amount of liquid vehicle. The enhancement in dissolution profile may be also due to increased wettability, increased surface area of the drug, loss of crystallinity and conversion to amorphous or solubilized form of drug in liquisolid formulation. It is observed that LS2 formulation with a carrier: coating ratio 10:1 with 10% drug solution exhibited better dissolution profile.

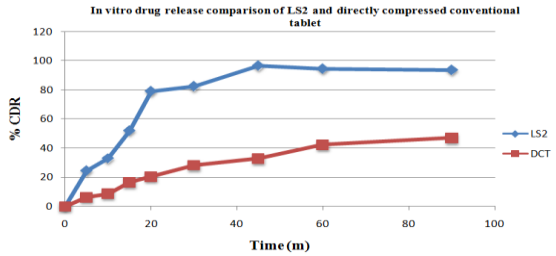

Figure 9: Comparison of in-vitro drug release profile of formulation LS2 and directly compressed conventional Deflazacort tablet

Deflazacort tablet

Liquisolid tablet showed 82.29% drug release in 30 m and 96.46% in 45 m while conventional tablet showed 28.32% drug release in 30 m and 32.8% in 45 m. Only 46.92% drug release was observed with DCT, even when dissolution was continued till 90 m.

Stability studies

Table 6: Results of hardness test, friability, disintegration time and % drug content of selected formulation (LS2) after accelerated stability study

Formulation code	Hardness (kg/cm^2)		Friability (%)		Disintegration time (sec)		% Drug content	
	Before charging	After charging	Before charging	After charging	Before charging	After charging	Before charging	After charging
LS2	6.6	5.8	0.126	0.117	20	24	98.8	97.2

Table 7: In-vitro dissolution study of LS2 after accelerated stability study

Formulation code	Time (min)	Percentage drug release	Percentage drug release
		Before charging	After charging
LS2	0	0	0
	5	24.46	23.97
	10	32.83	32.17
	15	52.02	50.50
	20	78.99	78.22
	30	82.29	80.64
	45	96.46	95.49
	60	94.48	92.59
	90	93.58	91.82

The evaluation of the optimized formulation after stability charging showed there was no significant change observed in the results of hardness, friability, disintegration time, % drug content and in-vitro dissolution study. Thus the above study showed that Deflazacort liquisolid system was stable under stability studies.

CONCLUSION

It can be concluded that dissolution rate of Deflazacort, a poorly water soluble drug could be enhanced by liquisolid technique. The higher dissolution rate displayed by liquisolid tablets may also enhance the bioavailability of these drugs. This may in turn decrease the dose and associated side effects of these drugs.

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