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FORMULATION, OPTIMIZATION AND EVALUATION OF CAFFEINE EFFERVESCENT TABLETS

Sk. Irfan Khan*, B. Navya, Chandan kumar, Dr.Y.Krishna Reddy, DR.K.N.V.Rao, Dr. K. Rajeswar dutt

Department of pharmaceutics, Nalanda College of Pharmacy, Charlapally, Nalgonda, Telangana-508001

Abstract:

The present study aims at developing a caffeine effervescent tablet formulation for the effective treatment of the central nervous system as it acts central nervous system stimulant of the methylxanthine class. And this dosage form is to provide the patient with the most convenient mode of administration, effervescent tablets will dissolve quickly in water and it releases CO_2. And effervescent tablet contains caffeine acts as central nervous system stimulant within seconds of time it will simulate the CNS, onset of action is rapid. Caffeine is a central nervous system stimulant of methyl xanthene class. It is the worlds most widely consumed psychoactive drug. Unlike many other psychoactive substances, it is legal and unregulated in nearly all parts of the world. Caffeine also stimulates certain portions of the autonomic nervous system. So the present work was aimed at formulating effervescent tablet for caffeine, total 6 formulations were developed by using synthetic superdisintigrants like sodium bicarbonate, citric acid, spray dried lactose, magnesium carbonate, sodium starch glycolate, sodium benzoate as superdisintigrants, in a different concentration and prepared by direct compression method and prepared tablets were evaluated for pre-compression and post-compression parameters after conducting pre-formulation studies. All the parameters were within the pharmacopoeial limits and solution time (3mins 10 sec.), PH of solution (8), Hardness 2.5kg/cm^3, thickness 0.6cm, Average weight of 0.48 in formulation (F2) containing sodium bicarbonate and based on these parameters F2 was selected as best formulation.

Key words: ***Central Nervous System Stimulant, Sodium Bicarbonate, Citric Acid, Spray Dried Lactose, Magnesium Carbonate, Sodium Starch Glycolate, Sodium Benzoate, Direct Compression Method.***

Corresponding author:

SK. Irfan Khan,
Asst.Professor,
Nalanda College of Pharmacy,
Charlapally, Nalgonda,
Telangana
E-Mail:ikhanu65@gmail.com

QR code

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INTRODUCTION:

These mixtures have been moderately popular over the years since along with medicinal activity they are attractive dosage form for the patients. Some active ingredients are difficult to digest in the stomach eg: calcium carbonate. Effervescent tablet is a tablet intended to be dissolved or dispersed in water before administration. A typical effervescent tablet (1 inch in diameter weighting 5 grams in total weight) can include more than 2,000 milligrams of water soluble active ingredients in a single dose. It generally contains in addition to active ingredients, mixture of acids/acid salts and carbonate and hydrogen carbonates which release carbon dioxide when mixed with water [1-3].

ROUTE OF ADMINISTRATION: Oral

Advantages of Effervescent Tablets

1. Less irritation and greater tolerability
2. Swallowing can be prevented.
3. More stability is achieved.
4. Improved palatability.
5. More portability.
6. Improved therapeutic effect.

Possible Drawbacks

1. Reactions due to moisture.
2. Expensive.
3. Require special packaging.
4. Maintenance of specified humidity and temperature is difficult.

Applications of Effervescent Tablets

1. Better stability and ease of transporting.
2. Programmed drug delivery can be achieved.
3. Effervescent osmotic pump tablets were used for controlled release.
4. Cosmetic effervescent tablets were also available.

MECHANISM: Caffeine is a central nervous system (CNS) stimulant of the methylxanthine class. It is the world's most widely consumed psychoactive drug. Unlike many other psychoactive substances, it is legal and unregulated in nearly all parts of the world. There are several known mechanisms of action to explain the effects of caffeine. The most prominent is that it reversibly blocks the action of adenosine on its receptor and consequently prevents the onset of drowsiness induced by adenosine. Caffeine also stimulates certain portions of the autonomic nervous system. Caffeine is a bitter, white crystalline purine, a methylxanthine alkaloid, and is chemically related to the adenine and guanine bases of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). It is found in the seeds, nuts, or leaves of a number of plants native to South America and East Asia and helps to protect them against predator insects and to prevent germination of nearby seeds. The most well known source of caffeine is the coffee bean, a misnomer for the seed of *Coffea* plants. Beverages containing caffeine are ingested to relieve or prevent drowsiness and to improve performance. To make these drinks, caffeine is extracted by steeping the plant product in water, a process called infusion. Caffeine-containing drinks, such as coffee, tea, and cola, are very popular; as of 2014, 85% of American adults consumed some form of caffeine daily, consuming 164 mg on average [4-10].

REVIEW OF LITERATURE

Patil UK et. al 2008 Amlodipine besylate effervescent floating tablets were developed in ten different formulations (F1 to F10) by employing different grades of polymers and effervescent agents such as sodium bicarbonate and citric acid. The formulations were evaluated for various physical parameters, buoyancy studies, dissolution parameters and drug released mechanisms. F10 formulation showed maximum floating time of 24 hours and gave slow and maximum drug release of Amlodipine besylate spread over 24 hours and whereas Amlodipine besylate released from marketed tablet was rapid and maximum 12 hour

Uali Mohammed El-hassan Ali et. al 2008 The aim of this study to design, constituteformulation &asses an effervescent formulafrom the Sudanese senna, which used widely in traditional medicine especially forconstipation as laxative, emollient & helping evacuation the gastrointestinal tract. Acompressed effervescent tablets prepared using the wet granulation method in whichthe polyethylene glycol 4000 having an emollient effect; used as a lubricant.The Anthraquinone (sennosideA&B) extracted using the known extraction methods in pharmacognosy & the active constituents were checked by different phyto-chemistry method which confirm the presence of the both Anthraquinone compounds (sennosoides A&B) in which an effervescent base was used in a constant form .The formulated tablets were subjected to the known official monographs requirements like: Resistance to crushing (hardnesstest),Weightvariation,DisintegrationTime/EffervescentTime,FriabilitTest,Contentuniformitytest, PHdetermination

This confirmed to comply with these formulae were found to have a quicker solubility, on set of action,

gaining more patients compliance, attractive, easy to use in known measured doses convenient to the users

S. B. Shirsand Et. Al 2010 Fast disintegrating tablets of lorazepam were prepared by effervescent method with a view to enhance patient compliance. A 3^2 full factorial design was applied to investigate the combined effect of two formulation variables: amount of crospovidone and mixture of sodium bicarbonate, citric acid and tartaric acid (effervescent material) on *in vitro* dispersion time. Crospovidone (2-8% w/w) was used as superdisintigrant and mixture of sodium bicarbonate, citric acid and tartaric acid (6-18% w/w) was used as effervescent material, along with directly compressible Mannitol to enhance mouth feel. The tablets were evaluated for hardness, friability, thickness, drug content uniformity and *in vitro* dispersion time. Based on *in vitro* dispersion time (approximately 13 s); the formulation containing 8% w/w crospovidone and 18% w/w mixture of sodium bicarbonate, citric acid and tartaric acid was found to be promising and tested for *in vitro* drug release pattern (in pH 6.8 phosphate buffer), short-term stability and drug-excipient interaction. Surface response plots are presented to graphically represent the effect of independent variables (concentrations of crospovidone and effervescent material) on the *in vitro* dispersion time. The validity of the generated mathematical model was tested by preparing two extra-design check point formulations. The optimized tablet formulation was compared with conventional marketed tablet for drug release profiles. This formulation showed nearly eleven-fold faster drug release (t50% 2.8 min) compared to the conventional commercial tablet formulation (t50% >30 min). Short-term stability studies on the formulation indicated that there were no significant changes in drug content and *in vitro* dispersion time (P<0.05).

M. Harris shoaib et. Al 2011 Effervescent tablets have always been convenient, simple and measured dosage form. They enhance the bioavailability of the drug and the addition of flavorant also masks the objectionable taste of the medicament in a more patient compliant way. The present study focuses on developing a new, simple, cost effective formulation of naproxen sodium 250 mg as an effervescent tablet using direct compression technique. Nine different trial formulations of naproxen 250 mg were assigned with varying proportions o sodium carbonate, sodium bicarbonate, citric acid and PEG 6000 and were prepared by direct compression method, and evaluated for pharmaceutical quality attributes. Quality assessment proved formulations F8 as a satisfactory one showing respectively mean weight of 2200 ± 50.52 having hardness and friability of14.78421 ± 1.3791 kg and 1.241 %. Tablets took 4 min and 36 s to disintegrate completely. The average pH of the solution was within the range of 5.65 to 5.85. Dissolution profile comparison with the conventional formulation was carried out and maximum drug release by the trial formulation was observed within 15min. spectrophotometric determination of drug content was found to be 99.82 ± 1.754. Stability characterization was also conducted on the formulations under stress (40 °C/75 % R.H.) that showed formulations remained stable throughout the study duration with acceptable difference in physical and chemical characteristics. Such formulations increases patient compliance and have possibly improved bioavailability. The work also emphasizes on the benefit of using direct compression method as a cost effective technique in terms of process, materials handling with productivity

Basawaraj S.Patil et. al 2011 Granisetron hydrochloride is a selective 5-HT3 receptor antagonist, which may have beneficial therapeutic effects in the treatment of vomiting and nausea resulting from cancer therapy. In the present work attempts were made to prepare fast dissolving tablets (FDT) of Granisetron hydrochloride by effervescent technique with a view to enhance patient compliance. sodium starch glycolate used as super disintegrant along with sodium bicarbonate, anhydrous citric acid and tartaric acid in different ratios(as effervescent material) were used. The prepared formulations were evaluated for pre-compressional and post-compressional parameters. The compatibility of drug with other ingredients was checked by FTIR studies, these results revealed that there was no interaction between dug and other excipients. The values of precompressional parameters were within prescribed limits and indicated good free flowing properties. In all the formulations the hardness test indicates good mechanical strength. Friability of all formulations was less than1. Drug content was found to be high (≥ 100.10%) and uniform in all the formulations. The tablet thickness was found to be 3.08 to 3.25 mm. The weight variation results revealed that average percentage deviation was less then ± 7.5%, which provides good uniformity in all formulations. The disintegration time of the tablets decreased significantly with increase in the concentration of effervescent agents. The formulations GE4, GE8 and GE12 50 % of drug released in 3.15, 2.11, 2.61 min, and 90 % of drug released in 7.23, 7.25, 6.25 min. Stability study carried out as per ICH guidelines for three months and results revealed that upon storage disintegration time of tablets decreased significantly (p<0.05).The release of drug from the GE12 formulation was quick when compared to other formulation

Sagar A Adichwal, et. al 2012 The purpose of this research was to develop a novel gastroretentive drug delivery system based on effervescent technology for controlled delivery of active agent. Glipizide, a poorly soluble drug has been used as a model drug and an attempt has been made to improve the solubility of drug by the incorporation of accelerating agents, such as dispersant, alkalising agent in conjunction with hydrophilic swellable polymer such as hydroxypropylmethylcellulose and present it in the form of gastroretentive floating tablets, which are designed to provide the desired controlled and complete release of drug for prolonged period of time. Floating tablets were prepared by direct compression method. Hydroxypropylmethylcellulose (HPMC K15M, HPMC K100M), Carbopol 940P, were incorporated for gelforming properties. Buoyancy was achieved by adding an effervescent mixture of sodium bicarbonate and anhydrous citric acid. The optimized formulation (F7) exhibited 98.60% drug release in 24 hrs, while the buoyancy lag time was 140sec. In-vitro drug release kinetics was found to follow both the Zero order and the Korsmeyer and Peppas equation (Table 7). The release of glipizide from the formulations was found to be non-fickian type. Evaluation of Gastric Retention Using X-Ray Imaging studies were performed on rabbit to justify the increased gastric residence time of the dosage form in the stomach, based on the floating principle. Optimized formulation (F7) showed no significant change in physical appearance, drug content, total buoyancy time, or *in vitro* dissolution pattern after storage at 40°C/75% (Figure 5) relative humidity for 1 month

Niraj Upmanyu, et. al 2012 Levofloxacin effervescent sustained release tablets were developed in eight different formulations (F1 to F8) by employing different grades of polymers and effervescent agents such as sodium bicarbonate and citric acid. The formulations were evaluated for various physical parameters, dissolution parameters and drug released mechanisms. F8 formulation showed maximum floating time of 12 hours and gave slow and maximum drug release of Levofloxacin spread over 12 hours and whereas Levofloxacin released from marketed tablet was rapid and maximum within 8 hours

Chauhan P, et. al 2012 Recently, fast-dissolving drug delivery system have started gaining popularity and acceptance as new drug delivery system, because they are easy to administer and lead to better compliance. Usually, elderly people experience difficulty in swallowing the tablet. Paracetamol having analgesic, antipyretic effect, they inhibit cyclooxygenase enzyme involved in prostaglandin (PG) synthesis but not in peripheral tissue while Ibuprofen inhibit prostaglandin (PG) synthesis in peripheral tissue so in this study Paracetamol and Ibuprofen combination used for analgesic, anti-pyretic and anti-inflammatory action simultaneously. The aim of this study was to formulate effervescent tablet with sufficient mechanical integrity and to achieve faster disintegration in the water. Effervescent tablets are uncoated tablets that generally contain acid substances and carbonates or bicarbonates and which react rapidly in the presence of water by releasing carbon dioxide. They are intended to be dissolved or dispersed in water before use. Effervescent compositions in the form of tablets are comprising a therapeutic agent, granulating agent, and an effervescent system which dissolve rapidly in water to yield an effervescent solution containing a completely dissolved therapeutic agent and a process for their preparation. In this study different ratio of Citric acid and Sodium bicarbonate was used, superdisintegrant like SSG and cross-providone was used, compared to cross-providone SSG decreases the Solution time of tablet. Granules prepared by Wet granulation technique and from the result it was found that the Particle size 355-500 µm of granules show good Solution time and Hardness property

K.R.Srinath, et. al 2012 The oral dosage forms are the most popular way of taking medication despite having some disadvantages like slow absorption and thus onset of action is prolong. This can be overcome by administrating the drug in liquid from but, many APIs have limited level of stability in liquid form. So, Effervescent Tablets acts as an alternative dosage form. The tablet is added into a glass of water just before administration and the drug solution or dispersion is to be drunk immediately. The tablet is quickly broken apart by internal liberation of CO2 in water due to interaction between tartaric a acid and citric acid with alkali metal carbonates or bicarbonates in presence of water.Due to liberation in CO2 gas, the dissolution of API in water as well as taste masking effect is enhanced. The advantages of effervescent tablets compared with other oral dosage forms includes an opportunity for formulator to improve taste, a more gentle action on patient's stomach and marketing aspects. In present work an attempt has been made to formulate an effervescent tablet containing immediate release of paracetamol using various acids and bases. In present work we are used different acids and bases in different concentration. In the preformulation study, compatibility evaluation was performed which implies that drug; acids, bases and other excipient are compatible with each other. The formulation of tablets was done by using wet granulation as well as dry granulation in that technique wet granulation which was found acceptable. The total nine placebo

tablets were prepared and evaluated for hardness, disintegration time, weight variation and solubility. All the formulation shows hardness and weight variation with in limit but the combination of citric acid (12.56%), tartaric acid (25.17%), sodium bicarbonate (38.20%), sodium carbonate (6.41%) ,binding agent PVP-K-30 (2.94%) and sodium benzoate (0.52%). for the final formulation,(F7) Because these ingredients shows the good \ effervescent reaction and has no problem in capping and sticking like other formulation

M. Karthik raja et. al 2012 Any drug delivery system was designed to provide a therapeutic amount of drug to a proper site in the body with intestinally to achieve desired release and thereby to maintain the desired drug concentration. Multiple-unit floating drug delivery systems has several advantages over monolithic ones, like avoiding all-or-nothing emptying, more predictable drug release kinetics. In addition to drug formulations that deliver the drug for a prolonged or extended period, itwas important for efficient therapy to achieve spatial and determined placement of the dosage form in the gastrointestinal tract. A gastroretentive effervescent tablet of tinidazole by direct compression was formulated in two different concentration of HPMC along with Sodium bicarbonate and citric acid. The gas forming agent's sodium bicarbonate was added in same concentrations. The formulated tablets were then evaluated for pre formualative studies, solubility, and post formulation evaluation like drug content, floating properties and invitro dissolution. The invitro release study showed about 80-84% of drug release at the end of 7 hrs with good buoyancy effect for the batch formulated with the combination of high concentration of HPMC. The above study demonstration EF1 formulation could be successfully employed for good Controlled release action and it was planned to effervescent Floating tablets formulation by using direct compression. Direct compression proves to be one of the best method of preparation of floating tablets

MATERIALS AND METHODS:

MATERIALS: Caffeine, Superdisintegrants (sodium bicarbonate, citric acid, spray dried lactose, magnesium carbonate, sodium starch glycolate, sodium benzoate), sugar based excipients, fillers or diluents, colours, sweeteners, Lubricants, glidants and preservatives.

Direct Compression

Direct compression normally requires careful selection of raw materials to achieve a free-flowing, non-segregating, compressible mixture. Effervescent tablets were prepared by direct compression technique using varying concentrations of different grades of polymers with Sodium bicarbonate and citric acid. All the ingredients were accurately weighed and passed through different mesh sieves accordingly. Then, except Magnesium stearate all other ingredients were blended uniformly in glass mortar After sufficient mixing of drug as well as other components, Magnesium stearate was added, as post lubricant, and further mixed for additional 2-3 minutes. The tablets were compressed using rotary tablet machine. The weights of all the tablets were kept constant for all formulation.

PREFORMULATION EVALUATION:

It includes different tests like Bulk density, tapped density, Carr's index, hausner's ratio, Angle of repose.

Evaluation of Caffeine Effervescent Tablets:

Weight variation:

20 tablets were selected randomly from the lot and weighted individually to check for weight variation.

Weight Variation Specification as per IP

Table 1: Weight Variation Specification

Average Weight of Tablet	% Deviation
80 mg or less	<10
More than 80 mg but less than 250 mg	<7.5
250 mg or more	<5

Hardness

The limit of hardness for the effervescent tablet is usually kept in a lower range to facilitate early disintegration in the mouth. The hardness of the tablet may be measured using conventional hardness testers (Monsanto tablet hardness tester). It is expressed in kg/cm2 or pound.

Friability

Friability of the tablet determined using Roche friabilator. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at I height of 6 inches in each revolution. Pre weighted sample of tablets was placed in the friabilator and were subjected to the 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. The friability (F) is given by the formula.

$$F = \frac{W_{initial} - W_{final}}{W_{initial}} \times 100$$

Thickness

Thickness of the core tablets and coated tablets were measured by using screw gauge. Ten tablets from each formulation were randomly selected and used. Thickness is expressed in millimeters.

Solution time

Time required for 2 tablets to dissolve in 180ml of water at 17.5 ± 2.5oC.

pH of the solution test: The pH of solution can measured by pH meter, pH of solution prepared by putting tablets into water was affected by storage condition due to liberation of CO_2.

Formulation Table

Table 2: Formulation design for caffeine effervescent tablets

Parameters	F1	F2	F3	F4	F5	F6
Caffeine	100mg	100mg	100mg	100mg	100mg	100mg
Sodium bicarbonate	200mg	228mg	200mg	228mg	200mg	228mg
Citric acid	128mg	100mg	128mg	100mg	128mg	100mg
Spray dried Lactose	20mg	20mg	20mg	20mg	20mg	20mg
Magnesium carbonate	20mg	20mg	20mg	20mg	20mg	20mg
Sodium starch glycolate	20mg	20mg	20mg	20mg	20mg	20mg
Sodium benzoate	10mg	10mg	10mg	10mg	10mg	10mg
Mannitol	2mg	2mg	--------	-------	-------	-------
Ethanol	--------	-------	2mg	2mg	--------	--------
Polyethyleneglycol-6000	--------	--------	--------	--------	2mg	2mg

RESULTS:

STANDARD GRAPH

Table 3: Standard graph

S.NO	CONCENTRATION	ABSORBANCE
1	**0**	**0**
2	**1**	**0.139**
3	**2**	**0.256**
4	**3**	**0.365**
5	**4**	**0.478**
6	**5**	**0.584**

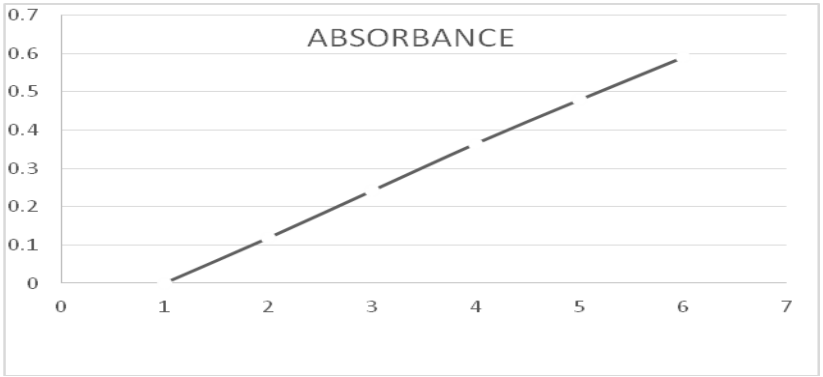

Fig.1: Standard graph

PRE EVALUATION PARAMETERS

Table 4: Pre evaluation parameters

Formulation code parameters	Bulk density gm/cc	Tapped density gm/cc	Hausner's ratio	Carr's index	Angle of repose
F1	166.6	300	0.55	80	0.67
F2	166.6	375	0.47	112.5	0.67
F3	176.4	375	0.47	112.5	0.74
F4	176.4	333	0.55	100	0.74
F5	187.5	428	0.43	128.5	0.64
F6	187.5	428	0.43	128.5	0.64

POST EVALUATION PARAMETERS

Table 5: Post evaluation parameters

Formulation code parameters	Average weight	Hardness	Thickness	Friability	Solution time	Ph of solution
F1	0.49	2.5	0.55	0.48	3min,10sec	8
F2	0.48	2.5	0.6	0.47	3min,10sec	8
F3	0.47	2.0	0.55	0.50	5min,12sec	7.5
F4	0.49	2.0	0.6	0.50	5min,10sec	7.5
F5	0.50	3.0	0.55	0.55	8min,4 sec	8
F6	0.50	3.0	0.6	0.55	8min,4 sec	8

DISCUSSION:

Pre compression parameters of blend: The bulk density of precompression blends was found to be in the range of 166.6 to 187.5gm/cc, tapped density in the range of 300 to 428.5 gm/cc, Carr's index value were in the range of 80 to 128.5%, Hausner's ratio in the range of 0.55 to 0.437, and angle of repose between 0.67 to 0.64. all the values were found to be within the prescribed limits according to the i.p, thus ensuring good flow properties of the formulation blends.

Post Compression Parameters

Hardness and friability: The hardness of the tablet formulations was found to be in the range of 2.5 to 3.0kg/cm. the friability and thickness values was found to be in the range of 0.47 to 0.60 and 0.55 to 0.6% respectively which was found to be within the prescribed ip limits and thus ensuring good mechanical strength of all the formulations.

Solution time: Among the tablets prepared F6 formulations was found to be promising and has shown wetting time of 3min to 8min.

Ph of the solution: Among the tablets prepared F6 formulations was found to be promising and has shown the ph of 7.5 to 8.

Uniformity of weight: All the prepared effervescent tablets were evaluated for weight variation. The weight of all the tablets was found to be uniform with low values of standard deviation and within the prescribed limits.

CONCLUSION:

Fast disintegrating tablets of caffeine prepared by using various of superdisintigrants like *sodium bicarbonate citric acid spray dried lactose magnesium carbonate sodium starch glycolate* sodium benzoate by direct compression method the prepared formulation were evaluated for the pre compression parameters and the values were within the prescribed limits and which indicates good free flowing properties the physical parameters were found *the* satisfactory and within the limits this method was shown good results for prescribed limits and which indicates good free flowing properties. The physical parameters were found satisfactory & within the limits. This method was showed good results for disintegration time, wetting time & in vitro drug release studies because disintegrating of tablets to increase the porosity of the tablets. The tablets prepared with sodium bicarbonate, citric acid, spray dried lactose, magnesium carbonate, sodium starch glycolate, sodium benzoate and F2 by direct compression method was found to be best formulation as it exhibited satisfactory physical parameters, least solution time (3mins 10 sec.), PH of solution (8), Hardness 2.5kg/cm^3,thickness 0.6cm, Average weight of 0.48.

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2. Pare A, Yadav SK and Patil UK* V N S Institute of Pharmacy, V N S Campus, Vidya Vihar, Barkheda Nathu, Neelbud, Bhopal (M P)-462044 * Corresponding Author E-mail: umeshpatil29@yahoo.com
3. UAli Mohammed El-hassan Ali AbedallaU;B. Pharm 2008 Omdurman Islamic University U Mobile:_0912127692 Email.shayoub2004@hotmail.com
4. Palanisamy P, Rabi Abhishekh, D Yoganand kumar Vinayaka mission college of pharmacy, Vinayaka Missions University, Saleem, Tamil Nadu,India Trainee Research Associste, Pharmacokinetics/Biostatistics,Axis Clinicals Ltd, Hyderabad,Andhra Pradesh, India Article received on:05/10/11 Revised on:30/10/11 Approved for Publications:19/11/11
5. M. Harris SHOAIB 1*, Muhammad GHIASUDDIN 1, Rabia I. YOUSUF 1,Wajhia EFFET 2, Iyad N. MUHAMMAD 1 & Muhammad HANIF 1Department of Pharmaceutics, Faculty of Pharmacy, University of Karachi, Karachi-75270, Pakistan. Dow College of Pharmacy, Dow University of Health Sciences, Karachi, Pakistan
6. Basawaraj S.Patil*, K. Dayakar Rao, Upendra Kulkarni, Mahesh M. Gada, Srinivas R.Soodam. PG Department of Pharmaceutics, R.M.E.S College of Pharmacy, Gulbarga 585102 Karnataka
7. Dubey vivek,* Arora Vandana M Pharma (pharmaceutics), Ljoyd institute of Management and Technology, Greater Noida, U.P, Mahamaya Technical University.
8. Basavaraj K Nanjwade*, Sagar A Adichwal, Veerendra K Nanjwade, Kishori R Gaikwad, Sachin A. Thakare and F V Manvi Department of Pharmaceutics, KLE University College of Pharmacy, JN Medical College Campus, Belgaum– 590010, Karnataka, India Hemant Sahu1, Vivek Jain1, Niraj Upmanyu1, Subhendu S. Mishra2* and Navdeep Raghuwanshi2
9. Depatment of Pharmaceutics, R.K.D.F College of Pharmacy, Bhopal, India Department of Pharmaceutics, Sapience Bioanalytical Research Laboratory, Bhopal, India
10. Shree Swaminarayan Sanskar Pharmacy College, Zundal, Gujarat-382421, India

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