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FORMULATION AND EVALUATION OF DOMPERIDONE CHEWABLE TABLETS

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ABSTRACT

Chewable tablets have an advantage over conventional tablets as well as liquid dosage forms in geriatric and paediatric patients. They enhance both the therapeutic efficacy and the bioavailability. Domperidone chewable tablets were formulated so that compliance in the drug in children is achieved by improving the solubility and dissolution. Domperidone chewable tablets were prepared by employing wet granulation. Examination of the tablets was undertaken about general appearance, size, shape, color, odor, taste, hardness, friability, weight variation, disintegration, and content uniformity. The key is dissolution testing to discover any physical change in an API and in the developed formulation. Mechanism of action and some tablet-making defects, for example capping, lamination, picking, sticking, and mottling, are discussed under the root cause of the problems. Examples of some chipped or edged product forms are antacids, aspirin for kids, and chewable vitamins.

KEYWORDS: Domperidone chewable tablets, paediatric patients, liquid dosage.

INTRODUCTION

INTRODUCTION CHEWABLE TABLET

Chewable tablet have the advantages of both conventional tablet and liquid dosage formulation especially in geriatric and paediatric Oral route of administration has received more attention in the pharmaceutical field. Chewable dosage forms have been demonstrated to improve therapeutic efficacy and better bio availability. Chewable tablets are designed for use by the children and such persons who may have dittculty in swallowing the tablet. These are intended to be allowed in the mouth prior to swallowing and not intended to be swallowed in tack Additionally chewable tablets facilitate more rapid and hence more rapid absorption of onset of action. Hence it was decided to formulate domperidone chewable tablet to improve the compliance in children and to improve the solubility and dissolution

TABLET MANUFACTURING METHOD

WET GRANULATON METHOD

Wet granulation forms the granules by binding the powders together with an adhesive, instead of by compaction. The wet granulation technique employs a solution, suspension or slurry containing a binder, which is usually added to the powder mixture; however the binder maybe incorporated dry into the powder mix, and the liquid may be the add by itself.

The method of introducing the binder depends on its solubility and on the components of the mixture. Since in general the mass should merely be moist rather than wet or pasty, there is a limit to the amount of solvent that may be employed. Therefore, when only a small quantity is permissible, the binder is blended in with the dry powders initially, when a large quantity is required, the binder is usually dissolved in the liquid the solubility of the binder also has an influence on the choice of method since the solution should be fluid enough to disperse readily in the mass. The liquid plays a key role in the Granulation process. liquid bridges are developed between particles and the tensile strength of these bonds increases as the amount of liquid added is increased these surface tension forces and capillary pressure are primarily responsible for initial granule formation and strength. once the granulating liquid has been added mixing continues until a uniform dispersion is attained and all the binder has been activated During granulation particles and agglomerates are subjected to consolidating forces by action of machine parts and of interparticulate forces granulation is large blenders requires 15 min to an hour The length of time depends on the wetting properties of the powder mixture and the granulating fluid and upon the efficiency of the mixer. A rough way of determining the end point is to press a portion of the mass in the palm of the hand if the ball crumbles under moderate pressure the mixture is ready for the next stage in processing which is wet screening.

The wet screening process involving converting the moist mass into coarse granular aggregates by passage through a hammer mill or oscillating granulator equipped with screens having large perforations The purpose is to consolidate granules increase particle contact points and increase surface area to facilitate drying overly wet material dries slowly and forms hard aggregates which tend to turn to powder during subsequent dry milling there are many instances in which wet milling may be omitted with a considerable saving of time the formulator should be alert to these opportunities and not follow the old method blindly.

A drying process is required in all wet granulation procedures to remove the solvent that was used in forming aggregates and to reduce the moisture content to an optimum level of concentration within the granules during drying interparticulate bonds result from fusion or recrystallization and curing of the binding agent with Vander walls forces playing a significant role.

After drying the granulation is screened again. The size of the screen depends upon the grinding equipment used and the size of the tablet to be made.

TABLET MANUFACTURING DEFECTS

Capping and lamination

Capping is a term used to describe the partial or complete separation of the top or bottom crowns of a tablet from the main body of the tablet lamination is the separation of a tablet into two or more distinct layers usually these processing problems are readily apparent immediately after compression however capping and lamination may occur hours or even

days later subjecting tablets to the friability test described earlier is the quickest way of revealing such problems capping and lamination have in the past been attributed to air entrapment. During the compression process air is entrapped among the particles or granules and does not escape until the compression pressure is released.

Tablet tooling can also be cause of capping the concave or beveled edge faces of punches gradually curve inward with use and form a “claw” that can pull off the crowns of tablet, wear in the upper punch guides accelerates this claw formation by permitting the punch tips to strike the edges of the die holes. Also, the greater the radius of curvature of the punch face, the greater is the force exerted on the edges and the less on the center of the tablet at the moment of compression.

Another cause of capping is an incorrect setup at the press.

Figure – 1.

Picking s a term used to describe the surface material form a tablet that is sticking to and being removed from the tablets surface by a punch. Picking is of particular concern when punch tips Have engraving or embossing. Small enclosed areas such as those in the letters “B”,”O are difficult to manufacture cleanly.

Tablet materials that stick to the punches can accumulate to the point of obliterating the tip design.” Sticking” refers to tablet material adhering to the die wall. When sticking occurs, additional force is required to overcome the friction between the tablet and the die wall during ejection. Serious sticking at ejection can cause chipping of a tablet’s edges and can produce a rough edge. Also, a sticking problem does not allow the lower punches free movement and therefore can place unusual stresses on the cam tracks and punch heads resulting in their damage sticking can also apply to the buildup material on punch faces.

Figure – 2.

MOTTLING

Mottling is an unequal distribution of color on a tablet with light or dark areas standing out in an otherwise uniform surface one cause of mottling is a drug whose color differs from the tablet excipients or a drug whose degradation products are colored the use of colorants may solve the above problem but can create others a dye can cause mottling

by migrating to the surface of a granulation during dry to overcome this difficulty the formulator may change the solvent system change the binder system reduce the drying temperature or grind to a smaller particle size the use of colorants in direct compression formulations can lead to mottling if the dye is not well dispersed or if its particle size is too large.

Figure – 3.

EVALUATION OF TABLET

General Appearance

The general appearance of a tablet, it's identify and general elegance is essential for consumer acceptance, for control of lotto lot uniformity and tablet-to- tablet uniformity. The control of general appearance involves the measurement of size, shape, color, presence or absence of odor, taste, etc.

Size shape

It can be dimensionally described & controlled. The thickness of a tablet is only variables. Tablet thickness can be measured by micrometer or by other device. Tablet thickness should be controlled within a±5% variation of standard value.

Tablet requires a certain amount of strength or hardness and resistance to friability to withstand mechanical shakes of handling in manufacture, packaging and shipping. Hardness generally measures tablet crushing strength.

Friability

Friability of a tablet can determine in laboratory by Roche friabilator. This consists of plastic chamber that revolves 25rpm, dropping the tablets through a distance of six inches in the fraibilator, which is then operating for 100 revolutions. The tablets are reweighed. Compress tablet that loss than 0.5 to 1.0% of the tablet weigh are consider acceptable.

Weigh variation Test

Take 20 tablets and weighed individually, calculate average weight and compare the individual tablet weight to the average. The tablet pass the U.S.P ,a test if no more that 2 tablets are outside the percentage limit and if no tablet differs by more than 2times the percentage yield.

Disintegration test

Disintegration test is widely used in the pharmaceutical industry for evaluation of disintegration capability of formulations (ex: tablets) and quality control of different dosage forms.

Disintegration Test Method

The disintegration test for each dosage form is given in the pharmacopoeia. There are some general tests for typical types of dosage forms. However, the disintegration test prescribed in the individual monograph of a product is to be followed. If the monograph does not specify any specific test, the general test for the specific dosage form may be employed. Some of the types of dosage forms and their disintegration tests are: 1.Uncoated tablets- Tested using distilled water as medium at 37+/-2 C at 29-32 cycles per minute; test is completed after 15 minutes.

It is acceptable when there is no palpable core at the end of the cycle (for at least 5 tablets or capsules) and if the mass does not stick to the immersion disc. 2. Coated tablets- the same test procedure is adapted but the time of operation is 30 minutes. 3. Enteric coated/ Gastric resistant tablets- the test is carried out first in distilled water (at room temperature for 5 min.; USP and no distilled water per BP and IP), then it is tested in 0.1 M HCL (unto 2 hours; BP) or Stimulated gastric fluid (1 hour; USP) followed by Phosphate buffer, pH 6.8 (1 hour; BP) or Stimulated intestinal fluid without enzymes (1 hour; USP). 4. Chewable tablets- exempted from disintegration test (BP and IP), 4 hours (USP). These are a few examples for illustration. The disintegration tests for capsules, both hard and soft gelatin capsules are also performed in a similar manner. Also, the USP also provides disintegration tests for suppositories, peccaries etc.

Content uniformity test

Uniformity of Content is a pharmaceutical analysis parameter for the quality control of capsules or tablets. Multiple capsules or tablets are selected at random and a suitable analytical method is applied to assay the individual content of the active ingredient in each capsule or tablet.

PROCEDURE

Take one tablet in a mortar and triturate with the help of pestle, the quantity equivalent to 10mg was taken in a 100ml volumetric flask and to it 100ml, 0.1N Hcl was added. From this stock solution 1ml aliquot were taken and diluted to 10ml with 0.1N Hcl, Finally the absorbence of prepared solution was measured against blank (0.1N Hcl) at 284nm using UV-Visible spectrophotometer (UV 1800-Shimadzu).

Dissolution testing is a requirement for all solid oral dosage forms and is used in all phases of development for product release and stability testing.[1] It is a key analytical test used for detecting physical changes in an active pharmaceutical ingredient (API) and in the formulated product. At early stages of development, *in vitro* dissolution testing guides the optimization of drug release from formulations. Over the past 50 years, dissolution testing has also been employed as a quality control (QC) procedure, in R&D to detect the influence of critical manufacturing variables and in comparative studies for *in vitro-in vivo* correlation (IVIVC).[2]

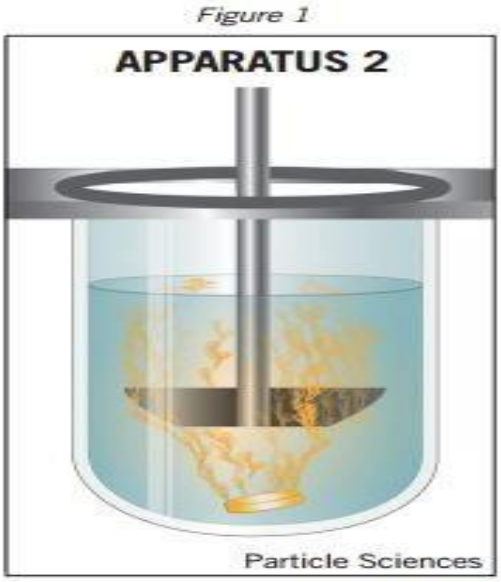


Figure – 4.

Specific the dissolution technique employed is determined by the dosage form characteristics and the intended route of administration. For solid dosage forms, industry.

MECHANISM OF ACTION

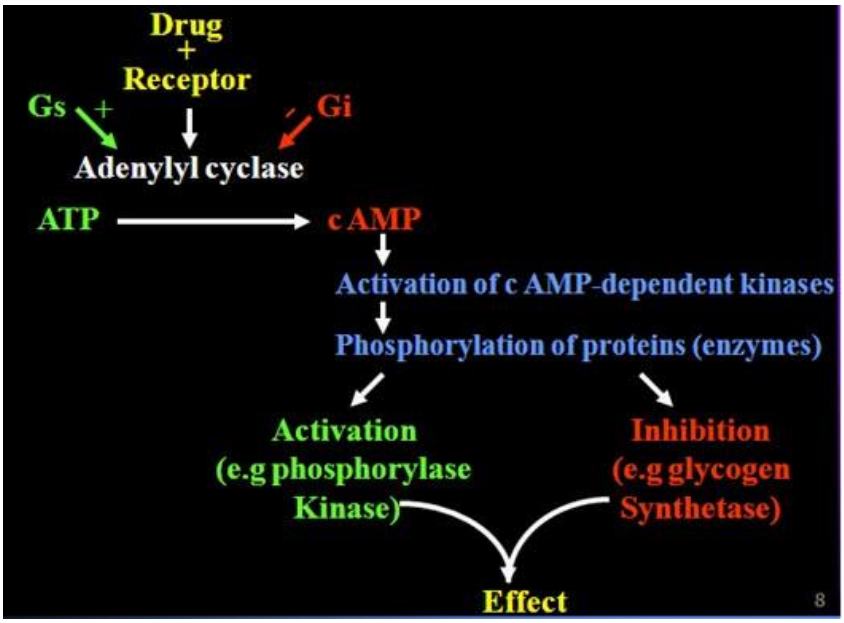


Figure – 5.

TABLET MANUFACTURING DEFECTS

During compression cycle we often come across the issue of tablet defects chipping and flashing. Here, we will analysis problems in machine as well as formulation leading to these defects.

ROOT CAUSE OF CHIPPING AND EDGING

If tablet after compression is not hard enough to handle the ejection it will cause chipping,

Proper assembly of knock off plate is necessary failing to adjust the knock off plate will lead to chipping in tablet.

Metal detector and deducted clearance will also lead to chipping and edging problem as in some cases the tablet edges tends to wear between sharp clearance of metal detector and detester.

Friability problem in granules in this case the technician cannot do much in machine except to minimize the thickness and increasing the weight than check the friability. If problem still persists formulation needs to be a changed.

Exit chute is not placing the tablet property in deduster and we are getting edged tablet. Provide quick and complete disintegration of the tablet and thus obtain a rapid drug effect after swallowing and dissolution.

Easy administration, especially elimination for infants and elderly people Patient convenience through elimination of need of water for swallowing.

EXAMPLES

Chewable Aspirin tablet (for children in the treatment of rheumatoid and to prevent clot formulation in adults.
Antacids tablets
Chewable multi vitamin tablet

LITRATURE REVIEW

Ahmad shuaib *et al.,* (2016) prepared and evaluated of albendazole chewable tablets by wet granulation method and. By using the materials are albendazole, maize starch, lactose, MCC, povidine, SLS, sunset yellow supra, sodium saccharin, croscarmillose sodium, orange and peppermint flavor, aerosol, magnesium stearate. The tablet punching is done by direct compression method was carried out by using superdisintegrants.

Yasir Mehmood *et al.,* (2015) formulated and evaluated of chewable modified-release tablet containing sodium fluoride and vitamin C. it is formulated by using the carbopal and HPMC with the ratio of 1:1 or alone. It can be seen that by increasing the concentration of HPMC/ Carbopol alone in the formulation, the drug release rate was found to be unsatisfactory. When combination of two polymers was used, the drug release rate was found to be decreased.

Jyoti *et al*., (2015) Formulated and evaluated of chewable tablets of loratadine by direct compression method by using lactose MCC, povidine K 30. Formulated chewable tablet characterized by the FTIR spectra of pure drug loratadine was compared. Comparison of formulation with marketed tablet formulation of loratadine (Claritin) showed better drug release profile.

Abdul et al., (2015) novel chewable tablet in tablet dosage form of orlistat and venlafaxine HCl: development and evaluation by direct compression method using orlistat and venlafaxine Hcl, maltodextrin, sucrolase, cherry and peppermint s flavor andmegnisium stearate. The developed press coated tablet in tablet of ORST and VLFXN can be excellent drug delivery system for treating patients with obesity and BED as it is palatable and can be chewed conveniently without water.

Fiza *et al.,* (2014) formulated and evaluated of chewable tablet of mebendazole by different techniques of aqueous granulation, non aqueous granulation ,direct compression by using lactose, starch, sodium starch glycolate, isopropyl alcohol, sodium saccharine etc, tablet prepared by direct compression method had the better dissolution rate when compared to ‘NAQ’ and ‘AQ’.

Charu bharti *et al.*, (2014) prepared and evaluated of pentoxifylline loaded chewable tablets for the treatment if peripheral vascular diseases by using wet granulation techniques by using the materials are the sodium starch glycolate, acacia, lactose, mannitol, magnesium stearate, talc and strawberry flavor was added. Lactose and mannitol produce significant effect on hardness and friability. It can be concluded that pentoxifylline loaded chewable tablets using superdisintegrant can provide better therapeutic response for treatment of peripheral vascular diseases.

Monika Sharma *et al.*, (2014) formulated amoxicillin and potassium clavulanate chewable tablets by dry granulation method. By using the materials are amoxicillin trihydrate, potassium clavulanate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate and aspartame. The accelerated stability studies as per ICH guidelines and was evaluated for various parameters such as description, assay, dissolution, water content at respective month intervals at accelerated condition. All the parameters were satisfactory thus the formulated chewable tablets.

Manisha *et al.*,(2013) formulated and evaluated of chewable tablet of Metformin HCl using stevia by different techniques of direct compression < non aqueous granulation > aqueous granulation by using mannitol, lactose anhydrous formulated chewable tablet characterized by the FTIR spectra of Metformin HCl was compared. The stevia as sweetening agent was used as some formulations its gives some beneficial effect than aspartame.

K Shruthi *et al.*,(2013) prepared and evaluated of Montelukast sodium chewable tablet using modified karaya gum by wet granulation method using mannitol as diluents, HPMC as binder, sodium starch glycolate as disintegrant aspartame as sweetening agent vanillin as flavor magnesium stearate as lubricantthe formulation was optimized acceptable results in terms of disintegration time and *in vitro* drug release has shown similar results in comparison with a marketed product.

A. Halder *et al.*, (2012) prepared loperamide HCl chewable tablet methods validation of HPLC using lactose sodium lauryl sulphate HPMC colours flavors' etc, Its prepared by the wed granulation technique use of simethicone to dry powder blend improve hardness and provides good physical appearance to the tablets loperamide HCl to binder solution and using proper amount of surfactant (SLS) to blend increase content uniformity and better dissolution of loperamide HCl.

Jayadev *et al.*, (2012) formulated and evaluation of chewable tablets containing non sedative antihistamine using loratadine was prepared by using aqueous wet granulation technique with MCC, lactose mono hydrate, mannitol as diluent. Ethyl cellulose as polymer for taste masking. Povidone and maize starch as binder. Trial 5 was the best one with almost 100%drug release at the end of 16 minutes which is formulated without use of ethyl cellulose and also having best dissolution within 60 minutes and 100% drug content.

Anusha *et al.*, (2012) formulated and characterization of albendazole chewable tablets by wet granulation technique using single rotary tablet machine by using sodium starch glycolate and sodium lauryl sulfate.

Sukhbir *et al.*, (2012) formulated and evaluated of chewable tablet of albendazole by different technique of non aqueous, aqueous and direct compression method using starch, lactose sodium starch glycolate, isopropyl alcohol, sodium saccharine. The dissolution profile of batches of tablets prepared by direct compression method has shown better results compared to the tablets prepared by other methods as well as marketed product.

Kashikar et al., (2011) Formulated and evaluated of taste masked chewable herbal tablet for cough remedy. Fresh Tulsi leaves, ginger powder, black pepper powder, clove powder, nutmeg powder, cinnamon powder and hydroxyl propyl methyl cellulose and using wet granulation method. It is used in the treatment of cough and cold.

Magdy et al., (2010) prepared polymeric and surfactant based etodolac chewable tablets formulation and *invivo* evaluation by using compression SLS, mannitol, ethanol and methanol. formulation of Etodolac chewable tablet not only improved its dissolution rate dependent bio availability but also provide a useful tool to improve patient convenience and compliance chewable tablet are suitable for administration of large tablets to geriatrics and pediatrics that have difficulty in swallowing solid dosage form.

Kathiresan et al., (2010) Formulated and evaluated of loratidine chewable tablets by using microcrystalline cellulose, lactose monohydrate, mannitol, ethyl cellulose, and povidine k 30.The loratidine was formulated as chewable tablets by using Avicel CE 15and starch paste showed better physical character of chewable tablets and better dissolution profile which was comparable to the innovator. This tablet used in the treatment of allergic rhinitis and urticaria.

AIM AND OBJECTIVE OF THE WORK

Domperidone is an anti emetic drug; oral route is the most common and the easiest way to administer a drug. But it is a challenge in children who not yet learned to swallow tablets. Hence it was decided to formulate domperidone chewable tablet to improve the compliance in children chewable tablets are the tablet which are required to be broken and dewed in between the teeth before have ingestion. The tablets are given to the children who difficulty in swallowing and to the adults who dislike swallowing. The advantage of chewable tablets includes palatability, stability precise dosing portability and ease of delivery. The available literature suggests that chewable tablets provides a safe, well tolerated alternative to traditional and offer significant advantage in children with two year of age above.

In the present study, domperidone tablets (F1-F6) are prepared by wet granulation method using two types of binding agent PVP, starch mucilage with, SSG as super disintegrant.

The main objective of the present study was to formulate and evaluate domperidone chewable tablet by wet granulation techniques.

PLAN OF WORK

1. STANDARD CURVES OF DOMPERIDONE

a). Determination of λmax of Domperidone.

b). Preparation of calibration curve for Domperidone.

2. PREFORMULATION STUDIES

a). Infrared spectroscopic (IR) studies to determine the interaction between excipients with drug.

3. FORMULATION AND EVALUATION OF DOMPERIDONE CHEWABLE TABLET

Pre Compression Evaluation Studies

a). Angle of repose

b). Bulk density

c). Tapped density

d). Carr's index

e). Hauser's Ratio

Post Compression Evaluation Studies

a). Shape of tablets

b). Tablet dimension

c). Hardness

d). Friability test

e). Weight variation

f). Drug content estimation

g). Disintegration test

h). *In vitro* dissolution test

i). Drug content uniformity test

MATERIALS AND EQUIPMENTS

Materials Used

S. No	Materials	Manufacture
1	Domperidone	Best care Formulation, pondycherry
2	Lactose	Thomas backer, Mumbai
3	Mannitol	Nice chemicals, Kerala
4	Starch	Research lab, Mumbai
5	PVP	Loba chime, Mumbai
6	SSG	Research lab, Mumbai
7	Magnesium Sterate	Loba chemie, Mumbai
8	Talc	Thomas, backer, Mumbai
9	Saccharin	Nice chemicals, Kerala
10	Vanilla	Research lab, Mumbai
11	Amaranth red	Research lab, Mumbai

Equipment Used

S. No	Equipment	Manufacture Model Number
1	Weighing balance	Sartourius (Max220g)
2	Hardness tester	Fizer apparatus
3	Disintegration tester	Electro lab ED-2AL(USP)
4	Friability tester	Electro lab EF-2 (USP)
5	Sieves	Jayant test sieves
6	Compression machine	Hand punching single unit
7	Dissolution test apparatus	Singhla apparatus
8	UV(Ultra violet spectrophotometer)	UV 1800 Shimadzu
9	IR(infrared)spectrophotometer	IR prestige shimadzu

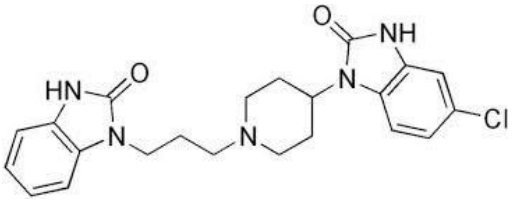
Drug Profile

Domperidone

1. Description

A specific of Domperidone receptors. It speeds gastrointestinal peristalsis, causes prolactin release and is used as antiemetic and tool in the study of doperminergic mechanisms.

2. Structure



3. Chemical formula

$C_{22}H_{24}ClH_5O_2$

4. IUPAC Name

5chloro-1[1-[3-(2-oxo-2,3-dihydro-1H-benzimidazol-1-y1propyl]piperidine4yl]-1,3-dihydro-2H-benizmidazol-2-one.

5. Molecular weight

425. 911g/mol.

6. Synonyms

5chloro-1[1-[3-(2-oxo-2,3-dihydro-1H-benzimidazol-1-y1propyl]piperidine4yl]-1,3-dihydro-2H-benizmidazol-2-one.

1-(3-(4-5-chloro-2-oxo2, 3 di-hydro Benzo [D]imidazole-1-yl) piper dine 1-yl) propyl)-1H- benzo [D] imidazole -2(3H)-1.

Domperidona

Domperidonum

7. Pharmacodyanamics

Domperidone is a specific blocker of dopamine receptor. It speeds gastrointestinal peristalsis causes prolactin release and is used as a antiemetic and tool in the study of doperimergic mechanisms.

8. Mechanism of action

Domperidone acts as a gastrointestinal emptying (delayed) adjust and peristaltic stimulant. The gastro properties of Domperidone are related to its peripheral dopamine receptor blocking properties. Domperidone facilitates gastro emptying and decrease small bowel transit time by increasing esophageal and gastric peristalsis and by lowering esophageal sphincter pressure. Anti emetic properties of Domperidone are related to its dopamine receptor blocking activity at both the chemo-receptor trigger zone and at the gastric level. It has strong affinities for the D2 and D3 dopamine, receptors, which are found in the chemo-receptor trigger zone located just outside the blood brain barrier. Which among others regulates nausea & vomiting?

9. Protein binding : 91%-93%

10. Metabolism

Substrate	enzyme	product
Domperidone-	cytochromeP450 3A4	5chloro1, 3 dihydro-1-(4-piperdinyl) 2-H Benzimidazole 2-one.

11. Half life : 7Hrs.

12. Toxicity

Side effects include galactorrhea, gynecomastia or menstrual Irregularities.

13. Dosage form

Form	Route	Strength
Tablet	oral	10mg

14. Drug interaction

Drug Interaction

Abiraterone	:	The serum conc. of Domperidone can be increased when it is combined with Abiraterone.
Acetaminophen	:	The serum conc. of Domperidone can be increased when it is combined with Acetaminophen.
		The serum conc. of Domperidone can be increased when it is combined with Afantinib.
Albendazole	:	The serum conc. of Domperidone Be increased when it is combined with Albendazole.
Alectinib	:	The serum conc. of Domperidone can Be increased when it is combined with Alectinib.
Aldestrone	:	The serum conc. of Domperidone can be increased when it is combined with Aldestrone.
Alfentani	:	The serum conc. of Domperidone can be increased when it is combined with Alfentanil.
Alfezosin	:	The serum conc. of Domperidone can be increased when it is combined with Alfezosin.
Amantidine	:	The serum conc. of Domperidone can be increased when it is combined Amantadine.

15. Food interaction

Take 15 to 30 minutes before meals.

16. Experimental properties

Property value

Water solubility 0.986 mg/c

Log p 3.90

Pka 7.9

EXCIPIENT PROFILE

LACTOSE

Synonyms

Fast – Flo; Lactohem; Microtose;

Chemical Name

O-β-D-Galatopyranosyl-(1 - 4)- α-D- gluopyranose monohydrate [64044-51-5]

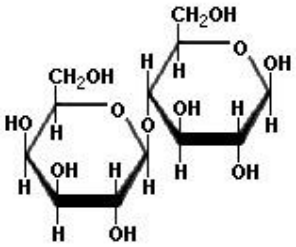
Chemical Formula

C_{12} $H_{22}O_{11}$

Molecular Weight

342.3 g/mol.

Structure



Functional category

Tablet and capsule diluents

Applications in pharmaceutical industry

Lactose is widely used as filler or diluents in tablets, capsules, and to a more limited.

Extent in lyophilized products and infant feed formulas. Usually, fine grades of lactose are used in the preparation of tablets by the wet granulation method or when milling during processing is carried out, since the fine size permits better mixing with other formulation ingredients and utilizes the binder more efficiently.

Description

White to off-white crystalline particles or powder. Lactose is odorless and slightly sweet-tasting; α-lactose is approximately 15 % as sweet as sucrose, while α-lactose is sweeter than the α-form.

Melting point

201-202ºC

Solubility

Soluble in water

Synonym

Cordycepic acid, Improve, manna sugar, D-mannite, peralitol.

Chemical name

D-mannitol

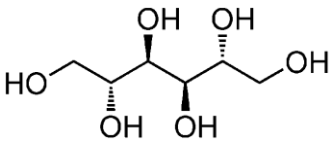
Chemical Formula

$C_6H_{14}O_6$

Molecular weight

182.17

Structure



Functional category

Diluents, plasticizer, sweetening agent tablet and capsule diluents, therapeutic agent, tonicity agent.

Application

It is widely used as diluents in tablet formulations. It is not hygroscopic hence can be used with moisture, Sensitive ingredients.

It may be used with direct compression with the wet granulation.

Description

It is a hexahydric alcohol related to mannose and is isomeric with alcohol. It occurs as a white, odorless, crystalline powder, or free flowing granules. It has a sweet taste, approximately as sweet as glucose and half as sweet as sucrose and imparts a cooling sensation in mouth.

Melting point

164-169°C

Solubility

1 in 5.5 in water,1 in 18 in glycerin and 1 in 83 in ethanol at 20°C.

STARCH

Synonym

Amylam

Chemical name

Starch

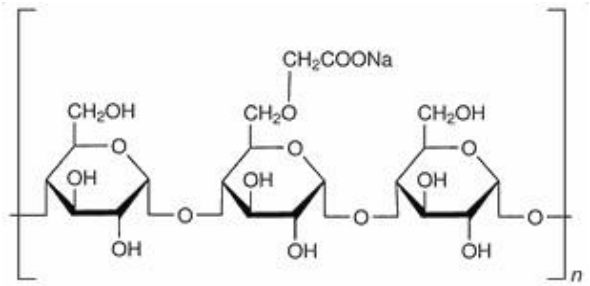
Chemical formula

(C6H10O5)n

Molecular weight

Variable

Structure



Functional category

Glidant, tablet & capsule diluents & disintegrant, tablet binder.

Application

Binder in tablet 5-25% Concentration. Disintegrate in tablet3-15% Concentration.

Description

It is odourless, tasteless fine, white colored powder compressed of very small spherical or avoids granules.

Melting point

Decomposes

Solubility

Soluble in water, starch swells instantaneously in water by about 5-10% at 3˚c.Insoluble in cold ethanol (95%) and cold water.

POLY VINYL PYRROLIDONE

Synonym

Povidone, Copovidone

Chemical name

2 pyrrolidone 1 ethenyl homo polymer,\vinyl -2-pyrollidone polymer.

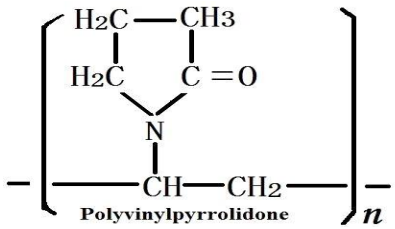
Chemical formula

$(C_6H_9NO)n$

Molecular weight

2.500-2.5000.000 $g.mol^{-1}$

Structural formula



Polyvinylpyrrolidone

Functional category

Binder, Plasma volume expander, Disinfectant.

Application

It is used as the binder, povidone is used as a lubricant in some eye drops.

Description

A while to creamy white, odourless hygroscopic powder.

Melting point

150-180˚c

Solubility

Unto 60% it is readily soluble in water. Freely soluble in many organic solvents.

Insoluble in ethers, hydrocarbons. Carbon tetra chloride, ethyl acetate & mineral oil.

SODIUM STARCH GLYCOLATE

Synonym

Carboxymethyl starch, sodium salt, caboxymethylamylum natricum, Explosol, Explotab, Glycolysis, Primojel

Chemical Name

Sodium carboxymtehyl starch

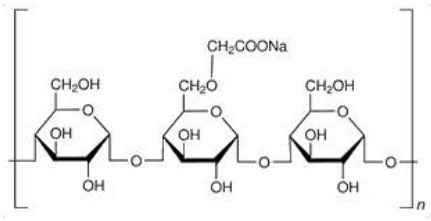
Chemical formula

$C_2H_4O_3$

Molecular weight

98.033g/mol

Structural formula



Functional Category

Tablet and capsule disintegrant.

Applications

Sodium starch glycol ate is widely used in oral pharmaceuticals as a disintegrant in capsule and tablet formulations. It is commonly used in tablets.

Description

Sodium starch glycol ate is a white or almost white free flowing very hygroscopic powder. Under microscope it is seen to consist of granules, irregularly shaped, ovoid or pear shaped, 30-100µm in size. Very fine, white or off white, free flowing powder; odourless or almost odourless.

Melting point

Does not melt but chares at approximately 200˚C.

Solubility

Partially soluble in methyllin chloride and translucent suspension in water.

MAGNESIUM STEARATE

Synonyms

Magnesium octadecanoate – octadecanoic acid, magnesium salt, satiric acid, magnesium salt.

Chemical name

Magnesium octadecanote

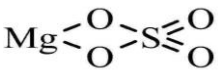
Chemical formula

$Mg(C_{18}H_{35}O_2)_2$

Molecular weight

591.3

Structural formula



Functional category

Tablet & capsule lubricant.

Application

It is used as a release agent.

It is used as lubricant in the production of pharmaceuticals and cosmetics.

Description

It is slightly odoured, Light white powder.

Melting point

88.5˚c

Solubility

Practically insoluble in ethanol, ethanol (95%), ether in water, slightly soluble in warm benzene & warm ethanol (95%).

Specific surface area: 1.6 – 14.8 m/g

TALC

Synonym

Hydrous magnesium calcium silicate, , magnesium hydrogen met silicate, , purified French chalk, soapstone, steatite, talcum.

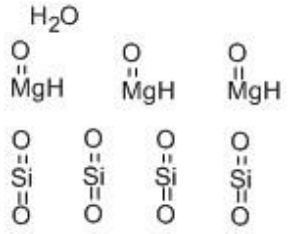
Chemical Name

Talc

Chemical formula

$Mg_6(Si_2O_5)_4(OH_4)$

Structure



Functional category

Anti caking agent, glidants, tablet and capsule diluents, tablet and capsule lubricant.

Applications

Used in oral solid dosage forms as lubricant and diluents. Talc is used as lubricant in tablet formulations

Description

It is very fine, white, odorless, impalpable, unctuous, crystalline powder. It adheres to skin and is soft to touch and free of grittiness.

Melting point

1500˚c

Solubility

Practically insoluble in dilute acids and alkalis, organic solvents and water.

SACCHARIN SODIUM

Synonym

Saccharin

Chemical name

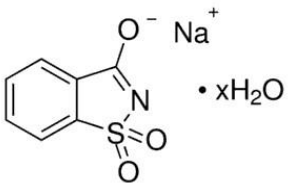
1,2,benzisothiazol 3(2H) 1,1-dioxidesodium salt

Chemical formula: $C_7H_4NNaO_3S$

Molecular weight

205.16

Structure



Functional category

Sweetening agent

Application

It is used to add sweetness to beveragesand food withourt calories.

Description

White, odourless, (or) faintly aromatic, efflorescent, crystalline powder and has an intensely sweet taste.

Melting point

Decomposes upon heating.

Solubility

Soluble in wateri. 1g per 290 ml.

VANILLIN

Synonyms

Vanillin Methyl vanillin Vanillic aldehyde.

Chemical name

4-hydroxy-3 methoxybenzaldehyde

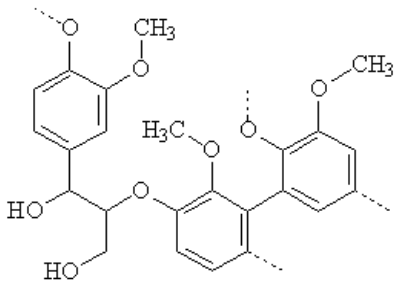
Chemical formula

$C_8H_8O_3$

Molecular weight

152.15 g/mol.

Structure



Functional category

Flavoring agent

Application

Vanillin and ethyl vanillin are used by the food industry; ethyl vanillin is more expensive, but has a stronger note. It differs from vanillin by having an ethoxy group (-O-CH2CH3) instead of a methoxy group(-O-CH3).

Description

Appearance: white crystals

Odour, vanilla, sweet, balsamic, pleasant

Melting point

81 to 83 ˚c;

178 to 181˚F;

354 to356K.

Solubility

Soluble in water

AMARANTH DYE

Synonyms

F D&C Red No2,

E123

C.I .Food Red 9,

Acid Red 27,

Azorubin S,

C.I.16185

Chemical name

Tri sodium (4E)-3 –oxo-4-[(4-sulfonato-1-napthyl) hydrazono] Naphthalene-2,7-disulfonate.

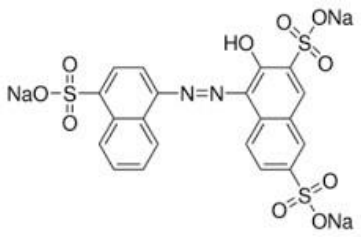
Chemical formula

$C_{20}H_{11}N_2\ Na_3\ O_{10}S_3$

Molecular weight

604.47305g/mol

Structure



Functional category

As a food additive it has E number E123.

Application

It is used as a food additive.

Description

Dark red solid

Melting Point

120˚C (248 ˚F;393K) (decomposes)

Solubility

Its soluble in water, and slightly soluble in ethanol.

EXPERIMENTAL PROTOCOL

STANDARD CURVES FOR DOMPERIDONE

Preparation of 0.1N HCl

8ml of concentrated HCl solution to dissolved in 1000ml of Distilled water.

(Indian Pharmacopeia, 1996).

Estimation of absorption maximum (λ max).

Stock solution

Domperidone (100mg) is accurately weighed, dissolved in 5ml of methanol and diluted with 0.1M Hcl to form a stock solution. (1000µg)

Working standard solution

The stock solution is further diluted suitably with 0.1M Hcl to get a working standard solution of concentration 100µg/ml. This working standard solution is suitably diluted to get a concentration of 10µg/ml and the resultant solution is scanned range of 200-400 nm in UV spectrometer to get absorption maximum**.(I.P 1996)**

Preparation of calibration curve of Domperidone

From the working standard solution, 1ml, 2ml, 3ml, 4ml, 5ml, are taken separately and diluted to 100 ml with the same 0.1M HCl buffer, so that the final concentration of 10-50 µg/ml solutions are obtained. The above solutions are analyzed by ultraviolet (UV) spectrophotometer at λmax.

The calibration graph is drawn by taking the concentration on X axis and respective absorbance in Y axis, to get a straight line as per like Beer's law, The standard curve is used to estimate the concentration of the drug release from the formulation during the *invitro* dissolution studies **(I.P 1996)**.

DRUG-EXCIPIENTS INTERACTION STUDIES

Infra red spectroscopic studies (IR)

IR spectra study is carried out to check the compatibility between drug and excipients. Infra red spectrum of Domperidone (pure drug) and Excipients are recorded using fourier transform infrared spectrometer (Spectrum RX-1 Perkin-Elmer, German)samples are prepared by using KBr (spectroscopic grade)discs by means of hydraulic pellets press at a pressure of five tons for 30 seconds at a resolution of 4cm-1 the samples are scanned from 4000-400cm-1**(I.P 1996).**

PREPARATION OF CHEWABLE TABLET

Chewable tablet of Domperidone was prepared by wet granulation (Aqueous granulation) method. Take a pure drug (Domperidone) and add required quantity of excipients (lactose, mannitol, sodium starch glycol ate, saccharin sodium) in a mortar triturated with the help of pestle in unidirectional &mix thoroughly add the binding agent **(starch mucilage & PVP)**, and continuously triturated, finally added the coloring agent (Amaranth dye), to form homogenize mass to sieve the mesh no.22, easily to form uniform size granules. Dry the uniform granules in hot air oven to maintain the temperature 30-40˚c. After dried add the talc, magnesium stearate and vanillin.

EVALUATION OF CHEWABLE TABLET

PRE COMPRESSION EVALUATION

Angle of repose

The frictional forces in a loose powder (or) granules can be measured by the of powder or granules and the horizontal plane.

Tan ɵ = h/r

ɵ= tan -1 (h/r)

Where, ɵ is the angle of repose h is the height of pile (cm)

r is the radius of pile (cm)

Method

A funnel was filled to the brim and the prepared granules are allowed to flow smoothly through the orifice under gravity. From the cone formed on a graph sheet was taken to measure the area of pile there by evaluating the flow ability of the granules. Height of the pile was also measured. **(Ujjwal Nautiyal *et al.*, 2014).**

Table 8. Relationship between angle of repose (θ) and flow properties.

Angle of Repose (θ) (degrees)	Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Bulk density

Bulk density is defined as the mass of a powder divided by the bulk volume. The bulk density of the powder depends primarily on particle size distribution particle shape &the tendency of the particles to adhere to one another.

Both loose bulk density (LED) & tapped bulk density (TBD) were determined. A quantity of accurately weighed powder (bulk) from each formula previously shaken to break any agglomerates formed was introduced into a 25ml measuring cylinder. After the initial volume was observed the cylinder was allowed to fall under its own weight on to a hard surface from the height of 2.5cm at 2sec internal the taping was continued until no further change in volume was noted.

h = _____

TBD (tapped bulk density) = _____!"#$%& ’( )’!*"+

&,))"* -’./0" ’( ),12#3$

Tapped density: (TD)

To measure tapped density (TD), a powdered sample was poured into a 100ml graduated cylinder at a 45˚ angle. The sample was mechanically tapped 1500 times. TD was calculated by dividing the sample weight by its final volume. The Tapped density of different Dmperidone chewable tablets were calculated and shown in (**Table 3). (F Farheen, S Bharadwaj, 2014)**

Carr’s index

Carr’s index is also known as percentage compressibility. It indicates the powder flow property .its expressed in % and is given.

$$\text{Carr's index} = \frac{\text{tapped density} - \text{bulk density}}{\text{tapped density}} \times 100$$

Compressibility index (%)	Flow property
5-12	Excellent
12-16	Good
18-21	Fair possible
23-25	Poor
33-38	Very poor
‹40	Extremely poor

Hausner’s ratio

Hausner’s ratio is an indirect index of ease of powder flow. It is calculated by following formula.

Hausner’s ratio = tapped density

Lower it (<to25) indicates better flow properties than higher ones (>1.25).

POST COMPRESSION EVALUATION STUDIES

Shape of Tablets

Round shape

Hardness

Hardnessis a force required to break a tablet across the diameter. The hardness of a tablet is an indication of its strength. The hardness was measured using Monsanto hardness tester. The values were expressed in kg/cm2. **(F Farheen, S Bharadwaj, 2014)**

Friability Test

Friability is the phenomenon where the surface of the tablet is damage or shown a site of damage due to mechanical shock.

The tablets should be careful degusted prior to testing. Accurately weigh the tablet sample, and place the tablets in the drum. Rotate the drum 100 times, and remove the tablets. Remove any loose dust from the tablets as before, and accurately weigh.

Generally, the test is run once. If obviously cracked, cleaved, or broken tablets are present in the tablet sample after tumbling, the sample fails the test. If the results are difficult to interpret or if the weight loss is greater than the targeted value, the test should be repeated twice and the mean of the three tests determined. A maximum mean weight loss from the three samples of not more than 1.0% is considered acceptable for most products.

Effervescent tablets and chewable tablets may have different specifications as far as friability is concerned. In the case of hygroscopic tablets, an appropriate humidity-controlled environment is required for testing.

PRECENTAGE OF FRIABILITY of the tablets of a badge can be find by the following formula:

$$\text{Percentage Friability} = W1 – W2/W1 \times 100$$

Where,

W1 = weight of tablets before testing

W2 = weight of tablets after testing. **(Der Pharmacia Sinica, 2013).**

Weight variation

The weight variation test is carried out in order to ensure uniformity in the weight of tablets in a batch. First the total weight of tablet 20 tablets from each formulation is determined and the average is calculated. The individual weight of the each tablet is also determined to find out the weight variation. The tablets meet the IP test, if not more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit. **(Mohini K *et al.*, 2009).**

***In vitro* Disintegration Time**

The disintegration time is defined as the time necessary for the fast disintegration tablet to completely disintegrate until no solid residue remains or only a trace amount of soft residue remains on the screen. Disintegration time is measured in 900ml 0.1 N Hcl with disc at 37±0.5˚C.The disintegration time of 3 individual tablets are recorded and the average is reported.

As per the European pharmacopeia the chewable tablets within 30 minutes **(Jain C *et al.*, 2009).**

***In vitro* Dissolution Test**

The release rate of Domperidone from the chewable tablet is determined using dissolution test apparatus USP Type II (paddle method). The dissolution test is performed using 900ml of 0.1 N Hcl 37±0.5˚C and 50 rpm. A sample (5ml) of solution is withdrawn from the dissolution apparatus at 5, 10, 15, 20 & 30 minutes. The samples are replaced with fresh dissolution of same quantity. The absorbence of these solutions are measured at λ max in UV- Spectrophotometer **(Parmar R B et al., 2009).**

Drug content uniformity Test

Take one tablet in a mortar and triturate with the help of pestle, the quantity equivalent to 10mg was taken in a 100ml volumetric flask and to it 100ml, 0.1N Hcl was added. From this stock solution 1ml aliquot were taken and diluted to 10ml with 0.1N Hcl, Finally the absorbence of prepared solution was measured against blank(0.1N Hcl) at 284nm using UV Visible spectrophotometer (UV 1800-Shimadzu).

RESULTS AND DISCUSSION

STANDARD CURVE OF DOMPERIDONE

The λ max of Domperidone was determined by scanning the 10µg/ml of the drug solution in 0.1N Hcl by UV-Spectrophotometer. It showed the λ max of 284nm in 0.1N Hcl were shown in **Figure (1.2)** Linear correlation coefficient obtained was r^2=0.999 of Domperidone.

Domperidone obeys the Beer's law with in concentration range of 10-50µg/ml the results was shown in **Table (2), Figure (1.2 & 1.3).**

DRUG –EXCIPIENTS INTERACTION STUDIES

a) Infra red spectroscopic(IR) studies

The Fourier Transform Infra Red spectroscopy studies were carried out for pure drug, excipients. The spectra were shown in **Figure 2.1-2.3.** The spectral analysis of pure drug showed the characteristics peaks at 3376.44 cm, 1708.11, 1205.73, 1081.24, 964.17, all the above characterstics peak appear in the spectra of all samples were within the same wavelength number. This indicates that there were no interactions between the drugs with excipients.

FORMULATION AND EVALUATION OF CHEWABLE TABLET

In the present study, 6 formulations of Domperidone Chewable tablet was prepared by using lactose, sodium starch glycolate, mannitol, starch and PVP in wet granulation method. The prepared chewable tablets were uniform and homogeneous appearance. The various compositions of all formulations were shown in **Table (1).**

PRE COMPRESSION EVALUATION

Bulk density

The bulk density of all the formulations were in the range of 0.377gm/ml to 0.420gm/ml. The results for all the formulations were shown in **Table (3) & Figure (3.1).**

Tapped density

The tapped density of all prepared granules was in the range of 0.38gm/ml to 0.56gm/ml. And the results for all the formulations were shown in **Table (3) & Figure (3.1).**

c) Carr's Index (or) % compressibility index

Determination of Carr's index, the ratio of bulk density and tapped density, was used to measure the flow property of all chewable tablet formulations. Lower the value of CI% would indicate the better flow properties of the powder. The Carr's index of the all formulations were found to be in range 12% to 16%.It was less than 25%,which indicates that the granules have required flow property the results of Carr's index of all formulations were shown in **Table (3) & Figure(3.2).**

d) Hausner's Ratio

The Hauser's ratio of the prepared granules were found to be in range of 1.6 to 1.25 which indicates better flow property. The results of all formulations were shown in **Table (4) & Figure (3.3).**

e) Angle of repose

The angle of repose is a characteristic of the internal friction or cohesion of the particles, the value will be low, if the powder s non-cohesive and high if the powder is cohesive. All the prepared formulations were in the range of 18˚30[1] to

29˚19', which indicate excellent to good flow property. The results of angle of repose of all formulations were shown in **Table (4).**

POST COMPRESSION EVALUATION STUDIES

a) Hardness

The hardness of the tablet was used to determine the resistance capacity of the tablets to chipping, abrasion or breakage under condition of storage, transportation and handling before usage. The hardness of the tablets of the all formulations were found to be 34kg/cm2.The results indicates that all the tablet had a good mechanical strength. The results of hardness for all the formulations were shown in **(Table 4).**

b) Friability test

Friability test was performed to ensure the mechanical strength of tablet. The results showed that the friability of all formulation were ranged from 0.35% to 0.84%.All the formulations showed less than 1% friability which indicates the tablets had a good mechanical resistance. The results were shown in **(Table 4).**

c) Weight variation

The weight variation test was used to ensure the uniformity of the tablet in all formulations. The average weight of the tablet was found to be in the range of 248-250mg.It were found that the entire tablets passes weight variation test, as the percentage weight variation was within the acceptable pharmacopeia limits of ±5%.

d) *In vitro* Disintegration time

The *In-vitro* Disintegration time was determined by disintegration test apparatus. Formulation F1, F2, F3, F4, F5, & F6 showed the disintegration time 50,30,25,53,27,33 minutes respectively. It was observed that formulation F3 Containing SSG & starch mucilage disintegrate rapidly in a short time (25 min 56 secs). The results of disintegration of all the tablets were found to be lesser than 30 minutes and so satisfied the criteria of chewable tablets. The result shown in **(Table 4).**

e) *In vitro* dissolution test

In vitro dissolution studies were carried out by USP Type II paddle method by using 0.1 N Hcl. The studies were performed in all the formulations (F1-F6) for 60 minutes. The samples were taken at 10 min interval and absorbence was measured in UV Spectrophotometer at 284nm.

The results of *in vitro* drug release studies from chewable tablets of Domperidone were shown in the **Table 6 & figure (4.1, 4.2, & 4.3).** The results showed the releases profiles of different formulation varied according to the ratio of binding agent to the formulations.

The formulations F1,F2,F3,F4,F5&F6 were prepared with SSG & Starch mucilage as binding agent, showed the cumulative percentage of drug release 93%, 95%, 98.3%, 89.5%, 92%, 95% respectively at 60 minutes.

The cumulative % drug release of Domperidone chewable tablets were found to be in the order of F3› F6› F2› F5› F1› F4.

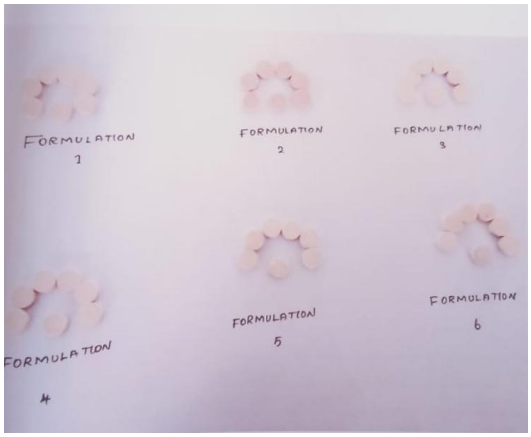
Formulation F3 showed maximum drug release 98.3 for 60 minutes. It may be due to the results in the rapid disintegration of tablet in dissolution medium resulting in maximum drug release among 6 formulations, formulations F3 was selected as a best formulation. Because of its faster disintegration time and higher drug release. Accordingly, this improved drug releases may result a higher drug absorption and thus, an improved oral bioavailability.

f) Determination of drug content

The drug content in the all formulations were estimated spectrophotometrically at 284 nm(Shimadzu UV 1800, pharmspec Japan). The drug content of prepared chewable tablets were found to be range of (F1-94.3%, F2-95%, F3-95.2%, F4-94%, F5-93%.6, F6-94.2%) indicating the uniform distribution of drug in the formulation. The results of all formulations and physical mixtures were shown in **Table (5), Figure (3.4).**

Table 1: Composition of domperidone chewable tablet.

S. No	Ingredients	(Quantities in mg/Tablet)					
		Formulation No.					
		F1	F2	F3	F4	F5	F6
1.	Domperidone	10	10	10	10	10	10
2.	Lactose	108	103	100	108	104	99
3.	Mannitol	107	104	99	107	103	100
4.	Starch mucilage	Q.S	Q.S	Q.S	-	-	-
5.	Poly vinyl pyrollidine	-	-	-	Q.S	Q.S	Q.S
6.	Sodium starch glycol ate	8	16	24	8	16	24
7.	Magnesium stearate	4	4	4	4	4	4
8.	Talc	4	4	4	4	4	4
9.	Saccharine	4	4	4	4	4	4
10.	Vanillin	5	5	5	5	5	5
11.	Amaranth red	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
12.	Average weight of tablet	250	250	250	250	250	250



Domperidone chewable tablet

Table 2.

S. no	Concentration	Absorbance
1	10	0.236
2	20	0.499
3	30	0.736
4	40	0.997
5	50	1.279

Table 3: Pre compression evaluation study of domperidone granules by wet granulation technique.

Formulation	Bulk density	Tapped density	Carr's index	Hauser's ratio	Angle of repose
F1	0.42	0.56	12	1.33	28˚ 02'
F2	0.34	0.38	10.52	1.11	15˚ 26'
F3	0.33	0.38	13.15	1.15	29˚ 23'
F4	0.28	0.45	16	1.6	21˚ 96'
F5	0.34	0.39	12.82	1.14	29˚ 19'
F6	0.37	0.42	10.8	1.22	18˚ 30'

Table 4: Compression evaluation study of domperidone.

Formulation	Thickness(cm)	Diameter(cm)	Hardness(g/cm2)	Friability (%)	Disintegration Time
F1	0.8	1.8	8	0.82	50mins
F2	0.8	1.8	8	0.84	30mins
F3	0.8	1.8	7	0.40	25mins 56sec
F4	0.9	1.8	8	0.39	53mins
F5	0.8	1.8	9	0.70	27mins 39sec
F6	0.9	1.8	8	0.35	33mins 25 sec

Table 5: % Drug Content.

S. No	Formulation	% Drug content
1	F1	94.3
2	F2	95
3	F3	95.2
4	F4	94
5	F5	93.6
6	F6	94.2

Table 6: In vitro drug release profile of domperidone chewable tablet.

		Percentage Cumulatve Drug Release					
S. No	Formulation	10min	20min	30min	40min	50min	60min
1	F1	23	42	60	71	82	93
2	F2	26	49	62	74	84	94
3	F3	29	50	71	82	90.4	98.3
4	F4	19	40	58	68	79	89.5
5	F5	23	45	61	70	82	92
6	F6	27	48	69	79.5	88.3	95

Figure 1.1: Determination of λ max of Domperidone.

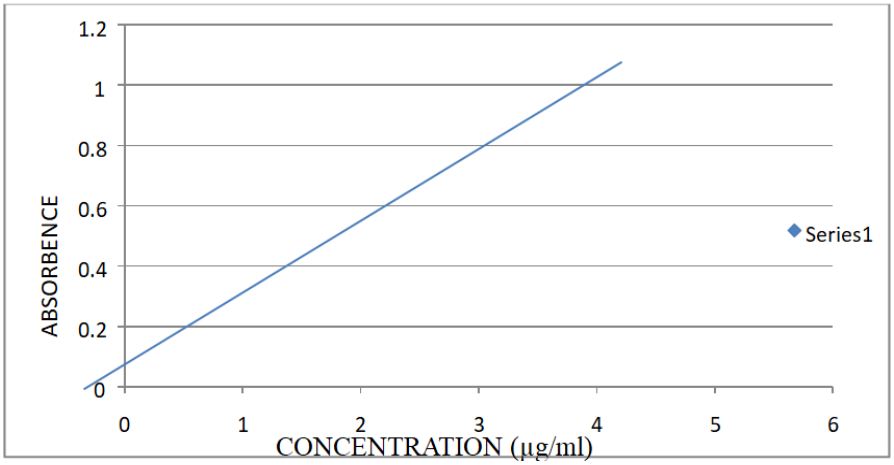
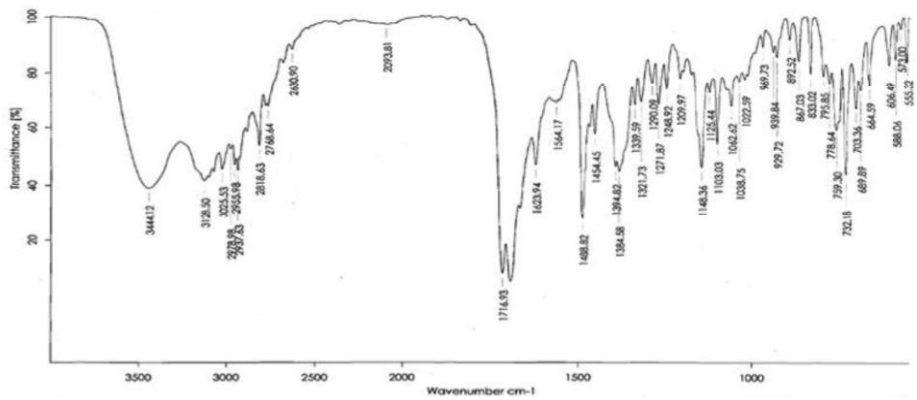
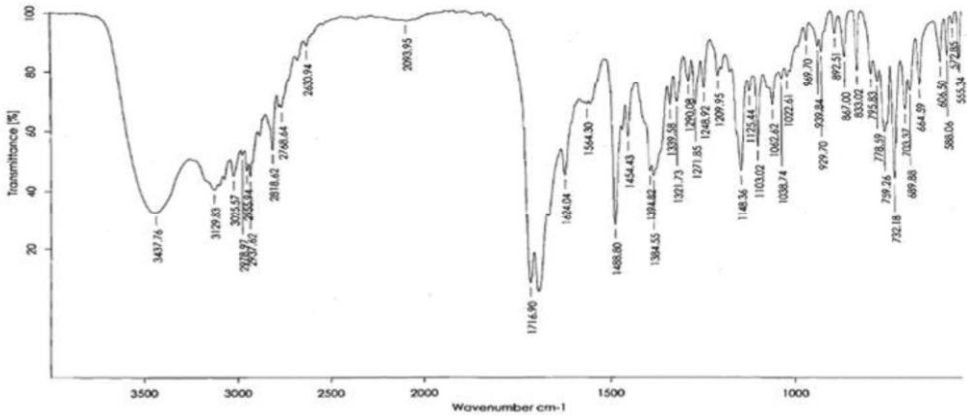


Figure 1.2: Calibration curve of domperidone.



FTIR spectrum of Pure Domperidone Drug

Figure 2.1: FTIR Spectrum of pure domperidone drug.



FTIR spectrum of Domperidone Drug + Physical Mixture

Figure 2.2: FTIR Spectrum of domperidone drug + physical mixture.

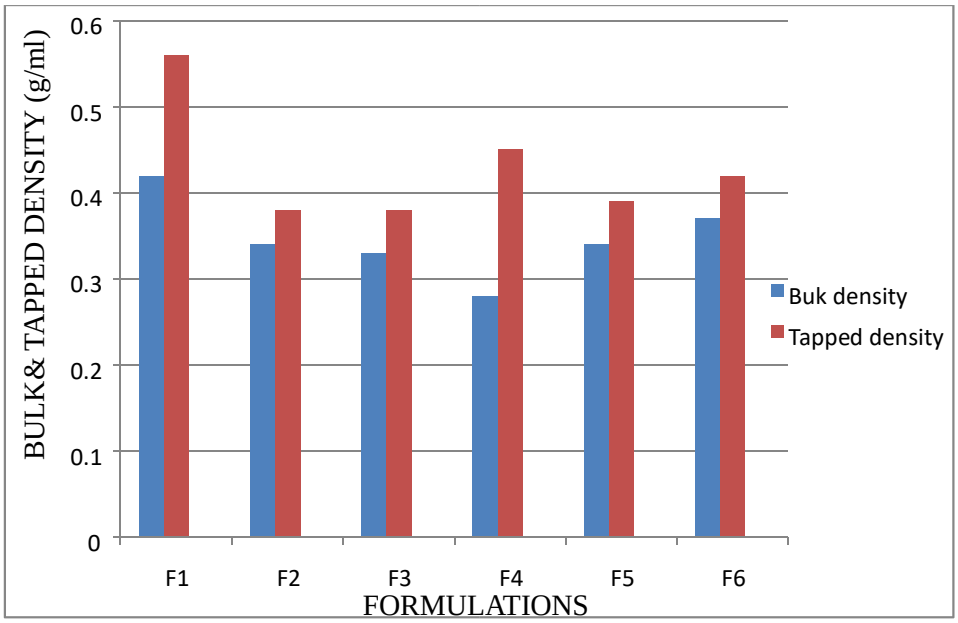


Figure 3.1: Comparison of bulk and tapped density of domperidone chewable tablet.

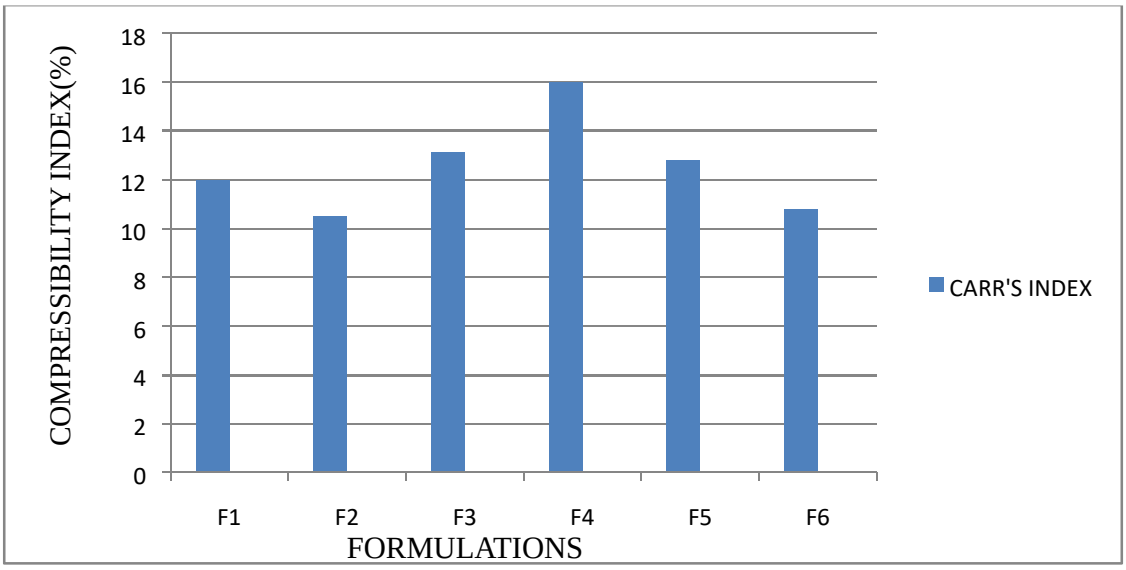


Figure 3.2: Comparision of compressibility index (%) of domperidone chewable tablet.

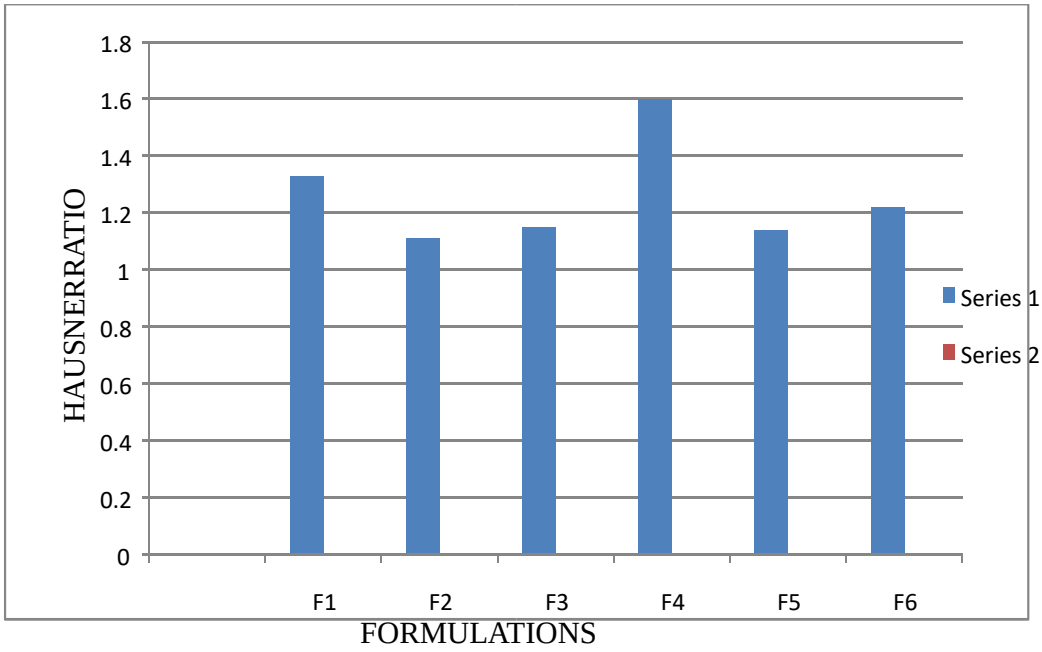


Figure 3.3: Comparision of hauner ratio domperidone chewable tablet.

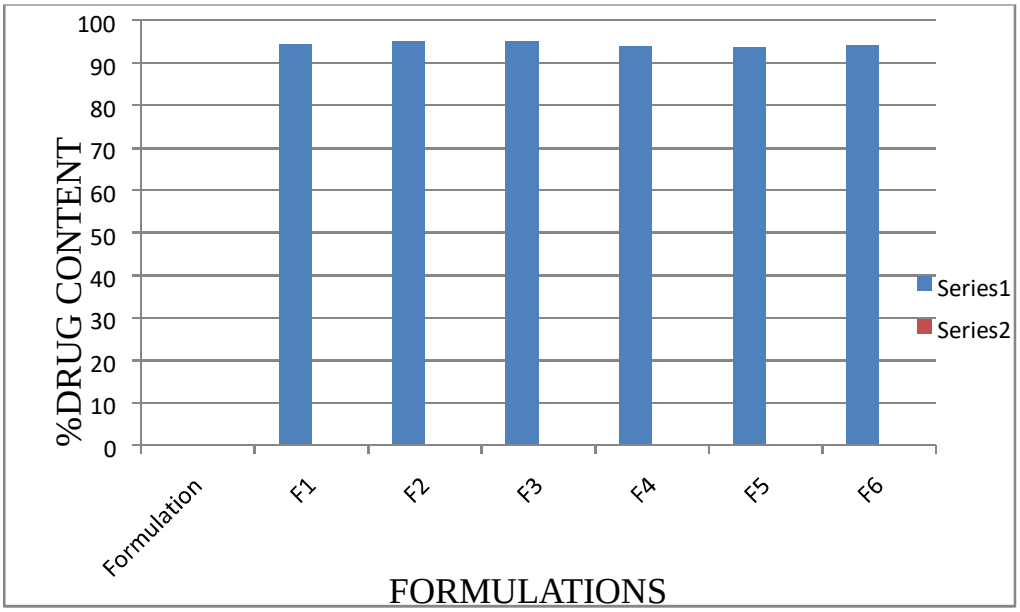


Figure 3.4: Percentage drug content of domperidone chewable tablet.

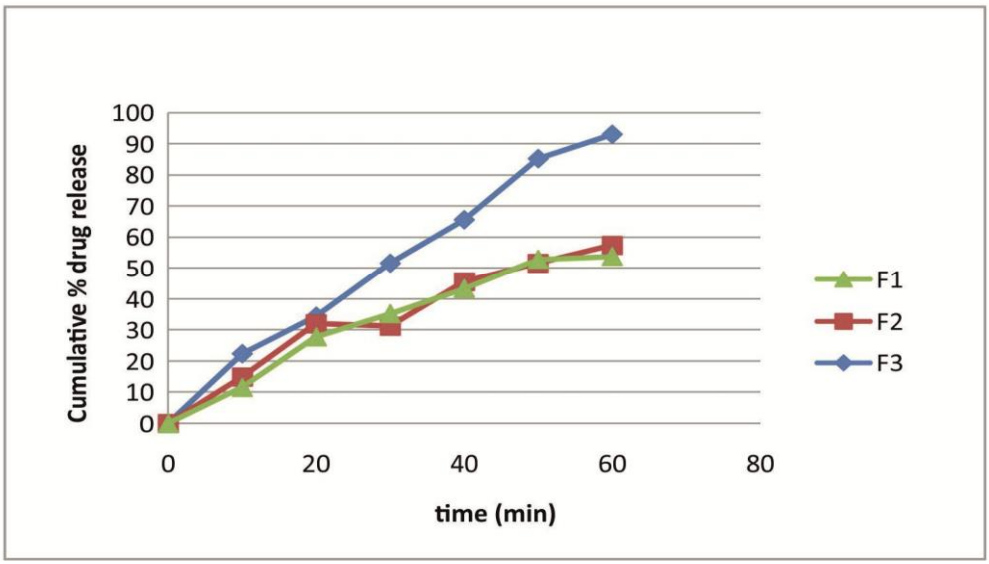


Figure 4.1: Comparision of *in vitro* drug release profile of domperidone chewable tablet using starch mucilage.

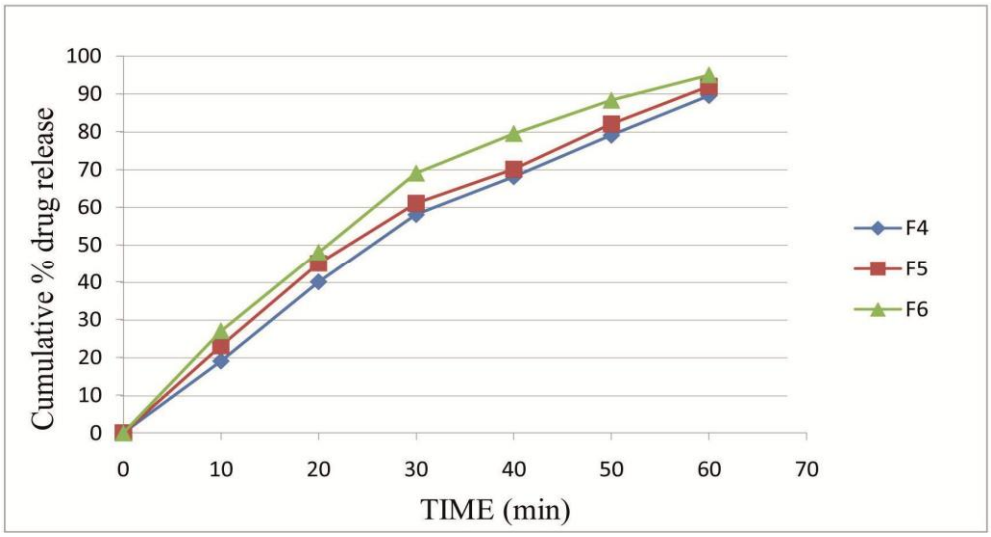


Figure 4.2: Comparision of *in vitro* drug release profile of domperidone chewable tablet using PVP.

SUMMARY AND CONCLUSION

The purpose of this study was to prepare chewable tablet of Domperidone to improve the solubility and dissolution rate.

Infra-Red spectroscopic studies showed that there was no interaction between the Drug (Domperidone) and the excipients (Mannitol, lactose, Magnesium stearate, SSG, PVP).

Wet granulation method was employed to prepare Domperidone chewable tablets.

All the prepared formulations were subjected to pre compression &post compression evaluation studies.

The Drug content analysis showed minimum variations suggesting uniform distribution of Drug in the all the formulations.

The formulated chewable tablets were characterized by in –vitro drug release in 0.1Hcl Buffer using I.P Type-II apparatus.

The chewable tablet of Domperidone prepared with the Binders like PVP& Starch mucilage& using super disintegrant SSG showed better *in-vitro* release.

Faster Dissolution rate was observed for formulations containing strarch mucilage as binding agent compared with PVP.

The in vitro release studies reveals that the chewable tablet formulation showed a faster drug release with increase in the ratio of super disintegrant(SSG).

CONCLUSION

From the study it was concluded that the Domperidone was formulated as, chewable tablet by using PVP& Starch as binding agent and SSG used as Disintegrant it give better physical characters of Chewable tablet & give the better Dissolution profile. Hence, the Chewable tablet formulation of Domperidone may be an advantage and alternative for other oral conventional Domperidone formulation and improve the compliance of children not yet learned to swallow tablet in the treatment of Anti-Emetic.

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