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Polyvinylpyrrolidone Superdisintegrant: The Effect of Mode of Incorporation on Disintegration Time in Both Wet and Dry Granulated Tablets

A thesis submitted by the faculty of pharmacy of Napata college in partial fulfillment of the requirements of B.S.c. degree in pharmacy

Presented by:

Mona Alshareef Almiski

Marwa Sami Mohammed

Fatima Mohammed Ali

Shadia Abdallah Izzeldin

Supervised by:

Dr. Motasim Humaida Al Obeid

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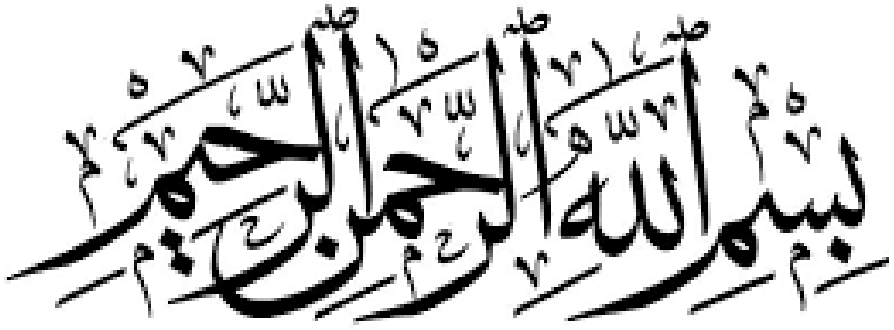
بسم الله الرحمن الرحيم

الآية

قَالَ تَعَالَىٰ:

﴿ وَمِنَ ٱلنَّاسِ وَٱلدَّوَآبِّ وَٱلۡأَنۡعَٰمِ مُخۡتَلِفٌ أَلۡوَٰنُهُۥ كَذَٰلِكَۗ إِنَّمَا يَخۡشَى ٱللَّهَ مِنۡ عِبَادِهِ ٱلۡعُلَمَٰٓؤُاْۗ إِنَّ ٱللَّهَ عَزِيزٌ غَفُورٞ ﴾

صدق الله العظيم

سورة فاطر الآية 28

DEDICATION

To my dear mother who was carrying my concern, and she always be there for every step I have taken in this college

To who my name ends with his name My Father and my attribution who was always motivated me and supported me in my life

to my brothers who supported me with all the strength they have and always been there when I need

To all my family from the youngest to the oldest one who were carried my concern and tried to ease it in many ways

To all those who carried my concern and prayed for me at difficult time

Finally to the strong little girl who endured the difficulties and resisted them since the beginning of the journey and the beginning of obstacles did not give up

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we could not have been here without guidance of Allah SWT, thank God for the number of people who remember.

To the family of the Faculty, all professors, teachers and teachers assistances who have helped us in all years we have spent in this college

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Abstract

Introduction: Superdisintegrats are used in tablets and capsules to ensure a faster breakdown into their primary particles facilitating the dissolution and release of active pharmaceutical ingredients.

Objective: To estimate the effect of PVP as superdisintegrant and its mode of incorporation on the disintegration time for both wet and dry granulated tablets. To decide which granulation method and incorporation mode is the best in decreasing disintegration time.

Method: for both wet and dry granulated tablets formtion, three batches of placebo tablets were formulated for each. The PVP superdisintegrant were incorporated extragranulary, intragranulary and partly intra-extragranulary. Then, formulations were compressed and tablets were subjected to disintegration time test.

Results and conclusion: the results indicate that PVP exerts a great influence in tablets disintegration time when incorporated as superdisintegrant in wet granulated tablets. The partly intra-extragranular mode achieved the best disintegration time in comparison to other modes

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Abbreviations

Abbreviation	Means
PVP	Polyvinylpyrrolidone
MCC	Microcrystaline cellulose
USP	United state pharmacopeia

CHAPTER ONE

INTRODUCTION& LITERATURE REVIEW

1. Introduction

1.1 Background

Controlled drug delivery systems are starting their pace in today's pharmaceutical market, but the solid orals particularly tablets are most common and favorable approach with patient compliance as on date.These conventional tablets are intended to be swallowed whole and desired to disintegrate, release the medicaments for dissolution and providing therapeutic efficacy rapidly in the gastrointestinal tract.As disintegration plays acrucial role, so for development of solid orals, formulators are fascinating towards selection of proper disintegrats /superdisintegrants in dosage system[1]

1.2 Disintegrants

Are substances or mixture of substances added to the drug formulations, which facilitate dispersion or breakup of tablets and contents of capsules into smaller .particles for quick dissolution.[1]

1.3 Superdisintegrants

Are those substances, which facilitate the faster disintegration with smaller quantity in contrast to disintegrants[1].

1.3.1 Types of Superdisintegrants

1.3.1.1 Natural Superdisintegrant

1.3.1.1.1 Isapghula Husk Mucilage (Plantago ovata)

The mucilage of plantago ovata is a recent innovation for its superdisintegration property when compared with Crospovidone.It shows faster disintegration time than the superdisintegrant , Crosspovidone.[1]

1.3.1.1.2 Modified Polysaccharides

Agar (AG) and guar gum (GG), natural polysaccharides are treated with water and cogrinded further with mannitol which exhibit superdisintegration property.These modified polysaccharides may call C-TAG (co grinded treated agar) and C-TGG (co grinded treated guar gum) respectively They are biodegradable, directly compressible, having desirable swelling dynamics. The above modified polyschharides were further used as superdisintegrants in

Roxithromycin fast dispersible tablets and compared with conventional tablets containing MCC. The C-TAG and C-TGG have shown better disintegration for their porous nature, better water intake ability and free flowing property than other.Another natural polysscharide, karaya gum is modified using distilled water to achieve superdisintegration property in dispersible tablet development. This modified karaya gum(MKG) is easy to prepare, cheap, easily available, biodegradable and stable compared to available synthetic super disintegrants in market. [1]

1.3.1.2 Synthetic Superdisintegrants

1.3.1.2.1 Sodium Starch Glycolate

The oldest and probably the most widely used disintegrant,the starch is modified with a dramatic disintegrating properties and are available as Explotab® and Primogel® These are low substituted carboxy methyl starches in granular forms. The mechanism involves rapid absorption of water leading to an enormous increase in volume of granules result fast and uniform disintegration.[1]

When these superdisintegrants are used in formulations they show the disintegration of solid dosage form within two minutes.The higher dissolution rates observed with superdisintegrants may be due to rapid disintegration and fine dispersion of particles formed after disintegration.[1]

The experimental work conducted by choudhary et al5 shows better dissolutions profile of sparfloxacin tablets with addition of primogel and other disintegrants such as cross carmellose sodium, cross povidone and potato starch. [1]

The sodium starch glycolate was incorporated in the beads of the enteric coated antigen micro spheres as a superdisintegrant by Zhang et al, shows significantly faster antigen release rate and reduction in breaking time of the film due to the swelling force generated by incorporation of this superdisintegrant .[1]

1.3.1.2.2 Cellulose Derivatives

Croscarmellose sodium is described as a cross-linked polymer of carboxy methyl cellulose (CMC). This polymer is different in synthesis and structure as compare to Sodium starch glycolate. Most importantly, the degree of substitution using Williamson’s ether synthesis of croscarmellose sodium is higher than that of sodium starch glycolate, and the mechanism of

crosslinking is also different. The chemistry of SSG is different that of cross carmellose sodium .[1]

As some of the carboxymethyl groups themselves are used to cross-link the cellulose chains. For example, in Primogel are phosphate ester rather than carboxyl ester links as compare to Cross carmellose sodium.[1]

1.3.1.2.3 Microcrystalline Cellulose

Avicel concentration of less than 10%, exhibits better disintegration. This mechanism is depending on entry of water to the tablet matrix through capillary pores, which breaks the hydrogen bonding between adjacent bundles of cellulose microcrystals. With more concentration, particularly in oral disintegrating tablet, it shows a tendency to stick to the tongue due to rapid capillary absorption and faster dehydration of the tablet surface. As Avicel has a fast wicking rate for water, hence this in combination with starch makes an excellent and rapid disintegration in OTD formulations. In a study, MCC was used as disintegrating agent in the formulation of fast releasing compressed propranol hydrochloride suppositories as reported.[1]

Watanabe used microcrystalline cellulose as disintegrant along with low substituted hydroxy propyl cellulose (L-HPC) to prepare rapidly disintegrating tablets.[1]

1.3.1.2.4 Chitin/Chitosan–Silicon Dioxide Coprecipitate

Chitin is one of the recent and most interesting category of superdintegrant. It is the second most abundant polysaccharide found in nature after cellulose.[1]

Naturally Chitin is extracted from the shell wastes of shrimp, crab, lobster, krill, and squid and used for the production of chitosan by a deacetylation reaction in alkaline medium. However, in large-scale handling of pharmaceutical blends both chitin and chitosan powders show poor bulk density, thus results in poor flowability and compressibility.To overcome such weakness they may be coprecipitated with colloidal silicon dioxide to improve their physical properties.[1]

The comparative study of other superdisintegrants with Chitin–silica coprecipitate has proved better disintegration and dissolution functionality.[1]

The particle rearrangement and plastic deformation ability of chitin–silica undergoes in the same extent compared with Avicel. The good compressibility and the good compactability properties of chitin–silica may allow it to be used in direct compression applications.[1]

The high hygroscopicity and high water capillary penetration of chitin-silica provides the driving force for disintegration. The ability of chitin–silica used as filler in solid dosage form with no concentration limits of the superdisintegrant, can impart further benefit in pharmaceutical applications.[1]

1.3.1.2.5 Indion

It is safe for oral consumption, economical and easily available polymer. By nature, it is ion exchange resin and if used as superdisintegrants as compared to conventional ones, swell on getting hydrated without dissolution and devoid of adhesive tendency, cause uniform tablet disintegration.[1]

They do not form lumps, do not stick to tablet press components and are compatible with commonly used active pharmaceutical ingredients as well as other pharmaceutical necessities. They offer better hardness to the tablets on compression. Indion 414 is more effective in hydrophobic formulations,as compared to the conventional disintegrants.For effective disintegration ability in the tablets, concentration of Indion 414 is used in range from 0.5 to 2% .[1]

1.3.1.2.6 Cross-linked poly-vinyl Pyrrolidone (Cross Povidone)

In case of mouth-dissolving formulations, Crospovidone quickly wicks saliva into them to generate the volume expansion and hydrostatic pressures necessary to provide rapid disintegration in the mouth. Unlike other superdisintegrants, it relies on both swelling and wicking principally for disintegration .[1]

When examined under a scanning electron microscope, crospovidone particles appear to be granular and highly porous. This unique, porous nature facilitates wicking of liquid into the dosage systems and causes rapid disintegration. Due to high crosslink density of crospovidone, it swells rapidly in water without gel formation than other.[1]

In contrast to other superdisintegrants like sodium starch glycolate and croscarmellose sodium, Crospovidone exhibit virtually no tendency toward gel formation, even at high ratio. As

disintegrants that result gel formation is not appreciable in orally disintegrating tablets (ODTs) and chewable products.[1]

1.3.1.2.7 Alginates

These are hydrophilic colloidal substances extracted naturally from certain species of Kelp or chemically modified from natural sources like alginic acid or salt of alginic acid. They are having higher affinity for water absorption and capable for an excellent disintegrants. They can be successfully used with ascorbic acid, multivitamins formulation.[1]

1.3.2 Ideal Properties of Superdisintegrants

1.3.2.1 Good Compressibility and Flow Properties

When the powders have 12-16% compressibility, they are considered as a good flow powders. Crospovidones are considerably more compressible relative to other superdisintegrants.[1]

1.3.2.2 Poor Solubility

The solubility of the key component in a tablet preparation can affect both the rate and the mechanism of action of tablet disintegration. Water soluble materials likely to be dissolved somewhat than disintegrate, while insoluble materials usually produce fast disintegrating tablets.[1]

1.3.2.3 Poor Gel Formation Capacity

Gels can slow down the dissolution because the drug need first diffuse through the gel layer before being released into the body. Primo gel is utilized as superdisintegrant in tablet preparation at a concentration of 4-6%.[1]

1.3.2.4 Good Hydration Capacity

Drugs and other excipients, which are hydrophobic and can be adsorbed on disintegrate surfaces, influence the degree of hydration and the efficacy of these disintegrates. Addition of rapid disintegrates of high hydration capacity is stated to decrease this problem, and therefore, increase dissolution.[1]

1.3.2.5 Complexation

Anionic disintegrants similar to croscarmellose sodium and primo gel form complex with cationic drug actives and may cause slow dissolution. Crospovidone a non-ionic polymer does not interact with cationic drug actives to hinder drug release. The effects of superdisintegrating agent as like croscarmellose sodium, primo gel and polyplasdone XL on the dissolution actions of numerous. Cationic drugs with changing water solubility reports that polyplasdone XL had a faster dissolution rate for the model cationic drugs, regardless of their aqueous solubilities.[1]

1.3.3 Mechanism of action of Superdisintegrants

1.3.3.1 Capillary Action

Disintegrating agents which does not swell they act by the mechanism of porosity and capillary action. Porosity of the tablet gives pathways for the fluid penetration into tablets. The disintegrating particles which have low cohesiveness and compressibility by their own increases porosity and gives these pathways into the tablet .Liquid is drawn up or "wicked" into these paths ways through capillary action and break the bonding of inter particles which causes the tablet to break apart, like Crospovidone, Croscarmellose.[1]

1.3.3.2 Due to heat of wetting

When disintegrating agents with their exothermic properties becomes wetted, capillary air expansion generates localized stress. It helps in tablet disintegration. This mechanism of action explains the action of some types of disintegrants and cannot explain the action of modern disntgration.[1]

1.3.3.3 Acid base reaction (Chemical reaction)

By internal release of CO2 in water because of interaction in citric acid and tartaric acid (Acids) with alkali metal bicarbonates or carbonates (Bases) in existence of water tablet Quickly fragmented [1].

1.3.4 Uses of superdisintegrant

Superdisintegrants are used to improve the efficacy of solid dosage forms. This is achieved by decreasing the disintegration time which in turn enhances drug dissolution rate. Superdisintegrants are generally used at a low level in the solid dosage form, typically 1- 10 % by weight relative to the total weight of the dose unit.[1]

The uses of superdisintegrants are extended in the applications of oral disintegration tablets, fast-dispersible tablets, capsules, mouth-dissolving films, etc. Particularly for ODTs and fast dispersible tablets, are optimized based on their disintegration time. ODTs need to be disintegrated in the presence of saliva in oral cavity within a minute. Thus these formulations achieve better patient compliance in all classes from pediatric to geriatric, bedridden and uncooperative patients including frequent travelers as it requires little or no access of water [1].

1.3.5 Methods of Incorporating

1.3.5.1 Internal Addition (Intragranular)

In Internal addition process, before wetting the powder mixtures with the granulating fluid the superdisintegrant is mixed with other powders. Thus the supedisintegrant is merged within the granules. In dry granulation technique, the disintegrate is added to other excipients before pressing the powder among the rollers.[2]

1.3.5.2 External Addition (Extragranular)

In this process, the superdisintegrants are mixed with prepared granules before compression.[2]

1.3.5.3 Partly Internal and External

In this technique, part of disintegrate can be part externally and added internally. This effects in instantaneous break down of the tablet into previously compressed granules while the disintegrant in the granules produces additional erosion of the granules to the original powder particles.[2]

This process can be more operative. If both intra granular and extra granular procedures are used, extra granular portion breakdown the tablet into granules and the granules more disintegrate by intra granular portion to discharge the drug substance into solution.[2]

However, the portion of intra granular disintegrate (in wet granulation methods) is generally not as operative as that of further granules due to the fact that it is exposed to wetting and drying (as part of the granulation method) which decreases the activity of the disintegrant.[2]

The intra granular disintegrate have a tendency to keep good disintegration activity in case of compaction process as it does not contain its exposure to wetting and drying.[2]

1.4 Literature Review

1.4.1 Effect of superdisintegrants and method of preparation on disintegration time and release profile of carbamazepine from immediate release tablet

In this experiment the effect of mode of incorporation of some superdisintegrants such as sodium starch glycolate, croscarmellose sodium, crospovidone (kollidon CL), ludiflash and Xanthan gum (XG) on dissolution profile and disintegration time of carbamazepine , apoorly water soluble drug was studied. The superdisintegrants were incorporated by extragranularly, intragranularly and in direct compression method[3].

Different amount of superdisintegrants (1%, 3% and 6%) was incorporated in different formulations whereas all the other excipients as well as the active drug remained same. The results indicated that sodium starch glycolate, when incorporated extragranularly in wet granulation method significantly enhanced the release profile of CBZ. Kollidon CL was the most effective superdisintegrant in decreasing disintegration time of different tablet formulations (1.95 minutes when extragranularly incorporated). On the other hand, tablets prepared with SSG were found most effective in % drug release irrespective of its mode of incorporation (99.99% when extragranularly incorporated and 99.75 when intragranularly incorporated within one hour)[3].

Tablets prepared by direct compression method also showed similar drug release with other methods but tablet hardness was found lower. So addition of superdisintegrants in tablet formulation may be an effective technique to comply compendial drug release.[3]

1.4.2 Effect of mode of superdisintegrant incorporation on tableting properties of metronidazole granules

Superdisintegrants are a special class of excipients used in a tablet formulation to aid disintegration and possibly enhance the release kinetics of a drug. The intragranular and extragranular effect of sodium starch glycolate (SSG) or croscarmellose sodium (CCM) as superdisintegrants on tableting properties of metronidazole granules were investigated. The granules were characterized for particle size analysis, angle of repose, bulk and tapped densities as well as Carr's index (CI) and Hausner's ratio (HR). Tablets were prepared from each batch of granules weighing 500 mg on a single punch tablet press using 12 mm flat-faced punches and compressed at 57.5 MPa. The tablets were kept at 25 ± 2 °C/75 % RH for 24 h to allow for elastic recovery and the properties of weight variation, content uniformity, thickness, crushing strength (CS), disintegration time (DT), and drug-release were evaluated. The results showed

that all the batches of granules exhibited good flow based on angle of repose < 30° , CI < 20 %, and HR ≤ 1.2. The evaluated tablet properties demonstrated that intragranular addition of either SSG or CCM lowered the CS and DT when compared to the extragranular effect.[4]

This indicates that the incorporation mode of superdisintegrant in a tablet formulation exerts an influence on tablet properties.[4]

1.4.3 Intra and Extra-granular Disintegrant Properties of Modified Underutilised Red Lima Bean Starch in Paracetamol Tablet Formulation

Red lima bean (Phaseolus lunatus Linn) Family Fabaceae, has been modified by succinylation and annealing, and used as intra- and extra-granular disintegrants at concentrations of 5 and 10 %w/ w in paracetamol tablet formulation in comparison with corn starch BP. The starches were characterised using FT-IR spectroscopy, SEM, proximate analysis, physicochemical and functional properties. FT-IR spectrometry revealed characteristic peaks at 1575.53 and 1713.99 cm-1 for the succinylated starch while the annealed showed no significant difference from the native starch. Modifications did not alter the ovoid shape of the native starch but reduced the particle size. Succinylation improved water absorption capacity, solubility and swelling of lima bean starch but annealing reduced the parameters. Tablets with disintegrants of lima bean starches generally had higher crushing strengths and lower friability than tablets with corn starch. Modifications reduced the disintegration time of the tablets when the starches were incorporated intra-granularly, which suggested particle-particle bond interruption and destruction of hydrogen bonds as mechanism of disintegration. Tablets containing 10 %w/ w succinylated red lima bean starch incorporated intra-granularly had the highest disintegration efficiency ratio, DER, indicating a great balance between mechanical and disintegration properties. Modified red lima bean starches incorporated intra-granularly into paracetamol tablets led to faster disintegration and could efficiently substitute corn starch as disintegrant.[5]

1.4.4 Comparsion Study of Effect of Superdisintegrant S on Formulation and Evaluation of Fluoxetine Hydrochloride Orodispersible Tablets by Wet Granulation and Sublimation Method

The purpose of this research was to investigate the efficiency of superdisintegrants such crosscarmellose sodium, cross povidone and sodium starch glycolate in formulating orodispersible tablets of Fluoxetine Hydrochloride tablets. Fluoxetine hydrochloride is a selective serotonin reuptake inhibitor drug which is used in psychiatric disorder like depression.

The efficiency of three super disintegrants were investigated by wet granulation and sublimation method with different concentratioins of 1.5%, 3% and 4.5%. The preformulation studies by FTIR confirmed no interactions between drug and polymers. The prepared formulations were evaluated for the pre-compression parameters & the values were within prescribed limits and indicated good free flowing properties. The tablets prepared by wet granulation & sublimation method were evaluated for physical parameters, wetting time, disintegration time, content uniformity and in vitro dissolution. The physical parameters were found to be satisfactory & within the limits. Upon comparison sublimation method was showed good results for disintegration time, wetting time & in vitro drug release studies because sublimation of camphor increases the porosity of the tablets. The tablets prepared with crospovidone at 4.5% concentration (FS-6) by sublimation method was found to be best formulation as it exhibited satisfactory physical parameters, least disintegration time (13 sec.), wetting time (10 sec.) & highest % drug release (99.5%) at 15 mins. In order to determine the mode of release, the data was fitted into various kinetic models and the optimized formulation followed first order kinetics.[6]

1.6 Aim of study

1.6.1 Justification

Any oral solid dosage form should ideally disperse into the primary particles from which it was prepared. Tablets and capsules which need rapid disintegration, the inclusion of the right disintegrant is prerequisite for optimal bioavailability .superdisintegrant are used to improve the efficacy of solid dosage forms. This is achieved by decreasing the disintegration time which in turn enhances drug dissolution rate.

1.6.2 Objective

1.6.2.1 General Objective

To estimate the effect of PVP superdisintegrant mode of incorporation on the disintegration time in both wet and dry granulated tablets.

1.6.6.2 Specific Objective

To decide which method of granulation (dry or wet), and, which mode of incorporation (extragranularly, intragranularly and partly extra- and intra granularly) of PVP as superdisintegrant has the best disntegrating time.

CHAPTER TWO

MATERIALS & METHODS

1.Material and method

2.1 Material

Polyvinylpyrrolidone (PVP) has been used as superdisentegrant, Microcrystaline cellulose (MCC) has been used as (filler and binder), Magnesium stearate has been used as glidant and Talc has been used as lubricant.

2.2 Methods

2.2.1 Study design

Experimental laboratory based study.

2.2.2 Study area

This Study was mostly conducted in laboratories of Pharmacy College at Omdurman Islamic University and partly at of Napata college

2.2.3 Dry granulated tablets

2.2.3.1 Intragranular

0.46g of MCC and 0.025 of PVP was weighed using electronic balance (Zhengzhou lab., China) and was mixed using mortar and pestle. Then was compressed into slugs using tableting press (Erweka, Germany), following this the slugs were milled to produce granules. The granules was sieved using standard test sieves (Xingiang co.,China) and 0.0075g of talc, 0.0075g of Mg-Sterate was added and mixed with granules. Finally the mixture was compressed to produce tablets.[2]

2.2.3.2 Extragranular

0.46g of MCC was weighted by balance and compressed into slugs using a tableting press, following this the slugs was milled to produce granules. The granules was sieved and the 0.0075g of talc, 0.0075g of Mg-Sterate was added and mixed with granules. Finally the mixture was compressed to produce tablets.[2]

2.2.3.3 Partly intra granular and extragranular

0.46g of MCC and 0.0125g of PVP was mixed and compressed into slugs using tableting press, following this the slugs was milled to produce granules. The granules was sieved and 0.0125g

of PVP, 0.0075g of talc , 0.0075g of Mg-Sterate was added and mixed with granules. Finally the mixture was compressed to produce tablets.[2]

2.2.4 Wet granulation

2.2.4.1 Intragranular

0.025g of PVP and 0.46g of MCC was mixed with granulating fluid to produce granules and the prepared granules was sieved, then put in oven, after drying the granules sieve again to insure that the granules are of the required size. 0.0075g of talc and 0.0075g of Mg-Sterate was added to granules and mixed, finally the mixture was compressed to produce tablets.[2]

2.2.4.2 Extragranular

0.46g of MCC was mixed with granulating fluid and the formed granules screened and put in the oven for drying .The dried granules are passed through a sieve to insure that the granules are of the required size.0.0075g of talc and 0.0075g of Mg-Sterate was added and mixed with granules, finally the mixture was compressed to produce tablets.[2]

2.2.4.3 Partly intra granular and extragranular

In this method the PVP was divided into two portions (internally and externally)0.46g of MCC and 0.0125g of PVP was mixed with granulating fluid and the granules was sieved, then the prepared granules was put in oven for drying, after drying the was sieved again to insure that the granules are of the required size. 0.0125g of PVP, 0.0075g of talc, 0.0075g of Mg-Sterate was added and mixed with granules, finally the mixture was compressed to produce tablets.[2]

2.2.5 Evaluation of tablet disintegration test

The time of tablet disintegration was measured by using the disintegration test apparatus (Wincom, China), the apparatus consists of a basket rack containing six open-ended tubes. In each tube of the basket, one tablet was placed. The basket with the bottom surface made of a stainless steel screen (mesh no. 10) was immersed in distilled water, at 37±2 °C. The time at which the complete disintegration of the tablet occurs in each tube should be determined. [2]

CHAPTER THREE

RESULTS

3 Results

Table 1: Disintegration time results

Process	Wet granulated tablets Disintegration time (minutes) *n=6	Dry granulated tablets Disintegration time (minutes) *n=6
Intragranular	0.24	16.22
Extragranular	0.35	18.8
Partly Internal and External	0.15	3.13

*n=number of tablets

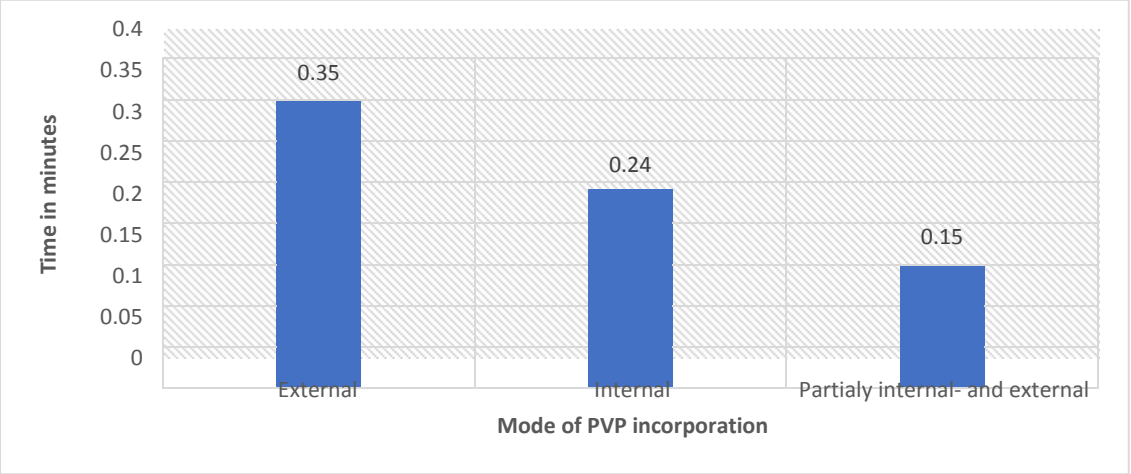

Figure 1: Disintegration time of the wet granulated tablets

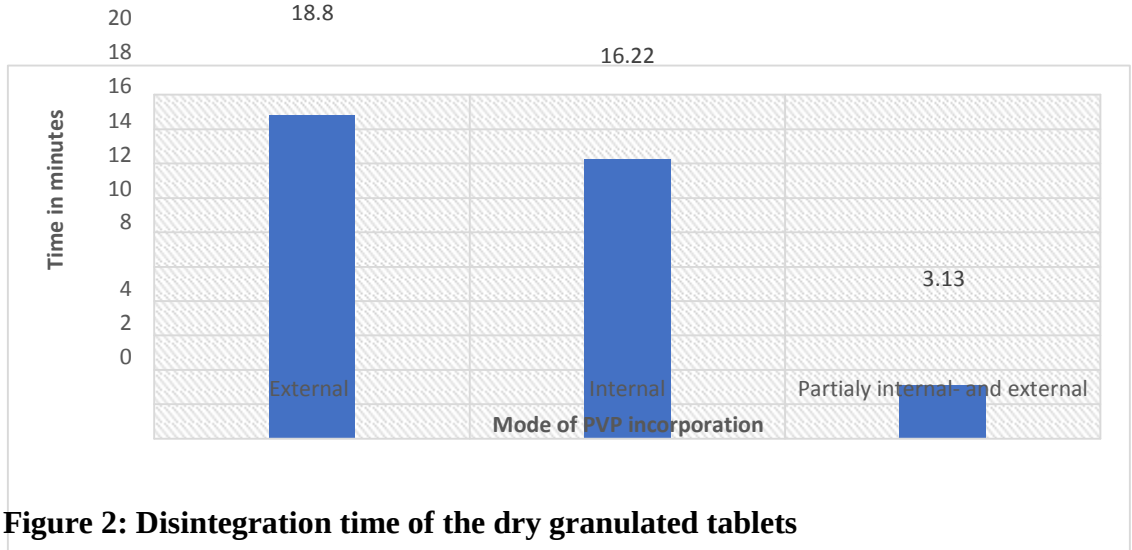

Figure 2: Disintegration time of the dry granulated tablets

CHAPTER FOUR

DISCUSSION

4 Discussion

As shown in (Table 1) and (Figure 1) in wet granulated tablets, the effect of PVP superdisintegrant incorporation on the disintegration time, is reduced as follows, partly internal and external than Intragranular and finally extragranular modes.

This probably because this technique, where part of superdisintegrant can be part externally and added internally. PVP cause water penetration into tablet then instantaneous break down of the tablet into previously compressed granules while the remaining PVP superdisintegrant in the granules produces additional erosion of the granules to the original powder particles.

The Intragranular mode showed faster disintegration than extragranular, this probably because the superdisintegrat is added within the granules allowing water to penetrate into each granule leading to complete erosion into powder particles.

As shown in (Table 1) and (Figure 2) for dry granulated tablets, the effect of PVP superdisintegrant incorporation on the disintegration time, is reduced as follows, partly internal and external than Intragranular and finally extragranular modes. This was for the same reasons and purposes as wet granulated tablets.

The results showed, the major different between wet and dry granulated tablets that is the latter took longer time for tablets to disintegrate. This is probably due to the double compression process which led to higher particle-particle interaction and eventually stronger granules. Which need more time to disintegrate in comparison to wet granulated ones.

The showed results showed that using PVP as superdisintegrant has significant effect in wet granulated tablets. In particular, the partly internal and incorporation mode. However, the dry granulated tablets tests showed results within the range of normal disintegrant for partly internal and external. Moreover, complete out of range results for both internal and external for normal disintegrant as stated in USP that the disintegration time for un-coated tablets must less than 15 minutes.

5. Conclusion

PVP was used as superdisintegrant in three different modes incorporations for both wet and dry granulated tablets. PVP as superdisintegrant has significant effect in wet granulated tablets. In particular, the partly internal and incorporation mode. However, using the same superdisintegrant with the dry granulated tablets has insignificant effects on reducing tablets disintegration time.

6 Recommendation

More extensive studies has to be carried out using superdisntegrant using dry granulation methods to reduce its disintegration time.

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