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Extraction, characterization and evaluation of the binding property of *Irvingia gabonensis* seed gum in paracetamol tablet

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ABSTRACT

This research was conducted to extract, purify, and investigate the physiochemical properties of *Irvingia gabonensis* seed gum (IGG) and to evaluate it binding property in paracetamol tablet. The *Irvingia gabonensis* seeds were crushed and dispersed in hot water (80˚C). IGG was extracted with 95% ethanol and it was defatted using Petroleum ether. The physico-mechanical properties of IGG were evaluated using parameters such as flow rate, angle of repose, bulk and tapped density, Carr's compressibility index, flow rate. IGG was granulated with other excipients and paracetamol powder using mixture of isopropanol and water (2:1) as granulating solvent. The granule size distribution revealed size and compactness in the following order: Acacia gum > IGG > Gelatin, and average granule size for the three set of batches were found to be 500 µm. The tablets were evaluated using the parameters: friability, disintegration time, weight uniformity and thickness, tablet hardness. The results obtained for crushing strength, friability, and disintegration time for F7 and F8 (having 7.5 and 10 %w/v IGG as binder) were: 54 N and 60 N, 0.12 % and 0.19 %, 27.00 and 29.10 min., respectively. F3and F4 (7.5 and 10 %w/v acacia gum as binder) 45 and 47 N, 0.1 and 0.13 %, 21.30 and 24.15 min., respectively; F11 and F12 (7.5 and 10 % w/v gelatin as binder) 100 and 110 N, 0.02 and 0.04 %, 45 and 60 min., respectively. In conclusion, at 7.5 and 10 %w/v, IGG proved to be a better binder than acacia in paracetamol tablets.

Keywords: *Irvingia gabonensis;* Seed gum; Tablet binder; Wet granulation; Natural polymer

INTRODUCTION

Scientific classification: Kingdom (Plantae), Order (Malpighiales), Family (Irvingiaceae), Genus (Irvingia). *Irvingia gabonensis* is a non-timber forest product made up of tree trunk (stem), leaves, roots and fruits, the fruit comprise a fleshy part and nut, which consist of a hard shell and the seed, its seeds have an outer brown testa (hull) and two white cotyledons, it belongs to genus Irvingia, species, *Irvingia gabonensis.* Two varieties have been identified in Nigeria, var gabonesis and var excels [1]. *Irvingia gabonensis* common names are bush mango, Africa mango, wild mango or dika nut plant and the local name is kwing (Agoi). Irvingia seeds constitute an important part of the rural diet in Nigeria. The sun-dried seeds are ground into flour and used as soup thickeners. The white cotyledons are roasted and eaten in the Bwenba community of Uganda; roasted seeds confer flavor and aroma and foods

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especially vegetables [2]. It is the food gum component of the seed that serves as thickening agent in water (especially hot water). Seeds are a prominent feature in the peasant dietary are becoming valuable sources of nutrients for man, especially in countries where the diet is plant based. Ignorance of their food value has resulted in their hostage of economic returns and post-harvest loses, [3,4]. Report on this seed nutrients content indicated that it contains 8.65% protein, 14.1%, carbohydrates, 2.1% moisture, 1.4% fibre, 16.8% and 38.9% dietary fibre [5].

Native medical treatment made use of the bark, leaves, roots and kernels of African mango tree for multitude of health ailments. The bark was known to have antibiotic qualities and was used to heal skin abrasions and to produce a remedy for toothaches when boiled. When injected orally, shavings from the stem bark have been used to treat hyena, dysentery and even yellow fever. [6] states that the roots, leaves and bark of Irvingia spp. are used medicinally, however others mention only the bark. *I. gabonensis* bark is mixed with palm oil for use in the treatment of diarrhoea and is taken by women to shorten their breast-feeding period [7]. It is also administered for colic and dysentery [8] as well as for hernias, yellow fever and as an antipoison [9]. Ndoye and Tchamou [7] report that the bark has antibiotic properties for healing scabby skin and, particularly when boiled, it can be given as a painkiller for toothache. Okolo and co-workers [8] investigated the analgesic properties of the bark after finding that the Mende tribe in Sierra Leone grind it and form it into a paste with water, which they use directly on the skin for pain relief. They found that it contains a narcotic-type analgesic agent and may also contain a non-narcotic active agent.
Irvingia gabonensis seeds might have lower cholesterol because of their high fiber content. The fiber increase removal of cholesterol from the body. Some research suggests that *Irvingia gabonensis* seeds might also affect fat cells, which might reduce fat cell growth and increase the breakdown of fats. Isimi *et al.* [10] have elucidated the gum as a possible emulsifying and suspending agent. The IGG mucilage compared with tragacanth in concentration up to 2 % w/v. Above 2 % w/v, IGG produced stable emulsions, comparable to acacia.

In this research, the gum from *Irvingia gabonensis* seeds will be extracted, purified, characterized and evaluated as a binding agent in paracetamol tablet formulation.

EXPERIMENTAL

Material The following ingredients were used: paracetamol (Tianjin Zhang Xin Pharma. Group of Co., Tianjin, China), lactose (Veghel, Netherlands), corn starch (standard grade), *Irvingia gabonensis* seed (dika nut; obtained locally from commercial source in Nigeria), Acacia gum, gelatin gum, talc and magnesium stearate (standard grade). Ethanol and methanol (analytical grade), isopropanol (Mopson Pharm. Ltd. Nigeria).

Extraction of *Irvingia gabonensis* gum. One kilogram of *Irvingia gabonensis* seed was size reduced using electric blender. The granules were then transferred into a dried clean beaker (1000 ml capacity). Distilled water was added up to 1000 ml mark and, with the aid of the hotplate, it was heated to 80^{o}C. The solution was constantly stirred; sodium metabisulphite was added and left to stand for 24hours for proper dispersion. After 24 hours, the dispersion was filter through a clean muslin cloth, the filtrate obtained contains biopolymer, fat, and water.
A sufficient quantity (10 litres) of 95% ethanol was added to the filtrate until the mixture of biopolymer and fat crumbled in the ethanol indicating complete precipitation and total separation from water. The residue was collected, while the filtrate was discarded. The residue extracted was properly spread on a clean brown paper and air-dried for 24

hours for complete drying; it was dried in an over at a temperature of 40ºC for 20 minutes.

Defattening the gum. The extracted biopolymer contains fat. It was defatted by the use of petroleum ether. This was done by adding 100 ml of petroleum ether onto the 100 g of extracted biopolymer with stirring, after which granular sediments (gum) were filtered from the petroleum ether. Multiple steps extraction procedure of defatting was done using 100ml each until the biopolymer was free of fat (600ml of petroleum ether was used). The biopolymer obtained was air dried for 24hours, after which it was dried in the oven at a temperature of 40ºC for 30minutes. The dried purified biopolymer was then size reduced using a dry porcelain mortar and pestle. The weight of the dried granules obtained was 30 g and the percentage yield was determined.

$$\text{Percentage yield (\%)} = \frac{\text{final weight}}{\text{Initial weight}} \times 100$$

Recovering the fat from petroleum ether. The several batches of the petroleum ether used for the purification of the biopolymer were collected together in a 1000 ml capacity beaker and left in an open air for 72 h, after which pet ether had evaporated leaving behind a semisolid mass, which is fat.

$$\text{Percentage yield (\%)} = \frac{\text{final weight}}{\text{Initial weight}} \times 100$$

Viscosity determination. A 0.6g of the powder was weighed using a digital electronic weighing balance and was transferred into a 120ml beaker and distilled water was added to bring it up to mark 120ml and the Haake viscotester VT-01 was used to measure the viscosity. This was done for the various batches of the gum.

pH Determination. A 1 g sample of the gum was weighed, dispersed in distilled water and the volume was made up to 120 ml stirred thoroughly to ensure complete dispersion, it was transferred into a pre-calibrated bottle. The pH was determined using a standard method.

Evaluation of granules

Measurement of bulk and tapped density. The bulk and tapped densities (B_d and T_d) respectively of the granules are determined by the modification of Kumer and Kothari method [11]. Tapped density of a powder is expressed as the ratio of the weight of powder to the volume occupied after tapping for a given period of time. Voids are reduced by tapping resulting to consolidation.

$$T_d = \frac{\text{weight of powder}}{\text{Tapped volume}}$$

$$B_d = \frac{\text{weight of powder}}{\text{Bulk volume}}$$

Bulk and tapped densities of IGG were determined using 50 g of the gum. It was poured into a 100 ml measuring cylinder and the volume occupied by the bulk noted. The tapped volume was obtained after tapping cylinder 200 times. Bulk and tapped densities were calculated using the equations given below. Carr's index and Hausner's ratio were calculated using the parameters of bulk and tapped densities.

Hausner's ratio. Hausner's ratio (H) is expressed as:

$$H = \frac{Td}{Bd}$$

Where, T_d and B_d are tapped and bulk densities respectively.

Carr's compressibility index. Carr and Neumann developed a simple test to evaluate flowability of a powder by comparing the poured (fluff) density and tapped density of a powder and the rate at which it packed down. A useful, empirical guide is given by:

$$Carr's\ index\ (\%) = \left(\frac{[Td - Bd]}{Td}\right) x100$$

Determination of flow properties of granules

Angle of repose. A clean plastic funnel of diameter 1.3 cm, and length 10 cm was

clamped firmly to a retort stand. A shutter was placed over the orifice. A 50 g of IGG or granules were accurately weighed and transferred into the funnel. The shutter was then removed and the powder was allowed to discharge completely into a plane white paper placed on the bench on a retort stand base. The height of the powder heap and the diameter of the circular base of the powder heap were measured. Average of three readings was taken and same procedure was done for the granules. The angle of repose (θ) was then determined as the tangent of the height of the cone "h" divided by the radius r.

Flow rate. The measurement of the flow rate was done using the funnel method. A clean dried funnel was clamped on a retort stand 10 cm from the surface of the bench. A 50 g quantity of the IGG powder was poured into the funnel and the time for complete discharge of the granules was recorded. A mean of three determinations was taken.

$$Flow\ rate\ (g/sec) = \frac{Weight\ of\ powder}{Time\ taken\ to\ flow}$$

Particle size analysis. A simple method of particle size analysis or distribution was adopted according to U.S.P (2003). The set of sieves used were 850, 500, 355, 250, 180 µm and fine <100 µm collected respectively. The sieves were arranged on an electric stand and the first batch of the granules was placed on the 850 µm size. The sieves were shaken for 10minutes using the electric shaker after which the sieves were dismantled and the weight of the powder retained (i.e. oversize) by individual sieve was determined using electrical balance.

Preparation of granules by wet granulation procedure. Four batches of granules consisting of *Irvingia gabonensis* gum as binder were prepared in different concentrations (2.5, 5.0, 7.5, 10.0 % w/v). Acacia gum and gelatin were employed as standard binder, while sodium alginate was used as a disintegrant due to its rapid swollen capability (Table 1).

Evaluation of flow properties of the granules. The standard methods previously described employed. The tapped density, bulk density, Hauser's ratio, Carr's compressibility index, flow rate and angle of repose were determined.

Granule size analysis. The same standard procedure as described under particle size analysis was adopted

Compaction of granules. The granules were used to formulate metronidazole tablets. The tablets were compacted in a single punch tabletting machine (Erweka, AR 400, Germany) at target weight of 500 mg using 12.5 mm diameter flat faced punch. Both the die and punches were lubricated with magnesium stearate. The tablets were compressed at 2 kN compression force.

Evaluation of compressed tablets

Tablet hardness. Ten tablets obtained from the compression were placed individually between the fixed jaw of the Monsanto hardness tester and the scale adjusted to zero. Pressure was then applied on the tablet by screwing the compression knob until the tablet shattered into pieces. The reading at this point was recorded for other 9 tablets in conformity with the official requirement and guidelines (4-7 kgf, B.P 1988) and the corresponding values recorded in kgf.

Tablet friability. The abrasion test was performed in a friabilator (Erweka, TA3R, Germany) operated at 25 r.p.m for 4 min. The weight of 10 tablets was taken before and after the test. The friability was calculated as the percentage weight loss.

A maximum weight loss of 1.0% of weight of the tablets being tested is considered acceptable in most products.

$$Friability\ (\%) = \left(\frac{[WI - WF]}{WI}\right) x\ 100$$

Where, W_I is the initial weight of the 10 tablets and W_F is the final weight of the corresponding tablets.

Tablet thickness and diameter. The Vernier caliper was used to measure the thickness and diameter of twenty tablets sampled from the batch. The mean and standard deviation were calculated.

Tablet disintegration time. Disintegration apparatus (Erweka, ZT3, Germany) was employed. Three tablets were used, one tablet was placed in each compartment of the disintegrating basket which was lowered into a glass beaker (1 L capacity) filled with deionised water to 800 ml mark and in turn was placed in a water bath maintained at 37 ^{0}C. The time taken for the dissociated tablet particles to pass through the mesh was recorded as the disintegration time.

Weight uniformity. The weight uniformity test was performed according to the B.P 1980. Twenty tablets were randomly selected from each batch and weighed. The average weight and the standard deviation was reported.

RESULTS

The 95% ethanol extract and the Petroleum ether defatted gum are shown in Plate. 1 and 2. Plate. 3 shows the recovered fat form the petroleum ether, which account for 70 % of the ethanolic precipitate of IG seed gum. Plate. 4 and 5 shows the dried granules of IGG recovered from pet. ether free fat, this constitute 30 % of ethanolic precipitate of IG seed gum. Table 2 illustrates the average weight of IGG and fats recovered from ethanolic precipitate of the seed gum, while plate. 3 shows the viscosity range with the concentration of the gum. It could be seen that the viscosity increases along with increase in concentration at a fixed shear rate (50 r.p.m).

The physico-mechanical properties of the gum were evaluated using parameters such as flow rate, angle of repose, bulk and tapped density, Carr's compressibility index, flow rate (table 4).

The gum granules exhibited good flow property as indicated by the angle of repose value of 25.27 %, while the Car's index value is a reflection of inherent poor compressibility property of IGG. The granule size distribution revealed size and compactness in the following order: AG > IGG > Gelatin, and average granule size for the three set of batches were found to be 500 µm (fig. 1).

The prepared granules were then tableted by direct compression method using single punch tablet machine at 2.0 KN; punch and die size 12 mm. The tablets were evaluated using the parameters: friability, disintegration time, weight uniformity and thickness, tablet hardness (table 6).

The results obtained were as follow: crushing strength, friability, and disintegration time for F7 and F8 (having 7.5 and 10 %w/v IGG as binder) were: 54 N and 60 N, 0.12 % and 0.19 %, 27 and 29 min., respectively. F3and F4 (contain 7.5 and 10 %w/v acacia gum as binder) 45 and 47 N, 0.1 and 0.13 %, 21.30 and 24.15 min., respectively. F11 and F12 (having 7.5 and 10 % w/v gelatin as binder) 100 and 110 N, 0.02 and 0.04 %, 45.41 and 60.30 min. respectively. It can be concluded that at 7.5 and 10 %w/v, IGG proved to be a better binder than acacia gum.

TABLE 1: Composition of wet granulation for paracetamol tablets

Constituent	Quantities											
Paracetamol (g)	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00
Lactose (g)	5.50	5.25	5.00	4.75	5.50	5.25	5.00	4.75	5.50	5.25	5.00	4.75
Corn starch (g)	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25
Acacia (g/10ml)	0.25	0.5	0.75	1.00	-	-	-	-	-	-	-	-
IGG (g/10ml)	-	-	-	-	0.25	0.5	0.75	1.00	-	-	-	-
Gelatin (g/10ml)	-	-	-	-	-	-	-	-	0.25	0.5	0.75	1.00
Talc MG (g)	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Stearate (g)	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25

Table 2: Physical Properties of *Irvingia gabonensis* seed gum (IGG)

Weight of IGG obtained	Weight of IGG after extraction	Weight after defatting
440.13g	100g (22.72 %)	27.45g (27.45 %)

Table 3: Viscosity of *Irvingia gabonensis* gum (IGG)

% w/v of IGG	Viscosity (mPas)
0.50	<50 mPas
1.00	75 mPas
1.50	125 -130 mPas
2.00	300 mPas

The pH of *Irvingia gabonensis* is 6.00

Table 4: Physicochemical Properties of *Irvingia gabonensis* seed gum

Material	Average flow rate (g/sec)	Average angle of repose (o)	Bulk density (g/cm^3)	Tapped density (g/cm^3)	Compressibility index (%)	Hausner's ratio
Irvingia gabonensis powder	2.797	25.27	0.226	0.305	25.90 %	1.349

Table 5: Physicochemical properties of granules

Binder	Batches	%	Average flow rate (g/sec)	Average angle of repose (o)	Bulk density (g/cm3)	Tapped density (g/cm3)	Compressibility index (%)	Hausner's ratio
AG	F1	0.25	1.36	38.83	0.46	0.64	27.00	1.37
	F2	0.50	1.96	31.55	0.46	0.65	28.00	1.39
	F3	0.75	1.84	36.35	0.49	0.65	20.00	0.98
	F4	1.00	1.02	36.98	0.66	0.67	28.00	1.40
IGG	F5	0.25	2.12	27.07	0.45	0.60	26.11	1.36
	F6	0.50	2.92	31.84	0.46	0.61	23.00	1.30
	F7	0.75	2.08	27.61	0.45	0.62	27. 00	1.38
	F8	1.00	1.18	32.74	0.49	0.68	28. 00	1.39
GN	F9	0.25	2.37	32.78	0.51	0.63	19. 00	1.24
	F10	0.50	2.32	31.84	0.52	0.65	20. 00	1.25
	F11	0.75	1.95	32.46	0.53	0.65	18. 00	1.25
	F12	1.00	1.94	37.31	0.54	0.70	23. 00	1.40

AG (acacia gum), IGG (Irvingia gum), GN (Gelatin)

Table 6: Physico-mechanical properties of paracetamol tablets

Binder	Batch	Material (% w/v)	Hardness (kg f)	Mean thickness (mm)	Friability	Weight uniformity	Disintegration time (mins)
AG	F1	2.5	3.00	0.34	1.20	0.490	20.20
	F2	5.0	3.50	0.35	1.20	0.495	22.00
	F3	7.5	4.50	0.34	1.10	0.500	21.30
	F4	10.0	4.70	0.34	1.03	0.500	24.15
IGG	F5	2.5	3.60	0.35	1.10	0.495	15.10
	F6	5.0	5.30	0.35	1.10	0.495	18.10
	F7	7.5	5.40	0.35	1.03	0.500	20.00
	F8	10.0	6.00	0.34	1.01	0.500	26.00
GN	F9	2.5	8.50	0.34	1.02	0.495	23.12
	F10	5.0	9.50	0.34	1.02	0.500	30.11
	F11	7.5	10.0	0.35	0.40	0.505	45.41
	F12	10.0	11.0	0.35	0.20	0.500	55.00

AG (acacia gum), IGG (Irvingia gum), GN (Gelatin)

Plate.1: Ethanolic precipitate of Irvingia seed

Plate.2:Pet. ether defatting IGG**.**

Plate.3: Recovered fats from Pet. ether

Plate.4: Recovered IGG from Pet. ether

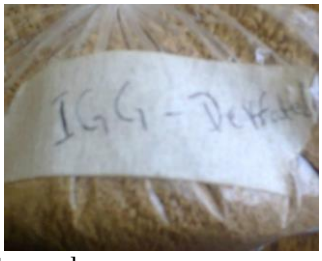

Plate.5: Dried IGG granules

Plate.6: Paracetamol granules made with IGG as binder.

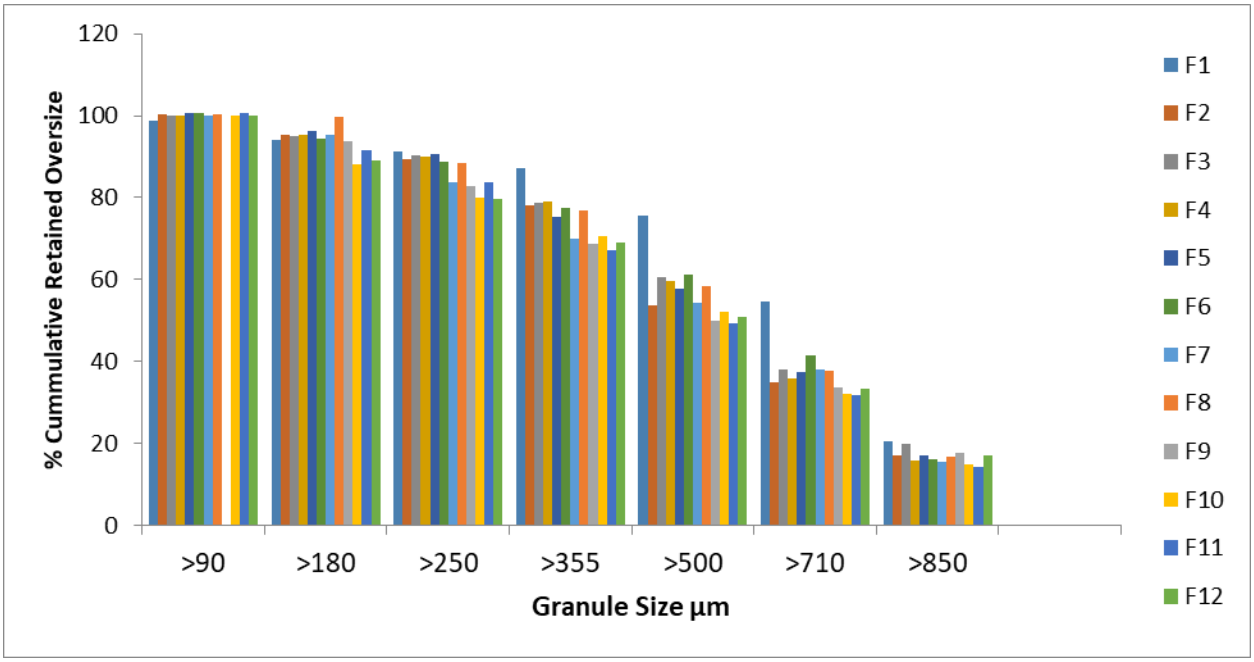

Fig 1: Granule size distribution (µ) vs. Cumulative retained oversize (%).
F_1[2.5% AG] ; F_2[5.0% AG] ; F_3[7.5% AG] ; F_4[10.0% AG] ; F_5[0.25% IGG] ; F_6[5.0%IGG] ; F_7[7.5% IGG] ; F_8[10.0% IGG] ; F_9[2.5% GN] ; F_{10}[5.0% GN] ; F_{11}[7.5% GN] ; F_{12}[10.0% GN]

DISCUSSION

From figure 1, as the concentration of gum increases, the granule sizes decreases. The percent retained cumulative granule sizes for F1 to F8 favours more of >180 to 355 µm than F9-F12 than F9 to F12. While, granule sizes >500 to 850 µm favoured F5 to F8 than F1 to F4 and F9 to F12. The results reflect a better granule size distribution for IGG granules than AG and NG. The cohesiveness of the former is better and higher than the latter.

From the table 6, the binding effectiveness of the test polymer (IGG) and standard polymer (AG and GN), is reflected by crushing strength, friability and disintegration. The stronger the binder the stronger the bonding functionality and higher the crushing strength hence, longer the disintegration time. From the result obtained, IGG and AG gave acceptable tablets as binder at 7.5 and 10 % w/v concentration, while GN, gave acceptable compact at 2.5 and 5.0 % w/v. The polymer functionality or binding strength resulting from bond summation is higher for GN than AG and GN. This is the reason why GN is used in lower concentration than AG and other pharmaceutical grade binders. The tensile strength and disintegration time of the resulting tablets increased with the concentration of the test and standard binder, whereas, friability decreased. In a similar report, Irvingia gum mucilage used as binding agent in metronidazole tablets formulations produced granules showing plastic deformation under compression pressure [12]. Despite the inherent elastic property of paracetamol active ingredient, IGG proved to be a better binder than acacia gum by yielding tablets of moderate crushing strength, friability, and disintegration time.

Conclusion. Due to the global economic recession, many developing nations have been clamoring for research into local pharmaceutical excipient in other to be self-reliant. The results of this research indicates that Irvingia seed gum used as binder in concentration range, 5 to 10 % w/v is appropriate for formulation of conventional

tablets having acceptable mechanical and drug release properties.

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