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Formulation and Evaluation The Oral Tablets Ibuprofen

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The purpose of the study is to investigate the effect of roller compaction (RC) parameter (auger speed) on the properties of flakes, granules and tablets. This study is carried out in six formulation preparing by changing auger speed(6-7, 10-11, 14-15, 18-19, 23-24, 27-28 rpm) of roller compactor resulting in flakes of different hardness were prepared, and its impact on the flow properties(bulk density, tapped density) of the granules and finally its effect on the properties of tablet such as hardness, thickness, friability. For this study ibuprofen is the model drug selected and the tablets formed by changing the auger speed is of ibuprofen. In this study the tablet's in vitro drug release were also performed and compare with the marketed ibuprofen tablet.

Keyword: Roller Compactor, Auger Speed, Ibuprofen

INTRODUCTION: Roll compaction is a widely used dry granulation method. It can be especially suitable for moisture or heat sensitive drugs, because this technique requires no liquid binder and drying step. In roll compaction process the powder is fed between two counter rotating rolls and compacted to dense ribbons. The produced ribbons are subsequently broken into granules. In most cases roll compaction is performed prior to tableting. There are several process factors affecting the properties of produced granules by roll compaction and the resulting tablets: for example, roll pressure, roll speed, roll gap, and the speed of powder feeding can be the critical parameters.

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MATERIALS AND EQUIPMENTS USED

Ibuprofen Ranbaxy Lab Ltd. Procured by Hydroxypropyl cellulose procured by Basf, Germany Microcrystalline Cellulose procured by N B Entrepreneurs.

Preformulation studies

The preformulation studies include the physicochemical characterization of the drug and excipients which are useful in formulation the dosage form.

Organoleptic characters

This includes recording of colour, odor and taste of the drug, record of color is very useful in establishing appropriate of batches. The results are shown in Table

Density

Powder flow, compressibility, dissolution and other properties may dependent on density.

Bulk density

The term bulk density refers to a measure used to describe a packing of particles. It is (gm/ml) and was determine using a balance and measuring cylinder. Initially the weight of the measuring cylinder was tarred. Then, 4 gm presieved (40#) bulk drug were poured into the measuring cylinder using a funnel. Then volume of the powder was taken. Bulk density of the granules was calculated using following formula.

Bulk density = Weight of powder / Volume of powder.

Tapped density

Tapped density is determined by placing a graduated cylinder containing same mass of powder used for B.D. on a mechanical tapper apparatus which is operated for a fixed number of taps (approx500) until powder bed volume has reached a minimum.

Tapped density = Weight of powder / min. volume of powder

Carr's Index (CI)

Tapped and bulk density measurements can be used to estimate the carr's index of a material. Carr's index was determined by,

Carr's index (%) = [(Tapped density – bulk density)/tapped density] * 100

Table 1: Standards for Carr's index

Carr's Index	Flow
5 – 15	Excellent
12 - 16	Good
18 – 21	Fair
23 – 35	Poor
35 – 38	Very poor
More than 40	Extremely poor

Hausner's ratio (HR):

It is stated by Hausner. It was calculated as follow:

Hausner ratio = Tapped density / Bulk density

Table 2: Standards for Hausner ratio

H.R.	Flow
1.2 – 1.3	Excellent
1.3 – 1.4	Good
1.4 – 1.5	Fair
1.5 – 1.6	Poor

Angle of repose (Tan θ):

Angle of repose is the tan inverse of angle between height (h) of pile of powder and the radius (r) of the base of conical pile. It can be obtained between the freestanding surface of the powder heap and the horizontal plane. The fixed funnel that is secured with its tip at a given height h, above graph paper, placed on the flat horizontal surface. Powder is carefully poured through funnel until the apex of conical pile just touches the tip of funnel.

Solubility studies

Aqueous solubility of NSAID as a function of pH was determined in different physiological media. Solubility of drug was studied at different Ph range i.e. pH 1.2 (0.1 N HCl), Ph 4.5 (Phosphate Buffer), Ph 6.8 (Phosphate Buffer), pH 7.4 (Phosphate Buffer).

Table 3: Standards for Angle of Repose

Angle of repose	Flow
25 – 30	Excellent
30 – 35	Good
35 – 40	Fair
40 – 45	Poor
45 – 50	Very poor

Analysis of drug

UV Spectrophotometric Analysis

Drug was dissolved in 100ml of 7.2 Ph buffer, stirred for 15 min, sonicated and filtered through membrane filter paper. 5ml aliquot of this sample was diluted to 10 ml and UV absorbance was analyzed for λ max. The results are shown in Fig no 7.1

Linearity

10 mg of drug was dissolved in 100 ml of 7.2 pH buffer solution, stirred for 5 minutes, sonicated, filtered through membrane filter paper to prepare a solution having concentration of 100µg/ml and this solution was serially diluted to get a range of concentration from 1 to 10µg/ml. The absorbances of these solution were noted at 221 λ max against appropriate blanks on UV spectrophotometer.

PREPARATION OF IBUPROFEN TABLETS.

The composition of different formulations of ibuprofen tablets is shown in table 6.6. Ibuprofen along with hydroxyl propyl cellulose and micro crystalline cellulose were weighed accurately and pass throw 44 # and mixed thoroughly. Then mixture blended for 13 min at 20 rpm by using V-blender og 100 lit. obtained blend is passed through roll compactor for compaction at varying auger rpm (6 to 7, 10 to 11, 14 to 15, 18 to 19, 23 to 24, 27 to 28). These obtained compacts were passed through multimill for milling which gives granules. Granules are mixed with magnesium stearate and cross carmellose sodium to improve its flow properties, then compressed on a 24 punch tablet machine (CMD4, Cadmach 20 station compression machine). The tablets were round and flat with an average diameter of 10.0 ± 0.1mm and a thickness of 4.1 ± 0.2mm.

Table 4: Formulation of ibuprofen tablets.

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Ibuprofen	200	200	200	200	200	200
Hydroxypropyl cellulose	32	32	32	32	32	32
Magnesium stearate	2	2	2	2	2	2
Crosscarmellose sodium	8	8	8	8	8	8
Microcrystalline cellulose	158	158	158	158	158	158
Total weight (mg)	400	400	400	400	400	400

Evaluation parameters of tablets

Appearance

Tablet from each formulation were randomly selected and organoleptic properties such as color, taste, and shape were evaluated. The results are shown in Table no 7.8 and 7.10.

Hardness test

The hardness of tablets for fast dissolving tablets is usually kept low for easy disintegration in the mouth. The hardness was measured using shulinger hardness tester. The results are shown in Table no 7.8 and 7.10

Thickness

The thickness of tablets was determined using a Digimatic vernier caliper (Mitutoya, Japan). Three tablets from each batch were used, and average values were calculated. The results are shown in Table

Friability test

The friability of tablets was determined using Roche Friabilator. It is express in percentage (%). Ten tablets were initially weighed and revolved at 25 rpm for 4 min. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated. The % friability was then calculated by,

$$F = W_{initial} - W_{fiinal} \times 100 / W_{initial}$$

Acceptance criteria for % friability % weight loss should be less than 1%. The results are shown in Table

Weight Variation Test

Twenty tablets were selected randomly from each batch and weighed individually on electronic balance. The individual weighed is then compared with average weight for the weight variations.

The following percentage deviation in weight variation is allowed. The results are shown in Table no

Table 5: Percentage weight deviations.

Average weight	% difference
130 mg or less	10
130 – 324 mg	7.5
324 mg and greater	5

Disintegration time Testing

It was determine using USP tablet disintegration test apparatus, using 900 ml of distilled water without disk at room temperature. Test was performed on 6 tablets. The results are shown in Table no 7.8 and 7.10

Content Uniformity Test

Weigh and powder 20 tablets. Weigh accurately a quantity of the powder equivalent to 0.5 g of Ibuprofen, extract with 60 ml of *chloroform* for 15 minutes and filter. Wash the residue with three quantities, each of 10 ml, of *chloroform* and gently evaporate the filtrate just to dryness in a current of air. Dissolve the residue in 100 ml of *ethanol (95%),* previously neutralized to *phenolphthalein solution,* and titrate with *0.1M sodium hydroxide* using *phenolphthalein solution* as indicator. Each ml of *0.1M sodium hydroxide* is equivalent to 0.02063 g of $C_{13}H_{18}O_2$.
The results are shown in Table no 7.8 and 7.10

In vitro drug release study

The release rate of ibuprofen from tablets was determined using United States Pharmacopeia (USP) Dissolution Testing Apparatus 2 (paddle method; Veego Scientific, Mumbai, India). The dissolution test was performed using 900ml of 7.2 pH phosphate buffer, at 37 ± 0.5 ^{0}C and 50 rpm. A sample (10ml) of the solution was withdrawn from the dissolution apparatus hourly and the samples were replaced with fresh dissolution medium. The samples were filtered through a 0.45µ membrane filter and diluted to a suitable concentration with 7.2 pH phosphate buffer. Absorbance of these solutions was measured at 221 nm using a Thermospectronic-1 UV/V is double-beam spectrophotometer. Cumulative percentage drug release was calculated using an equation obtained from a standard curve. The results are shown in Table no 7.15; 7.16; 7.17; 7.18; 7.19; 7.20 and Fig no 7.11; 7.12; 7.13; 7.14; 7.15; 7.16.

Stability studies

Stability of a drug can be define as the time from the date of manufacture and the packaging of the formulation, until its chemical or biological activity is not less than a predetermined level of labeled potency and its physical characteristics have not changed appreciably or deleteriously. In any design and evaluation of dosage forms for drugs, the stability of the active component must be a major criterion in determining their acceptance or rejection.

Objective of the study

The purpose of stability testing is to predict the quality of drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light, enabling recommended storage condition, re-test periods and shelf-lives. Generally, the observation of the rate at which the product degrades under normal room temperature requires a long time. To avoid this undesirable delay, the principles of accelerated stability studies are adopted. The international Conference on Harmonization (ICH) Guidelines titled "stability testing of New Drug substance and products" (QIA) describes the stability test requirements.

In the present work stability study was carried out for the optimized formulation at 40^0 C/75%RH for 2 month.

After time period of every month sample was collected and analysis is carried out for,

1. In vitro Drug release study
2. % Assay
3. Physical parameters

Table 6.: ICH guidelines for stability study

Study	Storage condition	Time period
Long term	25^0 C±2^0 C/60%RH±5 RH OR 30^0 C±2^0 C/65%RH±5% RH	12 month
Intermediate	30^0 C±2^0 C/65%RH±5%RH	6 month
Accelerated	40^0 C±2^0 C/75%RH±5%RH	6 month

Powder granulation is a process of powder size enlargement that incorporates small particles into larger ones. The definition of granulation comprises a range of different size enlargement methods that can be classified as either dry or wet. In wet methods, a suitable liquid is used to agglomerate the small powder particles into a mass. The wet mass is subsequently dried and sized for further downstream processing needs. Wet granulation methods have been the most widely used powder granulation technology in the production of pharmaceutical products, particularly in modern pharmaceutical manufacturing[1].

The chief reasons to granulate powders for the manufacture of pharmaceutical dosage forms are described:

- To improve powder flow properties for dosage filling and compression processes
- To eliminate wet granulation induced degradants and to improve product stability
- To prevent active product ingredient from segregating
- To reduce bulk volume, thereby minimizing storage and enhancing transport
- To reduce potential environmental and safety hazards.

The purpose of the study is to investigate the effect of roller compaction (RC) parameter (auger speed) on the properties of flakes (compacts), granules and tablets. This study is carried out by changing auger speed(6-7, 10-11, 14-15, 18-19, 23-24, 27-28 rpm) of roller compactor resulting in flakes of different hardness and its impact on tablet hardness, thickness and friability. For this study ibuprofen is the model drug selected. The tablets are also evaluated for disintegration time and in vitro drug release study

Drug study: This includes solubility, IR, UV, BD, TD, CI and HR

Table 7.: Test for drugs

Tests	Results of Analysis
Colour	White powder
Odour	No characteristic odour
Taste	Bitter taste
Solubility	Slightly soluble in water
Bulk density	0.384
Tapped density	0.588
Angle of repose	$42^0 70^{'}$
Carr's Index	34.69
Hausner's ratio	1.53
Assay	99.02 %

Solubility Studies

The solubility of drug was studied in different physiological media at 37^{O} C ± 0.5^{O} C.

Analysis of drug

Spectrophotometric Analysis:

λ max of drug in 7.2 pH buffer was found to be 221 nm.

Linearity

The standard curve of drug was prepared in 7.2 pH buffer as shown in fig. the standard values are given in the table.

Weight of drug: 10 mg

Concentration of stock solution: 100 µg/ml.

Table-8

S.No.	Volume of stock solution (ml)	Diluted to (ml)	Theoretical Conc. (mg/ml)	Theoretical concentration (ppm)
1	.1	10	0.001	1
2	.2	10	0.002	2
3	.3	10	0.003	3
4	.4	10	0.004	4
5	.5	10	0.005	5
6	.6	10	0.006	6
7	.7	10	0.007	7
8	.8	10	0.008	8
9	.9	10	0.009	9
10	1	10	0.01	10

Table9: Absorbance of drug in 7.2 pH buffer

S.No.	Conc. In ppm	Conc. (µg/ml)	UV absorbance
1	1	1	0.057
2	2	2	0.109
3	3	3	0.159
4	4	4	0.198
5	5	5	0.235
6	6	6	0.286
7	7	7	0.326
8	8	8	0.371
9	9	9	0.407
10	10	10	0.464

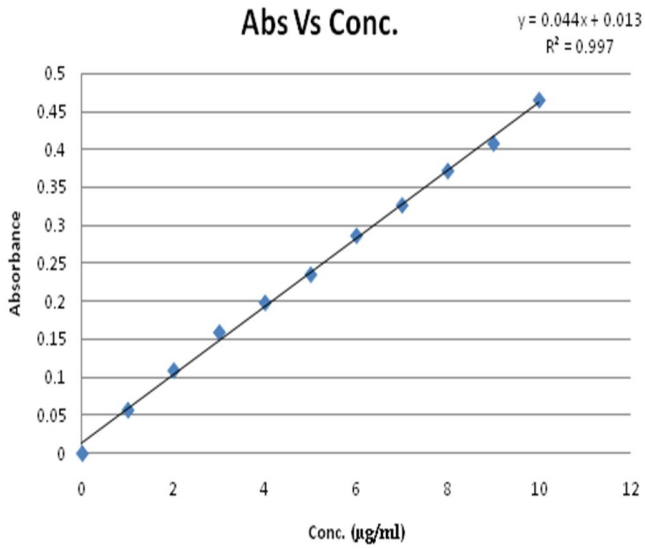

Fig1: UV Standard curve of drug in pH 7.2

Beer-Lambert's law was obeyed over the range and data was found to fit the equation

$y = 0.044x + 0.013$

$r^2 = 0.997$

Where,

x = concentration in µg/ml

y = Absorbance

Conclusion:

The standard curve prepared shown very linearity hence it was used for further analysis.

Table 10: Evaluation parameters of premix blend

Parameters	Results
Bulk density (gm/cm^3)	0.357
Tapped density (gm/cm^3)	0.526
Carr's index (%)	32.13
Hausner's ratio	1.47
Angle of repose (θ)	42^0 93'

Table 11: Evaluation parameters of compacts of batch F1 to F3

Parameters	F1	F2	F3
Density(gm/cm^3)	0.744	0.782	0.813
Weight(gm)	1.692	1.726	1.743
Hardness(kp)			
Top	2.93 ± 0.75	4.07 ± 0.51	5.14 ± 1.13
Middle	3.02 ± 0.48	4.37 ± 0.40	5.36 ± 0.80
Bottom	2.59 ± 0.69	4.86 ± 0.63	5.19 ± 0.88
Thickness(mm)			
Top	9.53 ± 0.06	9.61 ± 0.10	9.89 ± 0.11
Middle	9.70 ± 0.13	9.76 ± 0.09	9.97 ± 0.12
Bottom	9.61 ± 0.08	9.95 ± 0.19	9.91 ± 0.15

Table 12: Evaluation parameters of compacts of batch F4 to F6

Parameters	F4	F5	F6
Density(gm/cm^3)	0.847	0.876	0.881
Weight(gm)	1.761	1.785	1.810
Hardness(kp)			
Top	5.87 ± 0.85	7.71 ± 1.03	10.23 ± 1.15
Middle	6.13 ± 0.70	8.16 ± 0.95	11.05 ± 1.46
Bottom	5.94 ± 1.10	8.55 ± 1.11	10.91 ± 1.55
Thickness(mm)			
Top	9.88 ± 0.09	10.01 ± 0.81	10.19 ±1.06
Middle	10.06 ± 0.12	10.51 ± 1.12	10.28 ± 0.05
Bottom	9.99 ± 0.15	9.97 ± 1.11	10.16 ± 0.12

Conclusion:

The compacts of different formulations were prepared at different auger speed from 6 rpm to 28 rpm. It was observed that the hardness of the compacts increases with increase in auger speed. The hardness was measured measured by dividing the compacts into three different parts (top, middle and bottom). The density of the compacts were also increases.

Table 13: Evaluation parameters of blend F1 to F3

Formulations	F1	F2	F3
Bulk density (gm/cm^3)	0.365	0.390	0.440
Tapped density (gm/cm^3)	0.549	0.588	0.631
Carr's index (%)	33.5	33.67	30.26
Hausner's ratio	1.5	1.50	1.43
Angle of repose (θ)	41^0 32'	38^0 41'	35^0 55'

Table 14: Evaluation parameters of batch F1 to F3

Parameters	F1	F2	F3
Appearance	Round shaped	Round shaped	Round shaped
Average weight (mg)	402.1±1.490	398.2±0.643	399.17±1.220
Hardness (Kg/cm^2)	6.98±0.80	7.65±0.75	9.34±0.63
Thickness (mm)	4.56±0.013	4.56±0.011	4.57±0.06
Friability (% w/w)	1.2	0.96	0.61
Disintegration time	21sec	39sec	48sec
Assay (%)	97.6	99.1	100.8

n=3. All values are mean ± S.D

Table15 Evaluation parameters of blend F4 to F6

Formulations	F4	F5	F6
Bulk density (gm/cm^3)	0.480	0.500	0.510
Tapped density (gm/cm^3)	0.631	0.666	0.675
Carr's index (%)	30.26	24.92	24.44
Hausner's ratio	1.36	1.33	1.32
Angle of repose (θ)	33^0 12'	32^0 36'	32^0 24'

Table 16: Evaluation parameters of batch F4 to F6

Parameters	F4	F5	F6
Appearance	Round shaped	Round shaped	Round shaped
Average weight (mg)	401.17±2.140	400.1.226	402.98±2.143
Hardness (Kg/cm^2)	10.11±0.52	11.09±0.56	12.31±0.23
Thickness (mm)	4.57 ± 0.011	4.56 ± 0.01	4.57 ± 0.02
Friability (% w/w)	0.49	0.43	0.36
Disintegration time	57sec	1min 2sec	1min 11sec
Assay (%)	98.6	95.3	100.2

n=3. All values are mean ± S.D

COMPARATIVE STUDY OF DENSITY OF BLENDS OF THE FORMULATION

Table16: Comparative study of density of blends of the formulation

Auger speed (rpm)	Formulation	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)
6-7	F1	0.365	0.549
10-11	F2	0.390	0.588
14-15	F3	0.440	0.631
18-19	F4	0.480	0.631
23-24	F5	0.500	0.666
27-28	F6	0.510	0.675

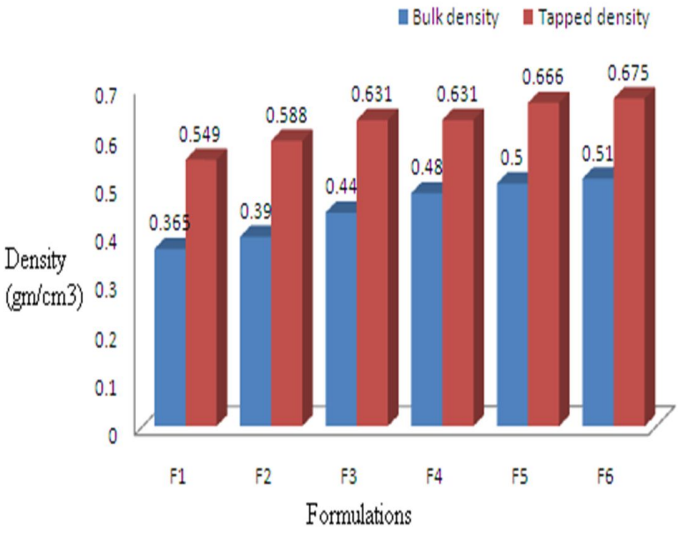

Fig 2: Comparative study of density of blends of the formulationCOMPARATIVE STUDY OF HARDNESS OF FORMULATIONS

Table 17: Comparative study of hardness of formulations

Auger speed (rpm)	Formulation	Hardness of tablets (kp)
6-7	F1	6.98
10-11	F2	7.65
14-15	F3	9.34
18-19	F4	10.11
23-24	F5	11.09
27-28	F6	12.31

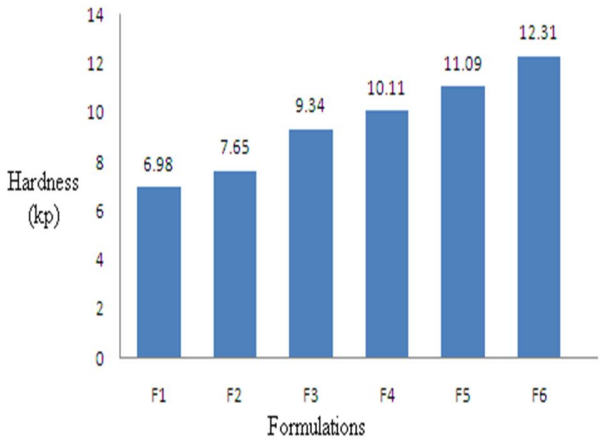

Fig 3: **Comparative study of hardness of formulation**

Marketed product study

In this study physicochemical parameters of marketed product were evaluated. Marketed product were compared and evaluated as per the pharmacopoeial in vitro drug release specification. A product of Abbott India Limited was selected was marketed product study.

Table 18 :Physical characterization of marketed product.

Parameters	Reference product: ibuprofen oral tablets Trade Name: Brufen 200
Appearance	Round dark pink tablets
Label claim(mg)	200 mg
Friability	0.357
Disintegration time	5min10sec
Assay (%)	99.2

Dissolution profiles of marketed product:

The dissolution profile of reference product was studied using earlier mentained parameters at specific time intervals, samples were withdrawn and drug concentrations were determined by UV. This was taken into a account in the calculation of the % drug release. Release profile was determined over a period of 60 minutes. Drug concentration in each withdrawn aliquot was determined by measuring the absorbance of the solution at 221 nm against blank on UV spectrophotometer. The drug amount was extrapolated from standard curve of the curve in 7.2 pH buffer.

Table 19 :Dissolution profile of marketed product

Time (min)	% Drug Release
0	0
5	15.74
10	34.13
15	45.13
20	58.33
30	72.16
45	86.51
60	98.97

COMPARATIVE STUDY OF IN VITRO DISSOLUTION PROFILE OF MARKETED PRODUCT AND OPTIMIZED FORMULATION F3.

Table 20: Dissolution profile of marketed product and F3

Time (min)	Marketed product	F3
0	0	0
5	15.74	21.99
10	34.13	41.93
15	45.13	53.18
20	58.33	67.81
30	72.16	83.97
45	86.51	99.20
60	98.97	

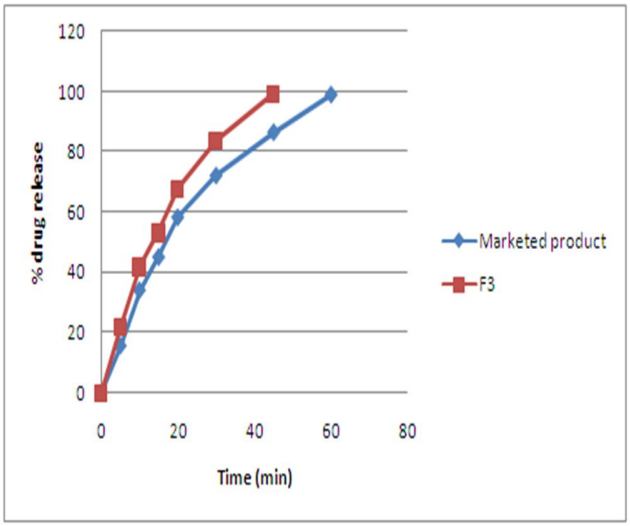

Fig 3: Dissolution profile of marketed product and F3

STABILITY STUDY OF OPTIMIZED FORMULATION F3

It is very essential that any product developed in the formulation department should be stable. The regulatory agencies in different countries try to ensure that the stability studies are carried out on the product. The formulation is subjected to accelerated stability conditions (40ºC ± 2ºC / 75% RH ± 5%).The effects of temperature and time on the physical and chemical characteristics of the tablet were evaluated for assessing the stability of the formulated tablets. The results indicate that there wasn't any significant change in hardness & % drug content . Disintegration and *in vitro* drug release was found to be increased a little more at 40^0C temperature. No significant change was observed in drug content.

Accelerated stability studies as per ICH guidelines:

The optimized formulation (F3) was wrapped in aluminum foils and kept in petri -dish at 40 ºC ± 2ºC / 75% RH ± 5% in humidity chamber. The stability studies were conducted after 30 and 60 days.

Table 20: Physical Characteristics of ibuprofen tablet F3 at Temperature (40ºC ±□2ºC/ 75% RH ±5%)

PHYSICAL PARAMETERS	0 DAYS	30 DAYS	60 DAYS
WEIGHT GAIN(mg)	**399.17 mg**	**399.15**	**399.12**
PERCENT DRUG CONTENT(%)	**100.8**	**100.1**	**100**
HARDNESS(kp)	**9.34**	**9.31**	**9.42**
DISINTEGRATION TIME(SEC)	**48 sec**	**45 sec**	**47 sec**

CONCLUSION:

The in vitro dissolution profile indicated faster and maximum drug release from formulation F-3. Formulation F-3 is fabricated by using auger speed . Stability studies shown that there was no significant change when compared with zero day of formulation (F-3). Inflammation is the initial response of the body to harmful stimuli and is achieved by the increased movement of plasma and leucocytes from the blood into the injured tissues . NSAID'S are used in the treatment of pain . In condition of pain , the

rapid disintegration also impose a placebo effect .

Table : 21 %Drug release at 40ºC 2ºC / 75% RH 5% of optimized batch F3.

Time (min)	% Drug release in 0 days	% Drug release in 30 days	% Drug release in 60 days
5	21.99	20.64	19.79
10	41.93	41.11	40.25
15	53.18	52.29	51.76
20	67.81	66.56	65.78
30	83.97	82.12	81.46
45	99.20	98.13	97.34

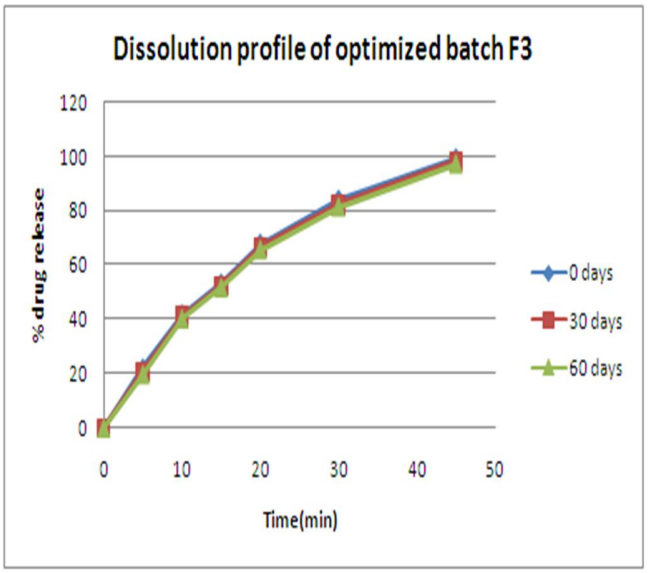

Fig 4: Dissolution profile at 40ºC 2ºC / 75% RH 5% of optimized batch F3.

Before the medicines effect actually begins and patients get released quickly .The present work was aimed to formulate the oral tablets ibuprofen by roll compactor at different auger speed.The absorption maxima (λ max) of ibuprofen was measured in phosphate buffer pH 7.2 and was found to be 221 nm. The drug and polymer were subjected to compatibility studies by IR and were found to be compatible to each other.Six batches (F_1 – F_6) were prepared by roller compactor method in the present study. The batches are prepared at different auger speed (6-7, 10-11, 14-15, 18-19, 23-24, 27-28 rpm). The tablets of all the batches were carried out weight variation, hardness, thickness, friability, disintegration time, assay and in vitro drug release and found to comply with the pharmacopoeial specification. The F_3 was selected as an optimized batch based on the results indicated.

The tablets of batch No. F_3 were subjected to accelerated stability studies at (40ºC ±□ 2ºC/ 75% RH ±5%) for 60 days. Analysis of the stability sample for all parameters (weight variation, hardness, disintegration time, thickness assay and in vitro dissolution study) at the end of 2 month complied with the standard specification limits.For the present study, it was concluded that the oral tablets of ibuprofen can be prepared successfully.From the result obtained in the present work, it was observed all the prepared batches fulfilled the official requirements. It was observed that the speed of auger affect the properties of flakes(compacts), granules and the tablets. The batch No. F_3 (14 - 15 rpm) was considered as the best formulation and compared with the marketed preparation. .

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