iJRASET
International Journal For Research in Applied Science and Engineering Technology

INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 10 **Issue:** VII **Month of publication:** July 2022

DOI: https://doi.org/10.22214/ijraset.2022.45399

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International Journal for Research in Applied Science & Engineering Technology (IJRASET)
ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 10 Issue VII July 2022- Available at www.ijraset.com

Synthesis, Purification, Identification of Aspirin and Evaluation on the Basis of Drug Release with Different Aspirin Formulation

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Abstract: ***Aspirin is 2-acetoxy benzoic acid. It is one of the derivatives of Benzoic acid. It is white crystalline fine powder. Aspirin is acetylated product. This drug is under non-steroidal anti-inflammatory drug in which they block cyclooxygenase receptor by inhibiting COX pathway.***

The drug can block the production of prostaglandin derivative. Therefore they can be used as an analgesic cum anti-inflammatory.

As we know prostaglandin is the inflammation mediator in human body, therefore, by blocking their production, Aspirin can used as pain killer as well as analgesic. It is also used as platelet aggregating agent. The present study focuses on the synthesis, purification, identification and evaluates better drug release with different aspirin formulation (tablet).

Keywords: ***Aspirin, Recrystallization, Wet granulation, compression method, Physical properties and Release Kinetics.***

I. INTRODUCTION

Aspirin is non steroidal anti inflammatory drugs as because it is having no steroidal nucleus. It is the acetylated derivative of Benzoic acid. The drug is basically white fine crystalline powdered.

Aspirin is used as analgesic cum anti-inflammatory drug.

It blocks cyclooxygenase (COX) receptor through COX pathway as this receptor is capable to form prostaglandins or PG derivatives. PG derivative is called as pain or inflammation mediator. Therefore by blocking those derivatives, Aspirin can inhibit the cyclooxygenase as well as they can be used for the treatment of pain [1].

Another one mechanism of the drug is based on their platelet aggregation.

Aspirin can also inhibit the production of thromboxane synthesis through COX pathway.

Thromboxane is important parameter related to platelet as well as coagulation pathway. By blocking thromboxane, platelets can be aggregated. Therefore, Aspirin can be used as blood thinner agent as well as it is used in the treatment of myocardial heart infraction and heart attack.

Aspirin is generally used as long term treatment with solid dosage formulations. Solid dosage forms are basically composed of solid compressed fine particles with different excipients, binders, etc. Solid dosage forms of Aspirin are having improved drug release property into the targeted site. In the category of solid dosage form, Aspirin tablet is usually prepared by weight granulation method. Besides main drug, some other excipients are mixed into it.

Different types of lubricants, glidants, binders, coating agents, polishing agents, coloring agents, flavoring agents, preservatives can be added to the main active drug for enhancement of the formulations consistency [2-4].

A. Binder

Binders are helps to hold the ingredients in a tablet each other and ensure that tablets can be formed with required mechanical strength.

Table 1: List of Binder used in the Tablet Formulation

Sl. No.	Binder types	Example
1.	Sugar (Saccharides, Polysaccharides)	Sucrose, Lactose, Starches, Liquid glucose
2.	Natural Binders	Tragacanth, Gelatin, Starch Paste,Pregelatinized Starch, Alginic Acid,Cellulose, Acacia, Gums , Mucilage
3.	Synthetic/Semisynthetic Polymer	Methyl Cellulose, Ethyl Cellulose,Hydroxy Propyl Methyl Cellulose (HPMC),Hydroxy Propyl Cellulose (HPC) Sodium Carboxy Methyl Cellulose (SCMC),Polyvinyl Pyrrolidone (PVP),Polyethylene Glycol (PEG) Polyvinyl Alcohols,Polymethacrylates,Xylitol , Sorbitol or maltitol

B. Lubricants

Lubricants are helps to prevents from clumping and sticking to the surface of upper and lower punches in tablet compression machine. They reduce friction between the two metal die and surface of the tablet. Lubricants helps to reduce ejection force and helps to ensure that tablets are ejected from die punches without cracking or breakage.

Table 2: Lubricants Used in the Tablet Formulation

Sl. No.	Lubricants	Example
1	Water Soluble	Boric acid, Sodium Chloride, Sodium Benzoate, Poly ethylene glycol
2	Water Insoluble	Magnesium Stearate, Talcum, Steraic acid,High melting wax, Maize starch,Colloidal Silicon dioxode

II. MATERIALS & METHODS

A. Materials

Salicylic acid, Acetyl chloride, Pyridine, Ethanol, Aspirin (synthesized in GCPT laboratory), Sodium acetate, microcrystalline cellulose, dibasic calcium phosphate, starch, PVP, sodium stearate, talc were procured from laboratory, GCPT, Krishnagar. All the chemicals and reagents were of analytical grade.

B. Instruments

Table 3: List of Instruments Used in Work

Sl. No.	Name of the Instrument	Manufacturer / Supplier
1	Digital weighing balance	KERRO, WENSAR
2	Digital pH Meter	EI (alpha 01)
3	Mechanical Sirrer	KOLKATA SCIENTIFIC & CO.
4	Water bath	KOLKATA SCIENTIFIC & CO.
5	Vacuum filter	DSZH
6	Hot air oven	KOLKATA SCIENTIFIC & CO.
7	Trinocular Research Microscope	OMAX
8	Melting point determining apparatus	INDOSATI
9	UV visible spectrophotometer	LABINDIA ANALYTICAL
10	Ball Mill	KOLKATA SCIENTIFIC & CO.
11	Double cone blender	KOLKATA SCIENTIFIC & CO.
12	Tablet compression machine	KARNAVATI
13	Tray dryer	KOLKATA SCIENTIFIC & CO.
14	Sieve	KOLKATA SCIENTIFIC & CO.
15	Tapped density determining machine	KOLKATA SCIENTIFIC & CO.
16	Vernier Caliper	KOLKATA SCIENTIFIC & CO.
17	Monsanto Hardness tester	KOLKATA SCIENTIFIC & CO.
18	Roche Friabilator	INDOSATI
19	Disintegration test apparatus	INDOSATI
20	Dissolution Apparatus	LABINDIA

ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 10 Issue VII July 2022- Available at www.ijraset.com

C. Synthesis of Aspirin

Salicylic acid is slowly dissolved in Pyridine in a round bottom flask and add acetyl chloride into the mixture with vigorous shaking. After addition of acetyl chloride round bottom flask is placed on boiling water bath for few minutes. Then allow the mixture cool under running water. After cooling add the content in cold water with vigorous shaking, the oil portion is separated from the solution. Aspirin is collected by filtration [5].

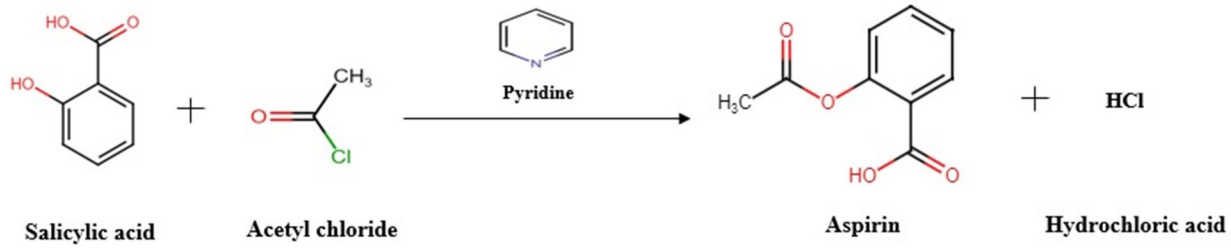

Figure 1: Synthetic route of aspirin

D. Recrystallization

Crude aspirin was transferred in an Erlenmeyer flask followed by adding sufficient ethanol and warm gently until all solid particles were dissolved. After dissolving immediately transfer the flask from heat and add cold water slowly. Cool the solution by using ice water bath. Aspirin crystal was formed and collects using vacuum filter. Dry recrystalline aspirin in hot air oven at 60^0C. After drying collect the raw material in air tight container and placed in desiccators [5].

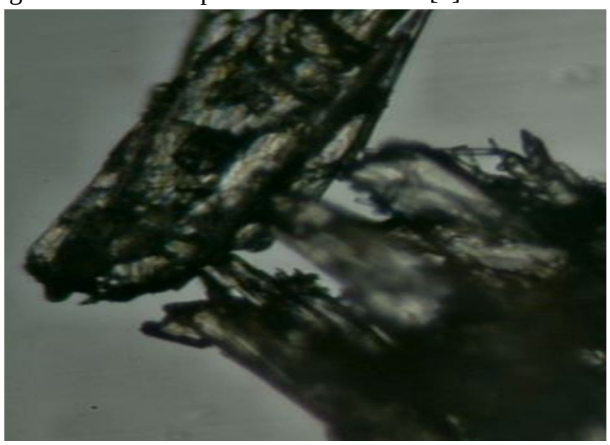

Figure 2: Crystalline structure of aspirin (5X / 0.10 lens)

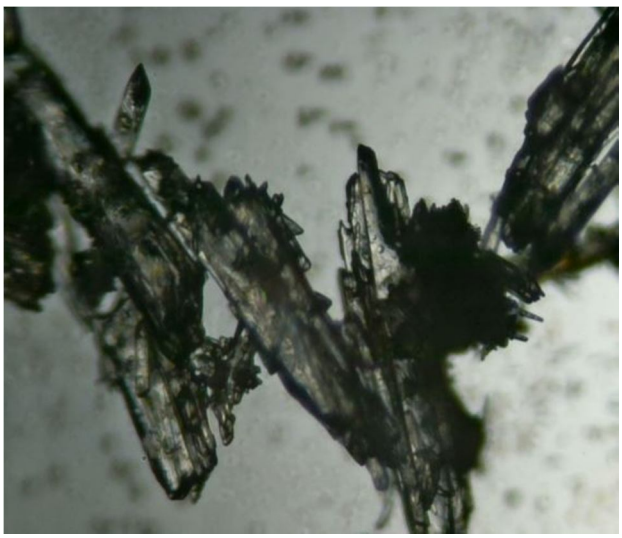

Figure 3: Crystalline structure of aspirin (10X / 0.25 lens)

E. Identification

1) The melting point was recorded as a range – the sample starts to liquefy at 133°C and completely melt at 135°C. Pure aspirin shows melting point at 135°C.

2) 0.5 gm of aspirin boiled with 10 ml of sodium hydroxide for 3 minutes and cool the mixture. After cooling 10 ml dilute sulphuric acid was added slowly. A white crystalline precipitate was produced. Then the solution is filtered. The filtrate was dissolved in sufficient amount of distilled water. A deep violet colour was formed after adding little amount of ferric chloride solution into it.

F. Calibration Curve

Aspirin was dissolve in acetate buffer at pH 4.5 and analyzed at 265 nm by spectrophotometrically and obtained data are given in Table 4.

Table 4: Absorbance data in respect of Concentration

Concentration X (µg/ml)	Absorbance Y (nm)
0	0
0.5	0.139
1	0.262
1.5	0.371
2	0.475
2.5	0.592
Regression Coefficient (R^2)	0.997

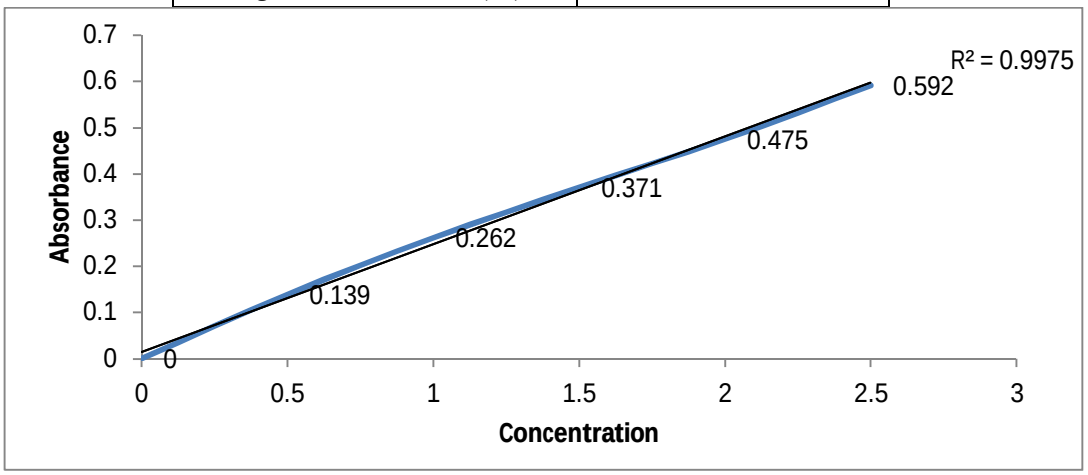

Figure 4: Concentration (µg/ml) vs Absorption plot

G. Method of Preparation of Aspirin Tablet

Three different batches of the tablet were prepared by wet granulation method and composition of each batches is given in Table 5.

Table 5: Formula Used to Prepare Tablet

Sl. No.	Ingredients (mg)	F1	F2	F3
1	Aspirin	300	300	300
2	Microcrystlline Cellulose	80	80	80
3	Dibasic Calcium Phosphate	50	50	50
4	Starch	25	25	25
5	Polyvinyl Pyrrolidone	qs	qs	qs
6	Sodium Stearate	0.5	0.5	1.0
7	Talc	2.5	5.0	10

The amount was calculated for preparation of 480 mg aspirin tablets which contain 300 mg Aspirin and 180 mg excipient like Microcrystalline cellulose, Dibasic calcium Phosphate Starch PVP, Sodium stearate and Talc. All API and excipients were mixed thoroughly and properly.

After Wet mass was prepared by slowly mixing API and excipient in starch paste wet mass was plunging and dried at 35 – 40^{0}C for six to seven hours in hot air oven.

After drying, the ratio of granules and powder has been fixed at 60:40 respectively by using a 20 and 40 mesh sieve. Dried granules were preserved in desiccators.

Tablet were prepared by using automatically operated tablet compression machine having 12 mm caplet shaped punch with 'KEL' printed on one face and during tablet preparation little amount of lubricants was added in granules to avoid friction between the two metal die and surface of the tablet.

Compressed tablet of different formulation were stored at room temperature in airtight amber colour container for future study [6-11].

III. RESULTS & DISCUSSION

A. Evaluation of Granules

All pre-compression parameter like bulk density, tapped density; Carr's Index; Hauser's ratio and angle of repose were evaluated as per specified in Indian Pharmacopoeia, 2018.

Table 6: Pre-Compression Properties of Granules

Properties	Batch 1	Batch 2	Batch 3
Bulk density (g/cm3)	0.389	0.385	0.383
Tapped density (g/cm3)	0.440	0.437	0.435
Carr's index	11.59	11.13	11.95
Hausner's ratio	1.131	1.135	1.141
Angle of repose (degrees)	28.81	28.37	27.92

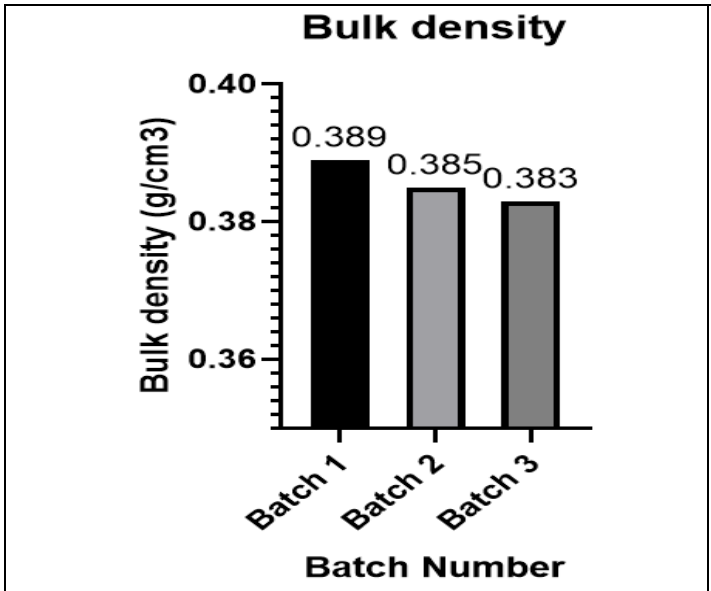

Figure 5: Graphical representation of bulk density between three batches

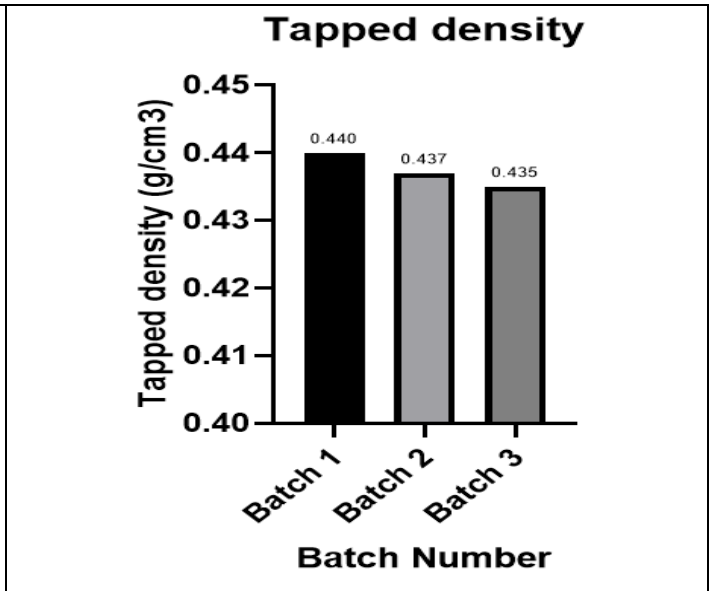

Figure 6: Graphical representation of Tapped density between three batches

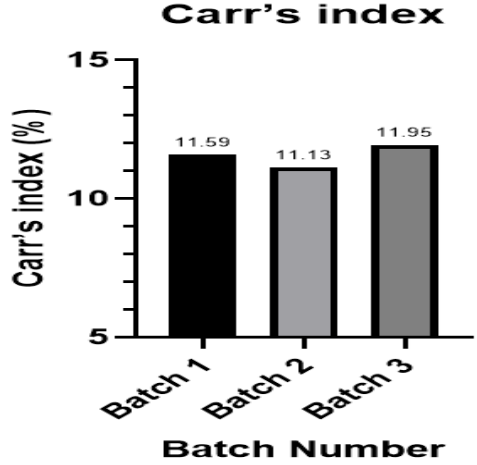

Figure 7: Graphical representation of Carr's Index between three batches

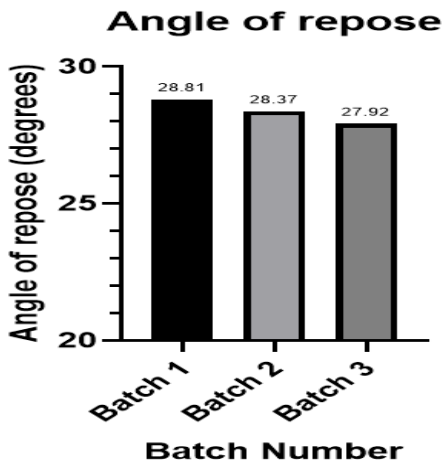

Figure 8: Graphical representation of Angle of repose between three batches

B. Evaluation of Tablets

1) Length (In mm): (Used Vernier Caliper)

Table 7: Length for formulated Tablet

Ten tablets were collect randomly from all three batches and measured length of tablet using Vernier Caliper [6]. Determine the mean value and standard deviation for all three batches.

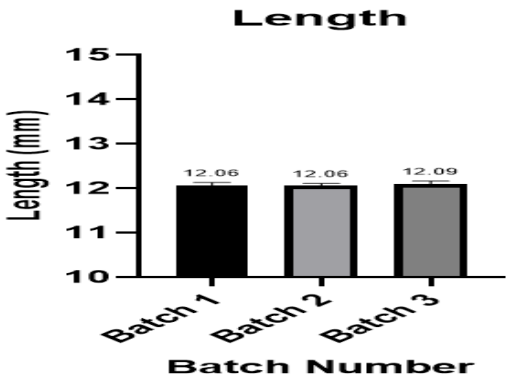

Figure 9: Graphical representation of mean **Length** of Tablet between three batches

→

Batch No.	**Observation**					**Range**	**Mean**	**SD**
Batch No. 1	1) 12.1	2) 12.0	3)12.1	4)12.2	5)12.1	12.0 – 12.2	12.1	0.069921
	6)12.0	7)12.0	8)12.0	9)12.1	10)12.0			
Batch No. 2	1) 12.0	2) 12.1	3)12.1	4)12.1	5)12.1	12.0 – 12.1	12.1	0.05164
	6)12.0	7)12.1	8)12.0	9)12.1	10)12.0			
Batch No. 3	1) 12.1	2) 12.1	3)12.1	4)12.0	5)12.1	12.0 – 12.2	12.1	0.073786
	6)12.1	7)12.2	8)12.2	9)12.0	10)12.0			

2) Breadth (In mm): (Used Vernier Caliper)

Table 8: Breadth for formulated Tablet

Ten tablets were collect randomly from all three batches and measured Breadth of tablet using Vernier Caliper [6]. Determine the mean value and standard deviation for all three batches.

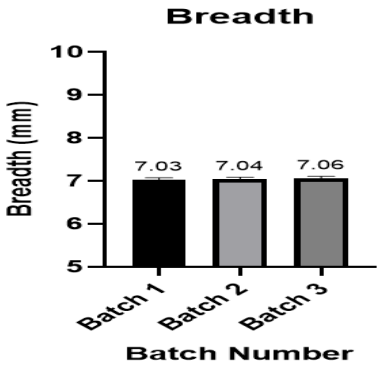

Figure 10: Graphical representation of mean **Breadth** of Tablet between three batches

→

Batch No.	Observation					Range	Mean	SD
Batch No. 1	1) 7.0	2) 7.1	3) 7.1	4) 7.1	5)7.0	7.0 – 7.1	7.1	0.048305
	6) 7.0	7) 7.0	8) 7.0	9) 7.0	10) 7.0			
Batch No. 2	1) 7.1	2) 7.1	3) 7.0	4) 7.0	5)7.0	7.0 – 7.1	7.1	0.05164
	6) 7.1	7) 7.0	8) 7.1	9) 7.0	10) 7.0			
Batch No. 3	1) 7.0	2) 7.1	3) 7.1	4) 7.1	5)7.1	7.0 – 7.1	7.1	0.05164
	6) 7.1	7) 7.0	8) 7.1	9) 7.0	10) 7.0			

3) Thickness (In mm): (Used Vernier Caliper

Table 9: Thickness for formulated Tablet

Ten tablets were collect randomly from all three batches and measured Thickness of tablet using Vernier Caliper [6]. Determine the mean value and standard deviation for all three batches.

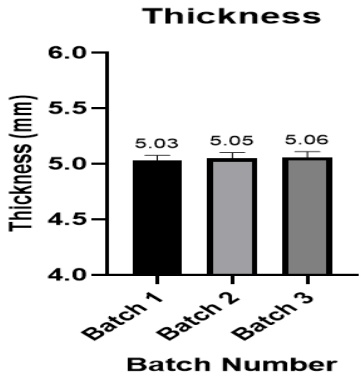

Figure 11: Graphical representation of mean **Thickness** of Tablet between three batches

→

Batch No.	Observation (in mm)					Range	Mean	SD
Batch No. 1	1)5.0	2)5.0	3)5.0	4)5.0	5)5.1	5.0 - 5.1	5.03	0.048305
	6)5.1	7)5.0	8)5.0	9)5.0	10)5.1			
Batch No. 2	1)5.1	2)5.0	3)5.0	4)5.0	5)5.0	5.0 - 5.1	5.05	0.052705
	6)5.1	7)5.1	8)5.0	9)5.1	10)5.1			
Batch No. 3	1)5.0	2)5.1	3)5.1	4)5.0	5)5.1	5.0 - 5.1	5.06	0.05164
	6)5.1	7)5.0	8)5.1	9)5.1	10)5.0			

4) Hardness (kg/cm^2): (Used Monsanto Hardness Tester)

Table 10: Hardness for formulated Tablet

Hardness is very essential parameter for tablet. Monsanto Hardness tester was used to determine tablet hardness [6].

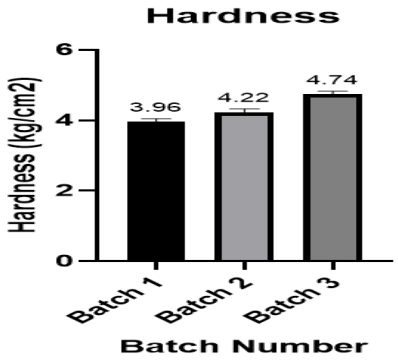

Figure 12: Graphical representation of mean **Hardness** of Tablet between three batches

→

Batch No.	Observation (in kg/cm^2)					Range	Mean	SD
Batch No. 1	1)3.9	2)4.1	3)4.0	4)3.9	5)3.9	3.9 – 4.1	3.96	0.089443
Batch No. 2	1)4.2	2)4.4	3)4.2	4)4.1	5)4.2	4.1 – 4.4	4.22	0.109545
Batch No. 3	1) 4.6	2)4.8	3)4.7	4)4.8	5)4.8	4.6 – 4.8	4.74	0.089443

5) Weight variation (in mg): (Electronic Digital Balance)

Table 11: Weight variation for formulated Tablet

Electronic Digital Balance was used to evaluate for weight variation of tablet as per Indian Pharmacopoeia, 2018, Monograph. Twenty tablets were collect randomly from all three batches and calculate the range, mean and the standard deviation.

Figure 13: Graphical representation of mean **Weight variation** of Tablet between three batches

→

Batch No.	Observation (in mg)					Range (mg)	Mean	SD
Batch No. 1	1) 480	2) 480	3) 483	4) 485	5)476	475 - 488	481.55	0.358
	6) 482	7) 488	8) 484	9) 488	10)477			
	11) 478	12) 479	13) 480	14) 480	15) 485			
	16) 485	17) 475	18) 481	19) 482	20) 483			
Batch No. 2	1) 481	2) 485	3) 485	4) 475	5) 480	475 - 491	482.9	0.326
	6) 480	7) 483	8) 489	9) 483	10) 490			
	11) 479	12) 481	13) 490	14) 491	15) 481			
	16) 476	17) 480	18) 478	19) 486	20) 485			
Batch No. 3	1) 484	2) 488	3) 489	4) 485	5) 481	473 - 493	483.85	0.303
	6) 478	7) 475	8) 491	9) 475	10) 486			
	11) 491	12) 473	13) 478	14) 493	15) 482			
	16) 482	17) 481	18) 490	19) 490	20) 485			

6) Friability (w/w%): (Used Roche Friabilator)

Table 12: Friability for formulated Tablet

Roche Friabilator was used to determine the friability of aspirin tablet in the laboratory. As per Indian Pharmacopoeia, 2018, monograph speed of the friabilator was 25 rotations per minute. Test was performed in triplicate for each batch [11].

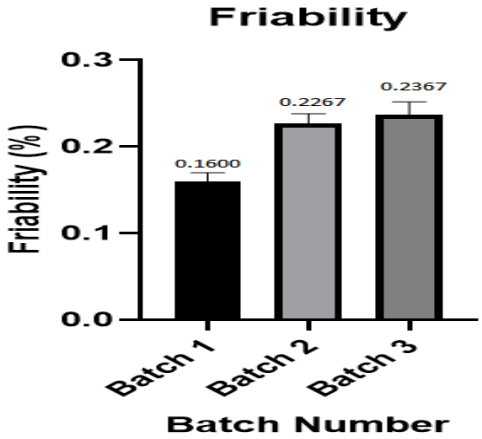

Figure 14: Graphical representation of mean **Weight variation** of Tablet between three batches

→

Observation	Batch 1	Batch 2	Batch 3
1	Tablet taken: 14 Wt. before friability: 6.742 g Wt. after friability:6.732 g % weight loss: 0.15	Tablet taken: 14 Wt. before friability: 6.761 g Wt. after friability:6.746 g % weight loss: 0.22	Tablet taken: 14 Wt. before friability: 6.774 g Wt. after friability:6.759 g % weight loss: 0.22
2	Tablet taken: 14 Wt. before friability: 6.722 g Wt. after friability: 6.710 g % weight loss: 0.17	Tablet taken: 14 Wt. before friability: 6.755 g Wt. after friability:6.739 g % weight loss: 0.24	Tablet taken: 14 Wt. before friability:6.783 g Wt. after friability: 6.766 g % weight loss: 0.25
3	Tablet taken: 14 Wt. before friability: 6.698 g Wt. after friability: 6.687 g % weight loss: 0.16	Tablet taken: 14 Wt. before friability: 6.729 g Wt. after friability:6.714 g % weight loss: 0.22	Tablet taken: 14 Wt. before friability: 6.714 g Wt. after friability: 6.698 g % weight loss: 0.24

7) Disintegration Time (In Minutes):

Table 13: Disintegration Time for formulated Tablet

Disintegration test were performed as per IP monograph. Temperature of water at 37 ± 2 °C and frequency of rotation was 28 to 32 cycles per minute. Test was performed in triplicate for each batch.
No. of Tablets Taken: 6 tablets for each batch
Temperature of Water: 37^0C ± 2^0C [12-13]

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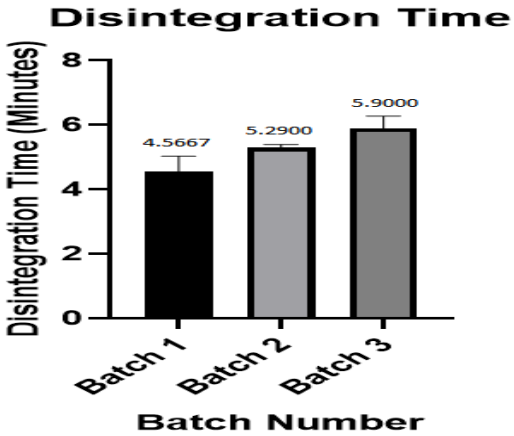


Figure 15: Graphical representation of mean Disintegration time between three batches

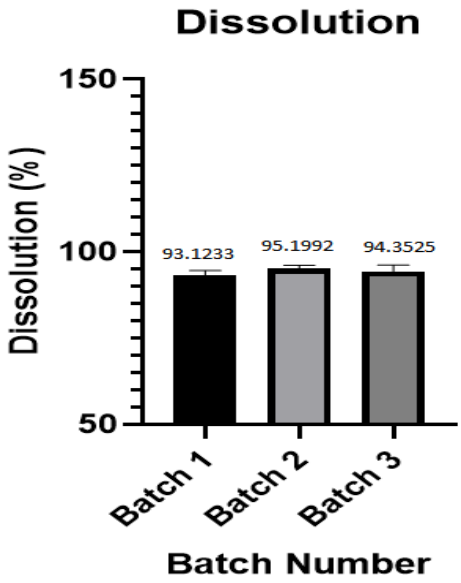
Batch	Observation 1	Observation 2	Observation 3
Batch 1	4 min. 35 sec	5 min 10 sec	4 min 25 sec
Batch 2	5 min 25 sec	5 min 41 sec	5 min 21 sec
Batch 3	6 min 08 sec	5 min 47 sec	6 min 15 sec

8) Dissolution

Table 14: Dissolution Result for formulated Tablet

Dissolution Apparatus : Apparatus 2
Dissolution Media : Acetate buffer
pH of Dissolution Media : 4.5
Temperature of Dissolution Media : $37^0C \pm 0.5^0C$
Time : 45 Minutes
RPM : 50
Wavelength : 265 nm [14]

Figure 16: Graphical representation of mean Dissolution test data between three batches



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Batch No.	Observation 1		Observation 2	
Batch 1	Tablet 1	91.22%	Tablet 1	93.33%
	Tablet 2	92.28%	Tablet 2	92.98%
	Tablet 3	92.63%	Tablet 3	90.87%
	Tablet 4	93.68%	Tablet 4	95.08%
	Tablet 5	94.38%	Tablet 5	91.57%
	Tablet 6	95.43%	Tablet 6	94.03%
	Range: (91.22% - 95.43%) D Value: Not less than 70%		Range: (90.87% - 95.08%) D Value: Not less than 70%	
Batch No.	Observation 1		Observation 2	
Batch 2	Tablet 1	94.03%	Tablet 1	94.73%
	Tablet 2	95.78%	Tablet 2	95.08%
	Tablet 3	96.49%	Tablet 3	94.73%
	Tablet 4	95.08%	Tablet 4	95.78%
	Tablet 5	94.38%	Tablet 5	96.49%
	Tablet 6	96.14%	Tablet 6	93.68%
	Range: (94.03% - 96.49%) D Value: Not less than 70%		Range: (93.68% - 96.49%) D Value: Not less than 70%	
Batch No.	Observation 1		Observation 2	
Batch 3	Tablet 1	97.19%	Tablet 1	91.92%
	Tablet 2	96.49%	Tablet 2	96.84%
	Tablet 3	92.28%	Tablet 3	92.63%
	Tablet 4	93.68%	Tablet 4	95.08%
	Tablet 5	93.33%	Tablet 5	94.03%
	Tablet 6	95.43%	Tablet 6	93.33%
	Range: (92.28% - 97.19%) D Value: Not less than 70%		Range: (91.92% - 96.84%) D Value: Not less than 70%	

9) Assay

20 tablets were powdered and accurately weight 50 mg equivalent of aspirin from powdered tablet. Transfer the powdered sample in 100 ml volumetric flask contain 25 ml phosphate buffer at pH 7.2. Dissolve the powdered drug and adjust the volume upto 100 ml with phosphate buffer. Filter the solution. 1ml filtrate was diluted and analyzed at 265 nm [15] by using UV-Vis spectrophotometer. Drug content of each batch was estimated triplicate from previously prepared standard curve.

Batch	Observation 1	Observation 2	Observation 3
Batch 1	298.86 (99.62%)	297.75 (99.25%)	296.61 (98.87%)
Batch 2	296.61 (98.87%)	297.75 (99.25%)	298.86 (99.62%)
Batch 3	297.75 (99.25%)	297.75 (99.25%)	298.86 (99.62%)

Table 15: Assay of Formulated Aspirin Tablets

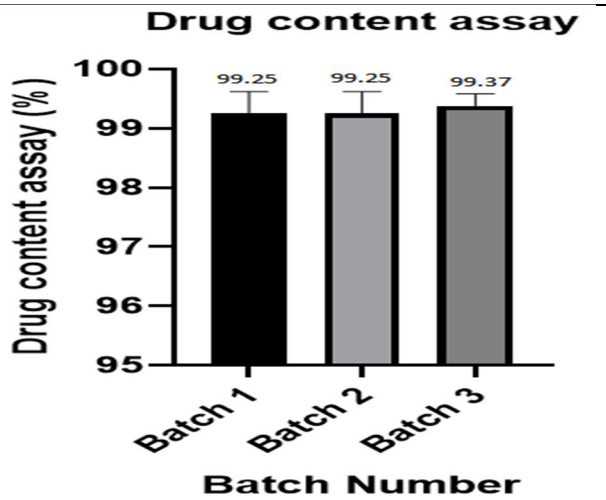

Figure 17: Graphical representation of mean drug content between three batches

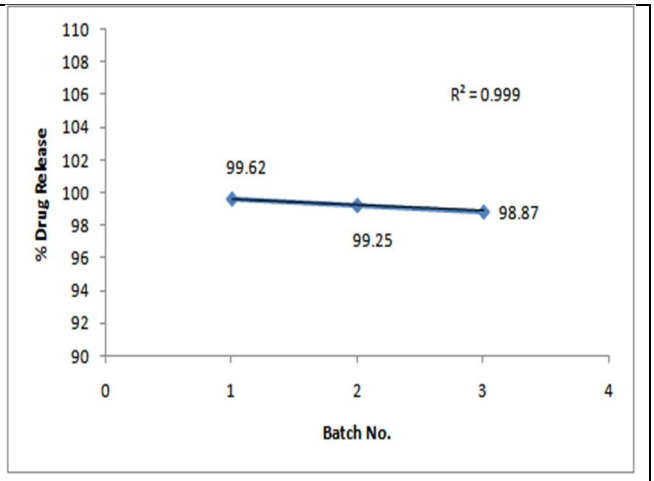

Figure 18: Graphical representation of individual drug content batch one

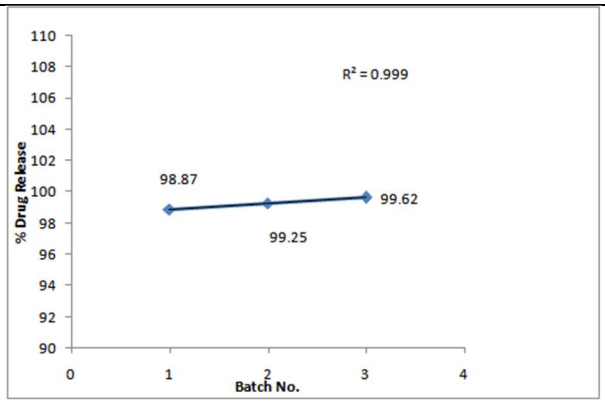

Figure 19: Graphical representation of individual drug content batch two

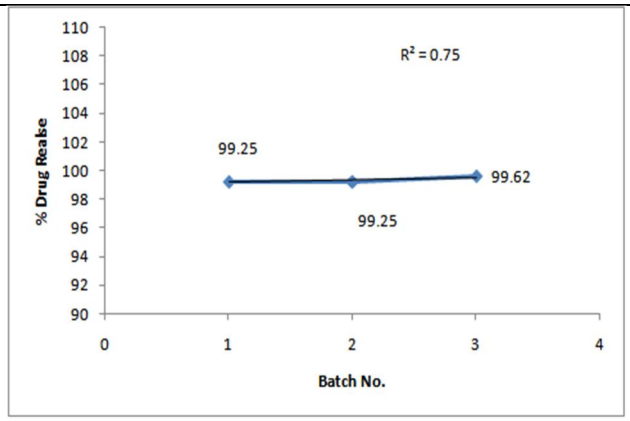

Figure 20: Graphical representation of individual drug content batch three

IV. CONCLUSION

Aspirin tablets were produced by using crude aspirin which is synthesized and purified by in-house method in college laboratory. Total no. of three batches tablets containing aspirin were prepared by compression methods. Different kinds of tests like weight variation, length-breadth-thickness measurement, hardness checking, Friability, Disintegration, Dissolution and assay for determining physicochemical parameters of prepared aspirin tablets were performed thoroughly. All three tablet batches were successfully passed after performing those tests. Tablet batch no. two was having the best results among three batches in respect of drug release.

Conflict of Interest: Nil

V. ACKNOWLEDGEMENT

Authors would gratefully thanks to the library department and laboratory technicians of Global College of Pharmaceutical Technology, Nadia, West Bengal, India for successfully completing this research work.

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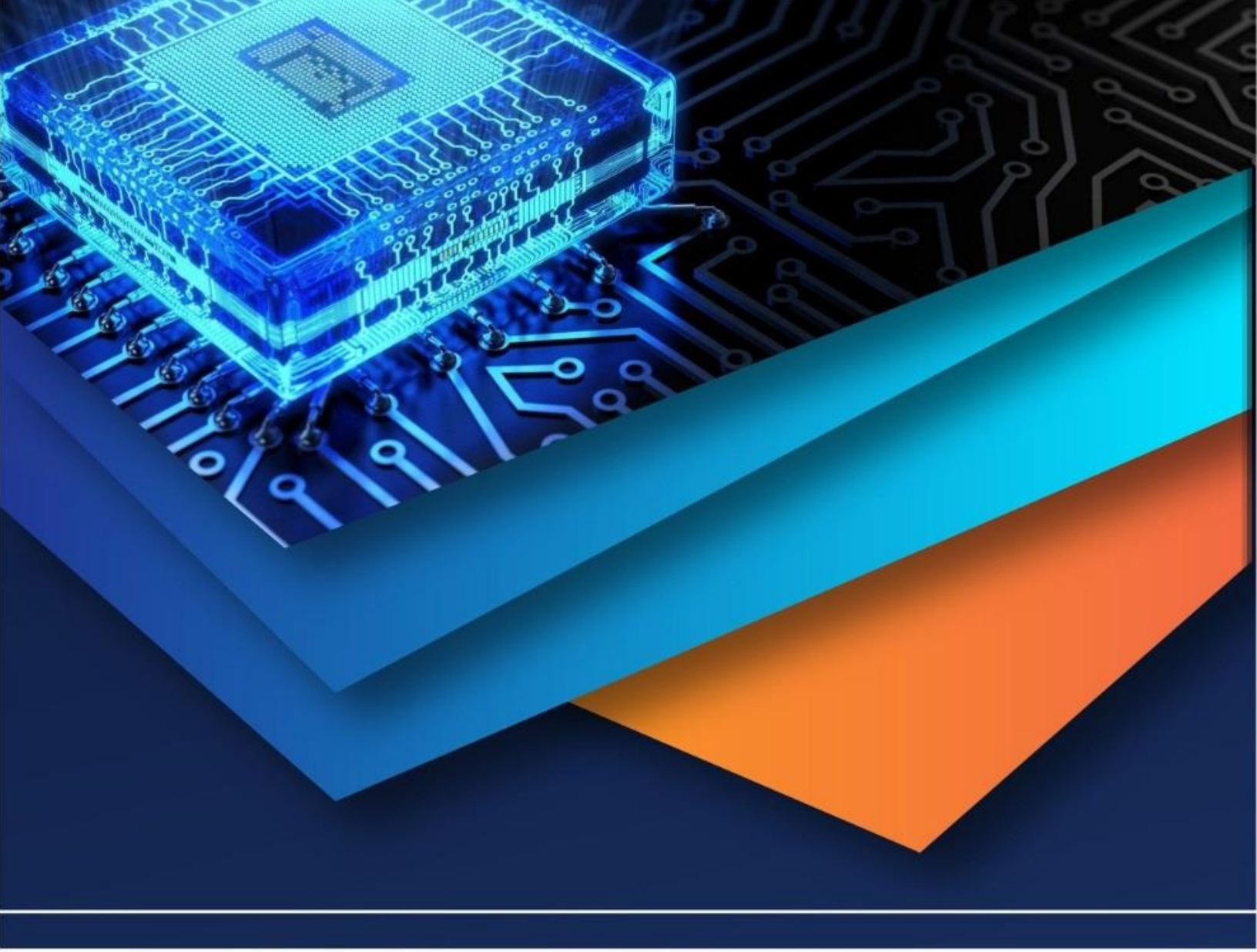

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