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Highlights

- Anti TB Drug Non-Adherence
- Comparative Quality Evaluation
- Tablet of Sodium Feredetate
- Governmental Health Institutions

Discovering Thoughts, Inventing Future

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Towering Levels of Transaminases; Acute Hepatitis versus Severe Leptospirosis: A Case with Review of Literature

By Omkarr De Hazra, Rajdeep Basu, Sukalpa Chaudhuri & Soumitra Ghosh

Abstract- Leptospirosis is a disease caused by leptospira a spirochete which involves multiple organs. Towering high transaminase levels in the severe form of the disease are unheard of till date. Thus we are going to present the story of a 32-yearmale, with an initial SGPT level of 3520 U/lit who came up with the diagnosis of leptospirosis and recovered due to timely initiation of antimicrobials and hemodialysis.

Keywords: *severe leptospirosis, marked transaminitis, multi-organ failure, early hemodialysis.*

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Towering Levels of Transaminases; Acute Hepatitis versus Severe Leptospirosis: A Case with Review of Literature

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Keywords: severe leptospirosis, marked transaminitis, multi-organ failure, early hemodialysis.

I. Introduction

Leptospirosis is a zoonosis, which is an emerging public health problem usually associated with the three 'R's, i.e. rats, rains, rice fields. Clinically it has a wide spectrum of manifestations from a mild form to severe, icterohemorrhagic fever known as Weil's disease. The later, presents as jaundice, with hepatic and renal failure, pulmonary alveolar hemorrhage, myocarditis, rhabdomyolysis in some cases even with CNS manifestations.[1] The liver derangement is frequently expressed as high bilirubin and a moderate transaminitis.[2] In South-east Asia, the incidence of Leptospirosis has been estimated as 0.1-1/100000 to 10-100/10000 depending on the climatic variations.[3] In India, the endemic states are, Gujarat, Maharashtra, Kerala, Tamil Nadu and Andaman and the Nicobar Islands.[4] Few cases have also been reported from West Bengal. [5]

Here we are reporting a case of severe leptospirosis with unusually raised transaminases along with multi-organ failure and successful response to early and appropriate treatment.

II. The Case

32 year, male, a non-alcoholic, non-diabetic, non-hypertensive, admitted with complaints of high-grade intermittent fever for last ten days with no chill and rigor, recurrent vomiting and diarrhea for about last six days, yellowish discoloration of urine for five days. Urine output was adequate. There was no significant drug history.

On examination, GCS E2V1M4, BP 120/80, Pulse rate 108/min, icterus present. The patient was drowsy and disoriented, the bilateral planter were extensor, bilateral pupils were mid-dilated and sluggishly reacting to light, neck rigidity was present, and Kernig's sign was positive. Rest of the systemic examinations was unremarkable.

The patient had a TLC of 18400/mm3, Total bilirubin 8.45 mg/dl, SGPT 3520 U/lit, Creatinine 2.4 mg/dl on day 1. After that, the patient had an episode of hematemesis and multiple episodes of malena. The patient was resuscitated and transfusion of three units of packed RBCs. At that time, Anti HAV IgM, Anti HBsAg, Anti HCV IgM, Anti HEV IgM were non-reactive. Serum CPK was 98 U/lit. Routine urine examination showed Albumin ++, Pus cell 8-10/hpf, plenty of RBCs. Concurrent USG of the abdomen revealed altered renal cortico-medullary differentiation suggestive of renal parenchymal disease with normal kidney size. A chest X-ray was also obtained which was unremarkable.

A provisional diagnosis of severe leptospirosis was made, and treatment was initiated with injection ceftriaxone 1 gram twice daily. On day 3 of hospital stay there was a fall in the trend of liver enzymes but a marked derangement of the renal profile (Hb 7.8 g/dl, TLC: 19700/ mm3 {N80 L15}, total bilirubin: 15 mg/dl ALP: 56 U/lit, ALT: 450 U/lit, AST: 135 U/lit, serum urea 203 mg/dl serum creatinine 7.2 mg/dl, serum sodium 133 mmol/lit, serum potassium 3.1 mmol/lit). On day four onwards, the patient developed oliguria with signs of volume overload. Early initiation of dialysis was considered, and after receiving three cycles of hemodialysis, blood picture showed progressive improvement of renal status in the form of urine volume and decreasing serum urea, creatinine as well. Meanwhile, serology for leptospirosis came with IgM positive.

The treatment was continued for two weeks, and the renal and hepatic impairment showed progressive reversal towards normal, and the patient was discharged in a hemodynamically stable condition at one month.

III. Discussion

Leptospirosis is characterized by the development of endothelial injury, and inflammatory infiltrates in the vessel wall. Clinically the manifestations range from more frequent, petechiae to various degrees

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of organ involvements, markedly in the liver, kidneys, heart, and lungs. The liver involvement is noted as, intrahepatic cholestasis, Kupffer cells hypertrophy, and hyperplasia without any significant structural damage. Whereas interstitial nephritis, renal tubular damage by cellular infiltration and minor changes in the glomeruli, are the chief findings in the renal histology. Among other organs involvements, interstitial myocarditis, pericardial effusion, pulmonary hemorrhages, focal necrosis in muscle fibres by infiltration of inflammatory cells, are common pathology noted.[6] Meningeal involvement is also reported.[7]

In our case, the patient suffered from hepatic, renal, vascular endothelial and meningeal involvement as evident from clinical and laboratory pictures. Though the initial higher level of transaminases brought confusion between the actual diagnosis and viral hepatitis, negative viral serology for hepatotropic viruses and positivity of leptospiraIgM confirmed our clinical suspicion. From the literature, we found a case, reported by NedaNozari[8] with almost similar liver enzymes still they were much higher here.

Leptospirosis accounts for 1.03 million cases and 58,900 deaths each year globally.[9] In India, according to 2005 data, the number of reported cases was 2355 and deaths were 167.[4]

The antibiotic therapy includes doxycycline for mild disease whereas intravenous penicillin or third-generation cephalosporin (ceftriaxone or cefotaxime) is prescribed for the severe form of leptospirosis.[10] Early initiation of hemodialysis has a crucial role in severe renal involvement [11].

In the above-mentioned case, the patient improved on Ceftriaxone and three sessions of hemodialysis with resolving renal and hepatic impairments and increasing urine output with no signs of meningeal impairment, no sign of bleeding. Finally, he was discharged in a stable condition and was instructed to follow up on an OPD basis. After four months of regular follow-up, he is leading a healthy life.

Multi-organ failure with transaminitis is well known in severe leptospirosis. Nonetheless, this marked rise in transaminase levels as shown here is being reported for the first time in medical literature to the best of our knowledge.

IV. Conclusion

Though such high transaminase levels are rarely associated with severe forms of leptospirosis, the possibility must be considered once the usual causes are ruled out. For deciphering the exact pathophysiology further scientific research is necessitated on this ground.

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Formulation and Evaluation of Taste Masked Tablet of Sodium Feredetate: Taste Masking Approach

By M. B. Vyas, K.S. Parekh, R. G. Bhura, M. Patel, Dr. J.L. Desai & Dr. S. K. Shah
Sardar Patel College of Pharmacy

Abstract- Iron deficiency is the most common cause of anemia worldwide. In India, 30% adult males, 45% adult females, 80% pregnant females and 60% children have iron deficiency. In our country important causes include poor dietary intake and bioavailability, increased requirement during pregnancy, lactation and growth spurt, blood loss due to menstrual disorders and hook worm infestation. So, oral supplementation with iron preparations is frequently required. Sodium Feredetate is an ant anemic agents and iron supplement drug which is widely used in iron deficiency anemia. It is having metallic taste associated with the iron. Thus, in the work under taken, attempts were made to mask the taste of drug by inclusion complex with **β**-cyclodextrin and fizzy chewable tablets were formulated.

Experimental work: Taste masking of drug was done by inclusion complex using **β**-cyclodextrin in molar ratio of 1:1, 1:2, and 1:3. Inclusion complex was done by kneading method and physical mixture of drug and **β**-CD. Different formulations were prepared using various concentrations of sweetener, binders and disintegrate by direct compression method. The formulations were evaluated for weight variation, hardness, friability, drug content, in vitro disintegration time and in vitro dissolution studies etc. The prepared tablets were characterized by FT-IR, DSC. The taste masking studies was done by with the help of E-Tongue.

Keywords: sodium feredetate, chewable tablet, taste masking, β-cyclodextrin, electronic tongue.

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Result and Discussion: Best taste masked complex was found with kneading method in 1:2 ratio. Disintegration time and release of drug of tablet prepared by using different concentration of diluent and sweetener showed thickness 16.0±0.05 mm, friability 0.13±0.01%,weight variation 1149.33±2.30 mgHardness 6.1±0.2kg/cm2,Disintegrating time 7.73±0.20 min, *In vitro* drug release 96.33%in 0.1 N HCl (900 ml) which were best results and within standard limits including acceptable taste.

Conclusion: Among all the formulations prepared with various concentration of mannitol, formulation F8 containing 345 mg of mannitol showed maximum release of drug in 40 min and disintegrate within the 7.73 min with good mouth feel which was considered as best formulation.

Keywords: sodium feredetate, chewable tablet, taste masking, β-cyclodextrin, electronic tongue.

I. Introduction

Iron deficiency is the most common cause of anemia worldwide. In India, 30% adult males, 45% adult females, 80% pregnant females and 60% children Have iron deficiency. In our country important causes include poor dietary intake and bioavailability (most common), increased requirement during pregnancy, lactation and growth spurt, blood loss due to menstrual disorders and hook worm infestation. So, oral supplementation with iron preparations is frequently required [1-2].The oral route of drugs administration is the most important method of administrating drugs for systematic effects. Except in case of insulin therapy, the parenteral route is not routinely used for self-administration of medication. It is possible that at least 90% of all drugs used to produce systemic effects are administered by oral route. When a new is discovered, one of the first questions a pharmaceutical company asks is whether or not the drug can be effectively administered for its intended effect by oral route. If it cannot, the drug is primarily relegated to administration in a hospital setting or physician's office. If patient self-administration cannot be achieved, the sales of the drug constitute only a small fraction of what the market would be otherwise [8-10]. These tablets are intended to disintegrate smoothly in mouth at a moderate rate either with or without actual chewing; characteristically chewable tablets have a smooth texture upon disintegration, are pleasant taste and leave no bitter or unpleasant taste [11-12]. Taste is the ability to detect the flavor of substances like food, drugs etc. Taste is now becoming an important factor governing the patient compliance. It gained importance as the most of the drugs are administered through oral route. Administration of unpalatable drugs is hampered by their unpleasant taste particularly in case of pediatric and geriatrics. Various methods like coating, inclusion complexes, microen capsulation, granulation, adsorption, prod rug approach, addition of flavors and sweeteners, ion exchange resins are used for masking the taste of obnoxious drugs. However, there is no universal method for taste masking. Each method offers specific advantages and applications. One method is not suitable for taste masking all the obnoxious drugs. Several parameters like extent of bitter taste, dose, dosage form and type of the patient influence, the method to be used for masking the taste of the bitter drugs. Evaluation of taste masking by electronic tongue is a recent innovation. Advatab, Microcap, Liquitard, Kleptose, Formulplex and Formulcoat are the new

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taste masking technologies, which are found to be better than existing ODT[13].Cyclodextrin are cyclic (α-1, 4)-linked oligosaccharides of α-D- glucopyranose, containing a relatively hydrophobic central cavity and hydrophilic outer surface. Owing to lack of free rotation about the bonds connecting the glucopyranose units, the cyclodextrin are not perfectly cylindrical molecules but the toroidal or cone shaped. Based on this architecture, the primary hydroxyl groups are located on the narrow side of the cone shape, while the secondary hydroxyl groups are located on the wider edge. During the past two decades, cyclodextrin and their derivatives have been of considerable interest in the pharmaceutical field because of their potential to form complexes with a variety of drug molecules. Cyclodextrin are used to increase the solubility of water insoluble drug through inclusion complexes formulation. The hydrophobic cavity of cyclodextrin is capable of trapping a variety of molecules within to produce inclusion complexes. Many advantages of drugs complex with cyclodextrin have been reported in scientific literature which includes-increased solubility, enhanced bioavailability, improved stability, masking of bad test or odor, reduced volatility, transformation of liquid or gas into solid form reduced side effect, and the possibility of a drug release system etc[19-21].

II. Material and Methods

a) Material

Sodium Feredetate, β-Cyclodextrin, Sodium Bicarbonate, Citric acid Anhydrous, Magnesium Stearate, Vanilla Flavour, Aspartame, Mannitol, Talc, Microcrystalline Cellulose (Avicel 102) was obtained as a gift sample from Pride drugs & Pharma (P)Ltd. Vodo dara, India, Lincoln pharmaceuticals Ltd. Ahemdabar, India. Other AR grade chemicals were purchased.

III. Preparation Inclusion Complexes

a) Physical mixture or grinding method

Sodium Feredetate and β-Cyclodextrin were accurately weighed in different molar ratios viz. 1:1, 1:2, 1:3 and 1:5 separately. Then it was mixed and blended thoroughly by triturating in a mortar for about 10 minutes. The powder mixtures were then pulverized through sieve no 80 and stored in desiccators till further use.

b) Kneading method

The inclusion complex of drug with β-Cyclodextrin was prepared by wetting the physical mixture of Sodium Feredetate: β-Cyclodextrin in the different molar ratios viz. 1:1, 1:2, and 1:3 in a mortar with water. Then kneaded the wet mixture thoroughly with a pestle to obtain a paste like consistency. The paste was then dried under vacuum at room temperature, pulverized by passing through sieve no 80 and stored in a desiccator till further use.

IV. Procedure of Evaluation of Taste by Electronic Tongue

The inclusion complexes were dissolved in purified water. All testing beakers contained 50ml of solution. When the reference electrode and sensors were dipped into a beaker containing a test solution, a potentiometric difference between each individually coated sensor with the Ag/Ag Cl reference electrode was measured and recorded by the E-Tongue software. Each sample was analyzed for 20sec. The liquid sensors and the reference electrode were then rinsed with purified water for 10sec after each sample analysis. Using well-conditioned sensors, each sample was usually tested five times by the rotation procedure.

V. Formulation of Chewable Tablet Containing a Complex of Sodium

a) Feredetate with β-cyclodextrin

i. *Direct Compression Method*

Direct compression technique was used to formulate chewable tablet of Sodium Feredetate. Formulations compositions of chewable tablets are given in Table 6.2 All raw materials used were passed through a sieve no. 60 prior to mixing. Prepared drug: β-CD complex, sodium bicarbonate, citric acid, mannitol, MCC, was mixed for 15 minutes. Talc and magnesium stearate were added lastly before compression and mixed properly. The final mixture, ready for compression was directly compressed into tablets using a single-punch tablet machine equipped with 16 mm flat punch.

VI. Evaluation of Tablets

a) Pre-compression parameters

Prior to the compression, the powder blends of various batches were evaluated for their bulk and tapped density and from these values compressibility index and Hausner's ratio were calculated. While the flow properties of the powder bled were accessed from the angle of repose. The evaluation parameters were studied before and after addition of lubricants to check and compare the inherent flow properties of powders.

Angle of repose (θ)

The frictional forces in a loose powder or granules can be measured by the angle of repose. This is the maximum angle possible between the surface of a pile of powder or granules and the horizontal plane.

$\tan \theta = h/r$

$\theta = \tan^{-1}(h/r)$

Where, θ is the angle of repose
H is the height
R is the radius

The granules were allowed to flow through the funnel fixed to a stand at definite height. The angle of

repose was then calculated by measuring the height and radius of the heap of granules formed.

b) Bulk density and Tapped Density

Both loose bulk density (LBD) and tapped bulk density (TBD) were determined. The accurately weighed amount of sample taken in a 25ml measuring cylinder of Borosil measured/recorded the volume of packing and tapped 100 times on a plane hard wooden surface and tapped volume of packing recorded and LBD and TBD calculated by following formula:

$$\text{LBD (Loose Bulk Density)} = \frac{\text{Mass of Powder}}{\text{Volume of Packing}}$$

$$\text{TBD (Tapped Bulk Density)} = \frac{\text{Mass of Powder}}{\text{Tapped Volume of Packing}}$$

c) Hausner's ratio

The Hausner's ratio is a number that is correlated to the flow ability of a powder or granular material.

Hausner's ratio: TD / BD

d) Compressibility index

Percent compressibility of powder mix was determined by Carr's compressibility index calculated by following formula.

$$\text{Carr's Index\%} = \frac{\text{TBD–LBD x100}}{\text{TBD}}$$

e) Post-compression parameters

i. *Shape and color of tablets*

Uncoated tablets were examined under a lens for the shape of the tablet, and colour was observed by keeping the tablets in light.

ii. *Uniformity of thickness*

Three tablets were picked from each formulation randomly and thickness was measured individually. It is expressed in mm and standard deviation was also calculated. The tablet thickness was measured using dial-caliper

iii. *Hardness test*

Hardness indicates the ability of a tablet to withstand mechanical shocks while packaging, handling and transportation. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm^2. Three tablets were randomly picked and analyzed for hardness. The mean and standard deviation values were calculated.

iv. *Friability test*

It is the phenomenon whereby tablet surfaces are damaged and/or show evidence of lamination or breakage when subjected to mechanical shock or attrition. The friability of tablets was determined using Roche Friabilator. It is expressed in percentage (%). Ten tablets were initially weighed (Initial) and transferred into friabilator. The friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions. The tablets were weighed again (Final). The % friability was then calculated by,

$$\text{Percentage friability} = \frac{\text{Initial weight - Final weight} \times 100}{\text{Initial weight}}$$

v. *Weight variation test*

Ten tablets were selected randomly from each batch and weighed individually to check for weight variation. U.S. Pharmacopoeia allows a little variation in the weight of a tablet. The following percentage deviation in weight variation is allowed.

vi. *Drug content uniformity*

Three tablets were randomly sampled from each formulation batch, finely powdered and individually estimated for the drug content after suitable dilution, using UV-Visible spectrophotometer at 511.2nm after suitable dilution with distilled water or 0.1N HCL. Mean percentage drug content was calculated as an average of three determinations.

vii. *In vitro disintegration time*

The process of breakdown of a tablet into smaller particles is called as disintegration. The *in vitro* disintegration time of a tablet was determined using disintegration test apparatus as per I.P. specifications. Disintegration test was carried out by using Disintegration test apparatus. One tablet is placed in each tube, and the basket rack was positioned in a 1-litre beaker of water, at 37°C ±2°C. A standard motor-driven device is used to move the basket assembly containing the tablets up and down through a distance of 5 to 6cm at a frequency of 28 to 32 cycles per minutes. The time taken for the tablet to disintegrate completely was noted.

viii. *In Vitro Dissolution Studies*

The *in vitro* drug release studies were performed using USP dissolution apparatus Type II (paddle) using 900ml of 0.1N hydrochloric acid as the dissolution medium. The temperature of the dissolution medium was maintained at 37±0.5°C and the paddle was rotated at 50 rpm. Aliquots were withdrawn at different time intervals of 5,10,15,25 and 35,45 minutes and replaced by adding equal volume of fresh dissolution medium. The samples were suitably diluted and absorbance of the solutions was determined at the wavelengths 511.2nm in a UV- visible spectrophotometer.

VII. Result & Discussion

a) Characterization of Sodium Feredetate Inclusion Complex

i. *Drug content estimation*

Inclusion complexes of sodium feredetate with β-CD were prepared by physical mixture, and kneading method. The results are shown in the Table 1. The percentage drug content for all the prepared complex

were found to be in the range of 97.76 ± 0.43 to 99.65 ± 0.32indicating uniform drug distribution.

ii. *Result of Taste Masking by Electronic Tongue*

The metallic taste of the Sodium Feredetate was masked by kneading method in ratio of 1:2 (drug: β-CD). The effect of a sweetener Aspartame, on masking Sodium Feredetate metallic taste was evaluated by e-Tongue and a PCA map was configured to determine the system discrimination power between the samples using the data generated (Figure 1 & 2). Sample 1-4 consist of pure drug, Sample 5-8 consist of 1:1 ratio of drug:β-CD, Sample 9-12 consist of 1:2 ratio of drug:β-CD, Sample 13-16 consist of 1:3 ratio of drug:β-CD, it shows that the Electric potential was decreases with decreasing the metallic taste of the drug.

VIII. Evaluation Parameters for Chewable Tablets of Sodium Feredetate: β-CD

a) Pre-compression Parameters

Angle of repose (θ)

Table 3 shows the results obtained for angle of repose of all the formulations. The values were found to be in the range of $30^0.00'$ to $32^0.93'$. All formulations showed the angle of repose within 32^0, which indicates a good flow property of the blend.

b) Bulk density and tapped density

Both loose bulk density (LBD) and tapped bulk density results are shown in Table 3. The loose bulk density and tapped bulk density for all the formulations varied from 0.50 gm/cm3 to 0.57gm/cm^3 and 0.59 gm/cm3 to 0.65 gm/cm3 respectively. The values obtained lies within the acceptable range and not large differences found between loose bulk density and tapped bulk density. This result helps in calculating the % compressibility of the powder.

c) Hausner's ratio

Table 3, shows the result obtained for Hausner's ratio of all formulations. The values were found to be in the range of 1.15 - 1.19. All formulations showed the Hausner's ratio within the range, which indicates a good flow property of the granules.

d) Percentage compressibility

This percent compressibility of powder mix was determined by Carr's compressibility index. Table 3, shows the results obtained for percentage compressibility. The percent compressibility for all the nine formulations lies within the range of 12.88to 20.00. All formulations are showing good compressibility.

IX. Post Compression Parameters

a) Post-compression parameters

All the tablet formulations were subjected for evaluation according to various official specifications and other parameters. Shape, thickness, hardness, friability, weight variation, *in vitro* disintegration time, drug content, *in vitro* dissolution studies.

b) Shape and color of tablets

Randomly picked tablets from each formulation batch examined under lens for shape and in presence of light for color. All tablets of all the batches showed flat, circular in shape and pale yellowish in color.

c) Uniformity of thickness

The thickness of the tablets was measured by using dial caliper by picking the tablets randomly. The mean values are shown in Table 4. The values are almost uniform in all formulations. Thickness was found in the range of 2.43 mm to 2.62 mm respectively.

d) Hardness test

Table 4, shows results of hardness. Hardness test was performed by Monsanto hardness tester. Hardness was found to be within 5.13kg/cm^2 to 7.00 kg/cm^2as these tablets are chewable tablet. The lower standard deviation values indicated that the hardness of all the formulations were almost uniform inspecific method and possess good mechanical strength with sufficient hardness.

e) Friability test

The study results are tabulated in Table 4, was found well within the approved range (<1%) in all the formulations. Formulation F1 to F9 possesses good mechanical strength.

f) Weight variation test

The percentage weight variation for all the formulation is tabulated in Table 4. All the tablets passed weight variation test as the % weight variation was within the pharmacy opoeial limits of ± 10 %. It was found to be from 950.33 to 1199.66mg. The weight of all the tablets was found to be uniform.

g) Drug content uniformity

Three tablets were randomly sampled from each formulation batch, finely powdered and individually estimated for the drug content after suitable dilution, using UV-Visible spectrophotometer at 511.2nm after suitable dilution with distilled water or 0.1N HCL mean percentage drug content was calculated as an average of three determinations.

h) In vitro dissolution studies

In vitro drug dissolution studies were carried out using Electro Lab dissolution tester USP type II (Model TDT 06PS).

i) Method

Dissolution medium: 0.1N HCL solution
Dissolution volume: 900mL
RPM : 50 RPM
Temperature : $37^0 \pm 0.5^0$
Samples withdrawn: 5, 10, 15,20,30,40 mins

The formulation F1, F2 & F3 the concentration of mannitol was less & showed improper hardness with % *in vitro* drug release up to 80% in 40 mins (Table 6& Figure 4). But with a view to get better table ting properties further formulation was prepared with addition of MCC.

In formulation F4, F5 & F6 (Table 7& Figure 5), MCC was added in same concentration and mannitol in different concentration, the result showed better hardness and better drug release but the disintegrating time of tablet was less and such a large amount of powder leads to inconvenient thus further formulation was developed with higher concentration of mannitol by omitting MCC.

In formulation F7, F8 & F9 (Table 8& Figure 6), mannitol concentration was increased and that formulations showed better hardness, good % *in vitro* drug release and disintegration time was increased up to the limit. From these formulations F8 had shown better properties.

X. Conclusion

In the present study attempt has to mask the metallic taste of Sodium Feredetate. Taste masking has been carried out by using two different method i.e. physical mixture and kneading method, it was found that the metallic taste of the drug masked by kneading method in ratio of 1:2 (drug:β-CD). The evaluation of taste was performed by E-tongue on the basis of electronic potential. Fizzy chewable tablets containing Sodium Feredetate was successfully formulated using suitable excipients to delivery drug via oral route. Further, by varying in amount of sweetener, binder and super disinter grant, nine formulations were prepared and coded as F1-F9. All the formulation has shown both pre-compression and post-compression characters within acceptable limits. The chewable tablets were prepared by the method of direct compression using16 mm curved flat punches.

XI. Summary

The use of conventional oral tablets may pose major problem due to large dose size and decreased patient compliance. Therefore, to overcome this drawback, chewable tablets were prepared with suitable sweetener, flavor for better patient acceptance. Apart from that chewable tablets have an added advantage that effectiveness of the therapeutic agent is improved by the reduction in size that occurs during mastication of the tablet before swallowing and also better bioavailability through by-passing disintegration. In the present work an attempt was made to design a chewable tablet containing Sodium Feredetate with suitable excipients for the treatment of iron deficiency anemia. The objective of the present research work was to select suitable excipients, which should show good pre-compression and post-compression parameters, and also chewable tablets with good acceptable property like flavor, taste and mouth feel. The drug is having metallic taste so taste masking of drug becomes an important step prior to formulating these drugs into an oral dosage form. Hence the aim of the project is to enhance and mask the taste of drugs and formulate them into an orally chewable tablet. So, with a view to enhanced the patient compliance, and provide a quick onset of action, May increase the solubility and masking its metallic taste. Among the various inclusion complexes prepared, formulation i.e., the inclusion complex of sodium Feredetate with β-CD (1:2 molar ratio) prepared by kneading method shows good dissolution rate. So, it was decided to use to formulate fizzy chewable tablets .Further, preliminary work for selection of suitable excipients was done and a final formula was developed with acceptable pre-compression and post- compression evaluation parameters.

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Table 1: Percentage Drug Content of Sodium Feredetate Inclusion complexes.

Formulation	Percentage drug content (%)
P1	97.76±0.43
P2	98.34±1.86
P3	99.65±0.32
K1	98.20±0.82
K2	98.34±0.45
K3	99.12±0.72

Table 2: Physical Parameters of Sodium Feredetate.

Parameters	Values
Bulk Density	0.442 g/cm^3
Tapped Density	0.634 g/cm^3
%Compressibility	23.283%
Hausner'sratio	1.43
Angle of Repose	28.32°

Table 3: Pre-Compression Parameters of Chewable tablet blend of Sodium Feredetate Inclusion Complex.

Formulation	Bulk density (g/cc)	Tapped density (g/cc)	Angle of repose (θ)	Carr's index (%)	Hausner's Ratio
F1	0.52±0.01	0.65±0.01	31.26±1.46	20±0.31	1.24±0.00
F2	0.54±0.01	0.64±0.01	32.93±1.58	15.54±0.36	1.17±0.00
F3	0.53±0.02	0.63±0.01	31.03±1.15	16.30±0.54	1.19±0.01
F4	0.50±0.01	0.59±0.02	31.5±1.05	15.17±38	1.17±0.00
F5	0.53±0.01	0.62±0.01	32.1±1.51	14.51±0.23	1.16±0.00
F6	0.57±0.01	0.64±0.01	31.56±1.10	12.88±0.51	1.15±0.01
F7	0.53±0.02	0.63±0.02	30±1.41	15.79±0.37	1.18±0.00
F8	0.53±0.02	0.62±0.01	31±1.24	14.52±0.47	1.16±0.00
F9	0.52±0.01	0.61±0.01	30.73±1.65	15.75±0.70	1.17±0.00

Table 4: Post Compression Parameters of Chewable tablet of Sodium Feredetate Inclusion Complex.

Formulation	Thickness (n=3) (mm)	Diameter (n=3) (mm)	Hardness (Kg/cm^3)	Weight variation (n=3) (mg)	Friability % (n=3)	Diisintegtion time (min)
F1	4.36±0.05	16±0.05	5.13±0.56	950.66±1.52	0.22±0.02	4.06±0.30
F2	4.6±0.00	16.1±001	5.56±0.25	998.66±2.08	0.14±0.01	5.1±0.15
F3	4.8±0.1	16.0±0.01	5.96±0.20	1051±1	0.15±0.02	4.8±0.1
F4	4.2±0.15	16.1±0.02	6.13±0.35	950.33±2.08	0.16±0.02	3.43±0.25
F5	4.46±0.01	16±0.0	5.86±0.15	999.33±1.15	0.12±0.04	3.75±0.56
F6	4.83±0.05	16.1±0.5	6.3±0.26	1051±1	0.13±0.02	2.73±0.20
F7	5.1±0.05	16.0±0.05	6.63±0.47	1100.33±0.5	0.08±0.01	7±0.1
F8	5.13±0.1	16.0±0.05	6.1±0.2	1149.33±2.30	0.13±0.01	7.73±0.20
F9	5.16±0.1	16.1±0.02	7.0±0.30	1199.66±0.57	0.15±0.01	7.66±0.25

Table 5: Percentage Drug Content.

Formulation	Percentage drug content (%)
F1	98.12±0.26
F2	98.12±0.26
F3	99.35±0.84
F4	100.21±0.57
F5	101.86±0.41
F6	99.65±0.32
F7	99.35±0.63
F8	98.85±0.32
F9	99.12±0.72

Table 6: In Vitrodissolution Profile of the Formulations F1, F2 and F3.

0.1N HCL, 900ml, USP-II (Paddle) Apparatus, 50 rpm, 37± 0.5^0c			
TIME (mins)	% CDR		
	F1	F2	F3
0	0	0	0
5	18.41	21.13	25.43
10	32.07	33.23	34.14
15	39.8	48.30	48.73
20	47.16	55.50	56.84
30	55.25	70.72	72.82
40	64.31	79.81	81.90

Table 7: In Vitro Dissolution Profile of the Formulations F4, F5 and F6.

0.1N HCL, 900ml, USP-II (Paddle) Apparatus, 50 rpm, 37± 0.5^0c			
TIME (mins)	% CDR		
	F4	F5	F6
0	0	0	0
5	25.43	29.44	35.66
10	34.14	40.94	46.04
15	48.73	50.13	56.99
20	56.84	60.95	67.82
30	66.93	69.75	72.23
40	72.83	79.06	84.23

Table 8: In Vitro Dissolution Profile of the Formulations F7, F8 and F9.

0.1N HCL, 900ml, USP-II (Paddle) Apparatus, 50 rpm, 37± 0.5°c			
TIME (mins)	% CDR		
	F7	F8	F9
0	0	0	0
5	31.72	35.35	38.30
10	48.97	57.53	60.76
15	55.49	72.52	73.27
20	66.76	79.74	81.51
30	72.35	87.73	87.51
40	89.60	96.33	93.81

Figure 1: Photograph of Voltametric Electronic Tongue.

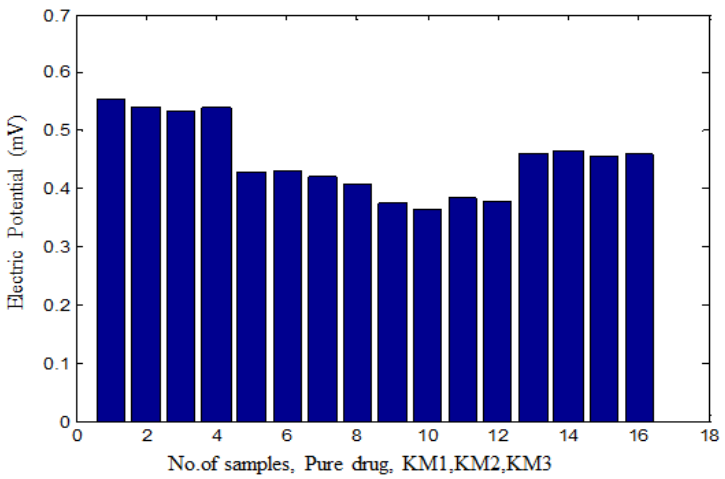

Figure 2: Response of electronic tongue to different ratio of Drug: β-CD

F1 F2 F3

F4 F5 F6

F7 F8 F9

Figure 3: Fizzy Chewable Tablet of Sodium Feredetate.

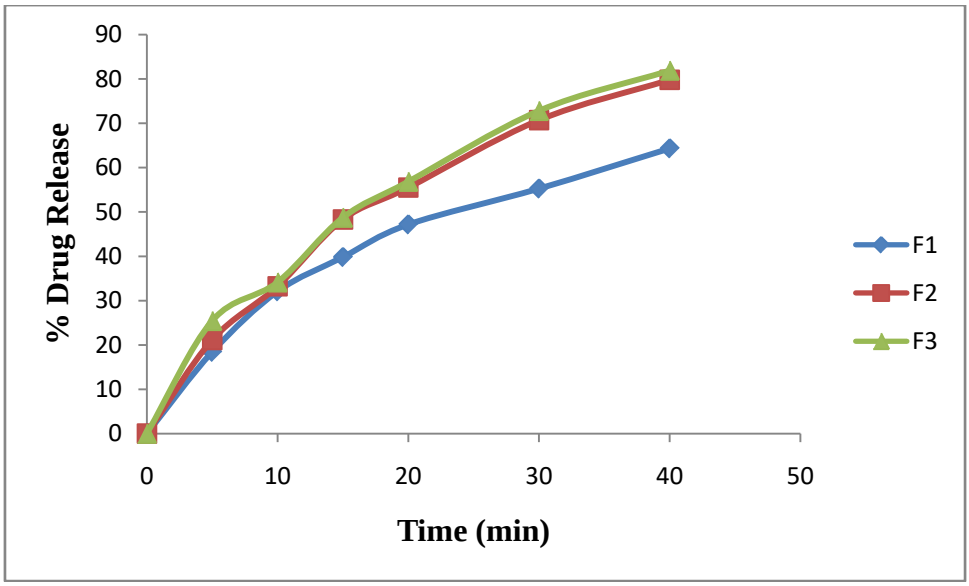

Figure 4: Comparative in VitroRelease Profile of Sodium Feredetate Chewable Tablets for Formulation F1, F2 and F3.

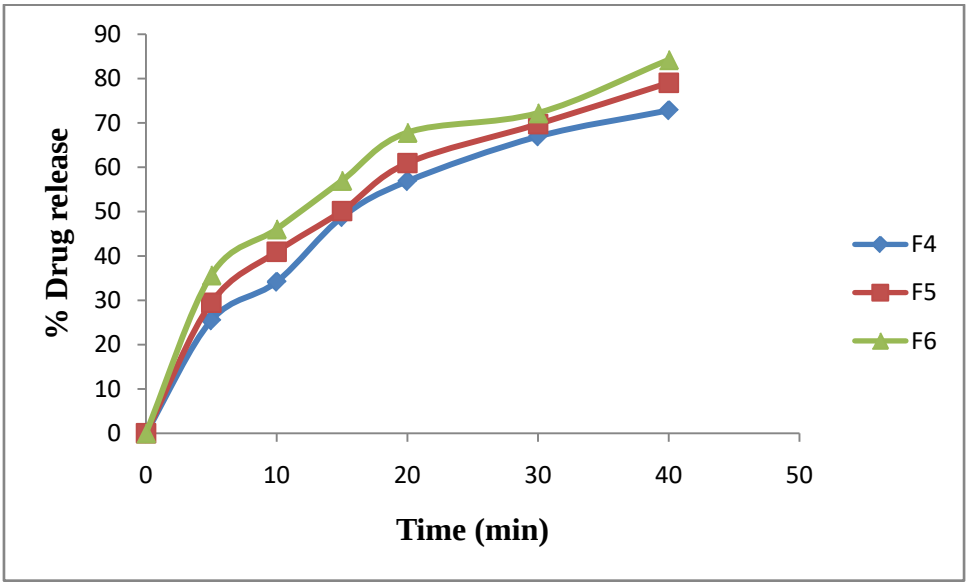

Figure 5: Comparative in Vitro Release Profile of Sodium Feredetate Chewable Tablets for Formulation F4, F5 andF6.

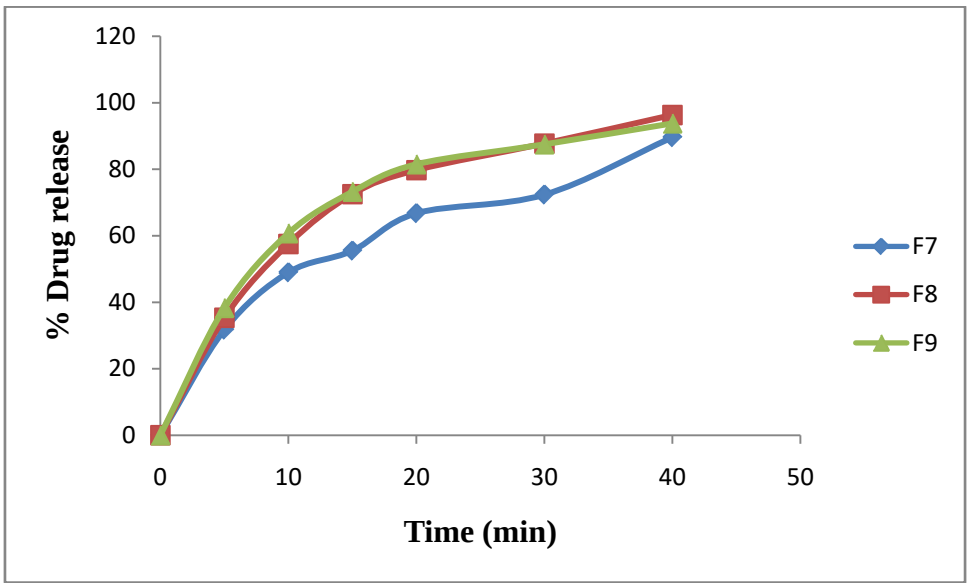

Figure 6: Comparative in Vitro Release Profile of Sodium Feredetate Chewable Tablets for Formulation F7, F8 andF9.

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Comparative Quality Evaluation of Three Different Marketed Brands of Ashwagandha Churna (Powder)

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Abstract- Ashwagandha has been a crucial herb in the traditional medical systems for more than 3000 years. The plant roots are categorized as Rasayana (tonic) for its wide-ranging health benefits.

Objective: As the standardization of herbal formulation is of great concern for its safety and efficacy for that reason this work is aimed at comparative evaluation of various quality parameters of three marketed brands of Ashwagandha churna (powder).

Methods: Three different and popular marketed formulations of AshwagandhaChurna (powder) were assessed comparatively for their organoleptic, physicochemical and phytochemical properties as per the methods prescribed in Pharmacopoeias.

Results: The data analysis revealed that all the parameters of three brands of AshwagandhaChurna (powder) had approximately similar values with some significant variations in a few. The value of water soluble and alcohol soluble extractives of Brand B was lesser than the standard values, and the pH was higher than the other two brands. There was also a considerable difference between the flow properties of the powder of all three brands. All the three brands were found to contain Cadmium concentration slightly more than the prescribed values.

Keywords: quality evaluation, ashwagandha churna (powder), pharmaceutical, physico-chemical, phytochemical, heavy metal analysis.

GJMR-B Classification: NLMC Code: QV 17

Strictly as per the compliance and regulations of:

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Princy Agarwal [α], Rajat Vaishnav [σ] & Anju Goyal [ρ]

Abstract- Ashwagandha has been a crucial herb in the traditional medical systems for more than 3000 years. The plant roots are categorized as Rasayana (tonic) for its wide-ranging health benefits.

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Conclusion: Therefore the present investigation reveals that there is a need to standardize the complete manufacturing procedure and to make more stringent quality control parameters to reduce variation among different Ayurvedic preparations.

Keywords: quality evaluation, ashwagandha churna (powder), pharmaceutical, physico-chemical, phytochemical, heavy metal analysis.

I. Introduction

Withaniasomnifera, also known as Ashwagandha has been a crucial herb in the Ayurvedic and indigenous medical systems for more than 3000 years. The roots of the plant are classified as Rasayana, which are renowned for promoting health and longevity by increasing the defense against diseases, stopping the aging process, revitalizing the body in conditions of weakness, increasing the Individual's ability to resist environmental factors adverse effects and creating a sense of mental well-being. It has been in use for a long time for all age groups and for both sexes and also during pregnancy without side effects. [1]

The biologically active chemical constituents are alkaloids (Isopelletierine, Ana ferine), steroidal lactones (With anolides, with a ferins), saponins containing an additional acyl group (Sitoindoside VII and VIII), and with anolides with a glucose at carbon 27 (Sitoindoside XI and X). It is also rich in iron. Much of Ashwagandha's pharmacological activity has been attributed to two main with anolides, with aferin A and With anolide D. Other constituents include: Anaferine, Anahydrine, Beta-Sisterol, Chlorogenic acid (in leaf only), Cysteine (in fruit), Cuscohygrine, Iron, Pseudo tropine, Scopoletin, Somniferinine, Somniferiene, with anineand with anolides A-Y. [2].

It boosts the function of the brain and nervous system and also improves the memory. It also acts as a reproductive enhancer by promoting a healthy sexual and reproductive balance. Being a powerful adaptogen, it improves the body's resistance to stress. Ashwagandha improves the body's defense against diseases by improving the cell-mediated immunity. It also has powerful antioxidant properties that help protect against cell damage caused by free radicals. It also possesses antioxidant, anxiolytic, adaptogenic, anti-Parkinson, anti-venom, anti-inflammatory, anti-tumor, immunomodulation, hypolip idemic, antibacterial, cardiovascular protection properties. [3]

II. Need for Evaluation

In the traditional medicine system, plants in raw form, both fresh and dried, are used for their healing effects against a variety of human disorders. The quality control of medicinal herbs and their biological components is critical to justify their acceptability in the modern medical system. The fundamental problem faced by the user industry is the lack of availability of rigid quality control profiles for herbal raw materials and their formulations. With the emergence of revolutionary analytical tools and instrumental technologies, it is possible to suggest a practical quality assurance profile for a raw drug or its bioactive component. [4, 5]

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This paper reports the comparative determination of pharmaceutical, physicochemical and phytochemical parameters like bulk density, tapped density, the angle of repose, ash values, extractive values, loss on drying, etc. of three marketed preparations of Ashwagandha Churna (powder).

III. Materials and Methods: [5-13]

a) Procurement of Samples

The following marketed Ashwagandha Churna (powder) preparations were used in the present study. Brand A (Batch No. AL 0207), Brand B (Batch No. F-1701), Brand C (Batch No. #A- A G C015). All brands of the Ashwagandha Churna (powder) were procured from the local market from the registered Ayurvedic Pharmacy.

b) Organoleptic Evaluation

All the organoleptic properties viz. color, odor, taste, and texture of the drug to touch were performed as per standard procedure and noted down.

c) Pharmaceutical Evaluation

Pharmaceutical parameters like Bulk density, Tapped density, Carr's Index, Hausner's Ratio and Angle of repose were determined as per standard protocols.

i. *Determination of Bulk Density and Tapped Density*

Bulk density is defined as the mass of many particles of the material divided by the total volume they occupy. The total volume includes particle volume, inter-particle void volume, and internal pore volume. Tapped density is the term used to describe the bulk density of powder (or granular solid) after consolidation/ compression prescribed regarding "tapping" the container of powder measured number of times, usually from a predetermined height.

The term bulk density refers to a measure used to describe a packing of particles or granules and the term Tapped density refers to the true density of the particles or granules.

The Formula for calculation:

$$Bulk\ Density = \frac{Weight\ of\ powder\ taken}{Bulk\ Volume\ of\ powder} = \frac{10}{\pi r^2 h_b}$$

$$Tapped\ Density = \frac{Weight\ of\ powder\ taken}{Tapped\ Volume\ of\ powder} = \frac{10}{\pi r^2 h_t}$$

Where,

$\pi r^2 h$ = Volume of Graduated Cylinder

h_b = Bulk height of the powder

h_t = Tapped height of the powder

ii. *Determination of Carr's Compressibility Index*

The Carr index is an indication of the compressibility of a powder. It is another indirect method of measuring the powder flow from bulk and tapped density.

The Formula for calculation:

$$Carr's\ Index\ (\%) = \frac{Tapped\ Density - Bulk\ Density}{Tapped\ Density} \times 100$$

iii. *Determination of Hausner's Ratio*

Hausner's ratio is related to inter-particle friction and as such can be used to predict the powder flow properties.

The Formula for calculation:

$$Hausner's\ Ratio = \frac{Tapped\ Density}{Bulk\ Density}$$

iv. *Determination of Angle of Repose*

The angle of repose is a parameter used to estimate the flow ability of a powder. It is defined as the maximum angle possible between the surface of the pile of powder and the horizontal plane. Powders with low angles of repose will flow freely, and powders with high angles of repose will flow poorly.

The Formula for calculation:

$$\tan\theta = \frac{h}{r}$$

Where,

θ = Angle of repose

h = Height of pile

r = radius of the base of the pile

Table 1: Relationship of Angle of Repose, Carr's Index & Hausner's Ratio with Flow Properties of Powder

Angle of Repose	Carr's Index	Hausner's Ratio	Flow Properties
25-30	<10	1.00-1.11	Excellent
31-35	11-15	1.12-1.18	Good
36-40	16-20	1.19-1.25	Fair
41-45	21-25	1.26-1.34	Passable
46-55	26-31	1.35-1.45	Poor
56-65	32-37	1.46-1.59	Very Poor
>66	>38	>1.60	Very Very Poor

IV. Physico-Chemical Evaluation

Physicochemical parameters like Foreign matter, Moisture content (Loss on Drying), pH, Total ash, Acid-Insoluble ash, Water-soluble extractive, Alcohol-soluble extractive values of all three samples were determined as per standard protocols. All the procedures are described as follows:

a) Determination of Foreign Matter

100 g of sample was taken and spread in a thin layer on a suitable platform and was examined in daylight with the unaided eye (or using 6x or 10x magnifying glass), and the foreign matter was separated and weighed. The percentage of foreign matter was calculated with reference to the drug sample.

Standard: The sample should not contain more than 2% of foreign matter unless otherwise specified in the individual monograph.

b) Determination of Moisture Content/ Loss on Drying (LOD)

An accurately weighed 5g of polyherbal formulation powder was taken in a tared evaporating dish. The crude drug was then heated at 105^{0}C in an oven for 3 hours. The drying and weighing were continued at half an hour interval until the difference between two successive weighing corresponded to, not more than 0.25 percent. Percentage moisture content of the sample was calculated with reference to the air-dried powdered drug material.

The Formula for Calculation:

$$\% \, LOD = \frac{W_2 - W_3}{W_3 - W_1} \times 100 \, \%$$

Where,
W_1 = weight of container (g)
W_2 = weight of container + wet sample (g)
W_3= weight of container + dried sample (g)
$W_2 - W_3$= weight of moisture
$W_3 - W_1$= weight of dried sample

c) Determination of Loss on Ignition (LOI)

An accurately weighed 5g of polyherbal formulation powder was taken in a previously ignited and tared silica crucible and was heated in the oven at 105^{0}C overnight (or the previously dried sample can also be used). The crucible was cooled and reweighed. The crucible was then placed into the furnace tray and was ignited in the Muffle-Furnace at 500^{0}C for about 4 hrs. The sample was then cooled in a dessicator for 30 min., and reweighed with the ash in it (W_A). The observations were noted.

The Formula for calculation:

$$\% \, LOI = \frac{W_S - W_A}{W_S - W_C} \times 100 \, \%$$

Where,
W_C = weight of crucible (g)
W_S = weight of the sample (g)
W_A = weight of ash (g)

d) Determination of Total ash

An accurately weighed 3 g of the sample was taken in a previously ignited and tared silica dish/crucible. The material was evenly spread and ignited in a Muffle-Furnace by gradually increasing the temperature to not more than 450^{0}C - 600^{0}C till the carbon-free ash was not obtained. The total ash value was calculated with reference to the air-dried powdered drug material.

The Formula for calculation:

$$\% \, Total \; Ash = \frac{Weight \; of \; Ash}{Weight \; of \; the \; sample \; taken} \times 100 \, \%$$

e) Determination of Acid Insoluble ash

Ash above obtained, was boiled for 5 min with 25ml of 1M Hydrochloric acid and filtered using an ash less filter paper. Insoluble matter retained on filter paper was washed with hot water, and filter paper was burnt to a constant weight in a Muffle-Furnace. The percentage of acid insoluble ash was calculated with reference to the air-dried powdered drug material.

The Formula for calculation:

$$\% \, Acid - Insoluble \; Ash = \frac{Weight \; of \; acid \; insoluble \; residue}{Weight \; of \; the \; sample \; taken} \times 100 \, \%$$

f) Determination of Water-Soluble ash

1g of ash obtained in Total ash experiment was boiled for 5 min with 25ml water and insoluble matter collected on an ashless filter paper which was then washed with hot water and ignited for 15 min at a temperature not exceeding 450^{0}C in a Muffle-Furnace. The difference in weight of ash and weight of insoluble matter was determined as difference represents the value. The percentage of water-insoluble ash was calculated with reference to the air-driedpowdered drug material.

The Formula for calculation:

$$\% \, Water \; Soluble \; Ash = \frac{Weight \; of \; watersoluble \; residue}{Weight \; of \; the \; sample \; taken} \times 100 \, \%$$

g) Determination of Extractive Values

i. *Determination of Alcohol Soluble Extractives*

5 gm of churna (powder) was accurately weighed and placed inside a glass-stoppered conical flask. It was then macerated with100ml of ethanol. The flask was shaken frequently during the first 6 hours and was kept aside without disturbing for 18 hours. It was then filtered, and about 25ml of the filtrate was transferred into a tared flat-bottomed shallow dish and

was evaporated to dryness on a water bath. It was then dried to 105° C for 6 hours, cooled and finallyweighed. The percentage of Alcohol Soluble extractives was calculated with reference to the air-dried powdered drug material.

The Formula for calculation:

$$\%\ Alcohol\ Soluble\ Extractive = \frac{Weight\ of\ \ residue \times 100 \times 100}{25 \times Weight\ of\ the\ sample\ taken}\ \%$$

ii. *Determination of Water-Soluble Extractives*

Proceed as directed for determination of Alcohol–Soluble Extractive, using *chloroform-water* (2.5 ml chloroform in purified water to produce 1000 ml) instead of *ethanol*.

h) Determination of pH Value

The powder sample of Ashwagandhachurna (powder) was weighed to about 5g and immersed in 100 ml of water in a beaker. The beaker was closed with aluminum foil and left behind for 24-hours at room temperature. Later the supernatant solution was decanted into another beaker, and the pH of the formulation was determined using a calibrated digital pH meter.

V. Phytochemical Evaluation

The aqueous and alcoholic extracts of the respective formulations were prepared and were subjected to preliminary phytochemical screening. These tests reveal the presence of various bioactive secondary metabolites which might be responsible for their medicinal attributes. Methods for preliminary qualitative phytochemical tests of the plant extracts are given below in Table 2.

Table 2: Preliminary Phytochemical Tests for Plant Extracts

S. No.	Phyto-Constituents	Name of Tests	Procedure	Observation
1.	Alkaloids	Mayer's test	2 ml extract + few drops of HCl + Mayer's reagent	Cream Precipitation
		Hager's test	2 ml extract + few drops of HCl + Hager's reagent	Yellow Precipitation
		Wagner's test	2 ml extract + few drops of HCl + Wagner's reagent	Reddish brown color
2.	Carbohydrates	Molisch test	2 ml extract + 2 Drops of Molisch reagent + few drops of Conc. H_2SO_4	Violet or Reddish color
3.	Reducing sugars	Fehling's test	1 ml extract + 1 ml Fehling Solution (A and B)	First a Yellow and then Brick Red Precipitation
4.	Flavonoids	Alkaline reagent test	2 ml extract + few drops of 40% NaOH solution	Intense yellow color forms which become colorless on the addition of dilute acid
		Lead acetate test	2 ml extract + few drops of the Lead Acetate solution	Yellow precipitation
5.	Saponins	Foam test	2 ml extract + 4 ml distilled H_2O Mix well and shake vigorously	Foam formation
6.	Tannins	Braymer's test	2 ml extract + 2 ml H_2O + 2-3 drops of 5% $FeCl_3$	Black green or bluish color
7.	Steroids	Salkowski's test	2 ml extract + 2 ml Chloroform + 2 ml Conc. H_2SO_4	Chloroform layer appears red, and acid layer shows greenish-yellow fluorescence
8.	Proteins	Millon's test	3 ml extract + 5 ml Millon's reagent	White precipitate which turns brick red on warming
9.	Glycosides	Keller Killiani's test	2 ml extract + Glacial Acetic Acid + 1 drop of 5% $FeCl_3$ + Conc. H_2SO_4	Reddish brown color appears at the junction of 2 layers, and upper layer appears bluish green
10.	Phenols	-	2-3 ml of extract + few drops of 5% $FeCl_3$ solution	Deep blue-black color
			2-3 ml of extract + few drops of the Lead Acetate solution	White precipitate

11.	Amino acids	Ninhydrin test	3 ml of extract + 3 drops of 5% Ninhydrin solution Keep in boiling water bath for 10 min.	Purple or bluish color appears
12.	Terpenoids	Copper Acetate test	2 ml extract dissolved in water + 3-4 drops of Copper Acetate solution	Emerald green color

VI. Determination of Heavy Metals (Lead and Cadmium)

a) Method (Direct Calibration Method)

Three reference solutions of the element being examined having different concentrations were prepared to cover the range recommended by the instrument manufacturer. Separately the corresponding reagents were added to the test solution, and the blank solution was prepared with the corresponding reagents. The absorbance of the blank solution and each reference solution were measured separately, and the readings were recorded. A calibration curve was prepared with the average value of 3 readings of each concentration on the ordinate and the corresponding concentration on the abscissa. A test solution of the substance being examined was prepared as specified in the monograph. The concentration was adjusted such that it falls within the concentration range of the reference solution. The absorbance was measured three times, and the readings were recorded, and the average value was calculated. The mean value was interpolated on the calibration curve to determine the concentration of the element.

b) Preparation of Lead standard solution

Lead standard solutions were prepared from Stock solution (1000 ppm Sisco Research Laboratories Pvt. Ltd. stock solution). Standard solutions of concentrations, 2, 4, 6, 8 and 10 ppm were prepared. The absorption of the standard solution measured at 217 nm using hollow cathode lamp as a light source & air acetylene blue flame on Atomic absorption Spectrophotometer.

c) Preparation of Cadmium standard solution

Cadmium standard solutions were prepared from Stock solution (1000 ppm Sisco Research Laboratories Pvt. Ltd. stock solution). Standard solutions of concentrations 0.2, 0.4, 0.6, 0.8 and 1.0 ppm was prepared. The absorption of the standard solution measured at 228.8 nm using hollow cathode lamp as a light source & air acetylene blue flame on Atomic absorption Spectrophotometer.

d) Preparation of Test solution

About 0.5 g of the coarse powder of the substance being examined was accurately weighed, transferred into a casparian flask, 5-10 ml of the mixture of nitric acid (HNO_3) and perchloric acid ($HClO_4$) in the ratio of 4:1 was added. A small hopper was placed on the flask-top, macerated overnight, heated to slake on the electric hot plate, till white smoke dispersed, and the slaked solution becomes colorless and transparent. It was then cooled, and transferred into a 50 ml volumetric flask. The container was washed with 2% nitric acid solution (HNO_3), and the washing solution was added into the same volumetric flask and diluted with the same solvent to make-up the volume. Synchronously the blank reagent solution was also prepared according to the above procedure.

e) Determination

An accurate of 1 ml of the test solution and its corresponding reagent blank solution respectively were measured, and to it 1 ml of the solution containing 1% $NH_4H_2PO_4$ and 0.2% $Mg(NO_3)_2$ was added. The mixture was shaken well, and an accurate of 10-20 all solution was pipetted out to determine the absorbance.

f) Sample analysis

The analysis of the digested samples was carried out using an Atomic Absorption Spectrophotometer (EC Electronics Corporation of India limited AAS Element AS AAS4141) for Lead and Cadmium. The instrumental conditions for Lead analysis are depicted in Table 3.

Table 3: Instrumental Conditions for Analysis of Lead and Cadmium

Parameters	Pb	Cd
Wavelength (nm)	217	228.8
Slit width (nm)	1.0	0.5
Light Source	Hollow Cathode Lamp	Hollow Cathode Lamp
Flame type	Air/C_2H_2	Air/C_2H_2
Current	10	3.5
AAS Technique	Flame	Flame

VII. Results

a) Organoleptic Evaluation

The observations for the organoleptic evaluation of three brands of Ashwagandha Churna (powder) are reported in Table-4.

Table 4: Results for Organoleptic Evaluation of different brands of Ashwagandha Churna (powder)

S. No.	Properties	Brand A	Brand B	Brand C	Standard(IP)
1.	Appearance	Powder	Powder	Powder	Powder
2.	Color	Creamish	Yellowish Brown	Off-White	Buff to Greyish Yellow
3.	Odor	Characteristic	Characteristic	Characteristic	-
4.	Taste	Bitter	Very Bitter	Very Bitter	Slightly mucilaginous/ Bitter/Acrid
5.	Texture	Fine Powder	Fine Powder	Very Fine Powder	

b) Pharmaceutical Evaluation

The observations for the pharmaceutical evaluation of three brands of Ashwagandha Churna (powder) are reported in Table-5.

Table 5: Results for Pharmaceutical Evaluation of different brands of Ashwagandha Churna (powder)

S. No.	Properties	Brand A	Brand B	Brand C
1.	Bulk Density	0.478	0.381	0.584
2.	Tapped Density	0.641	0.612	0.751
3.	Hausner's Ratio	1.34	1.37	1.29
4.	Carr's Index	25.43%	27.17%	22.24%
5.	Angle of Repose	37.715^0	32.619^0	29.052^0

c) Physico-Chemical Evaluation

The observations for the physicochemical evaluation of three brands of Ashwagandha Churna (powder) are reported in Table-6.

Table 6: Results for Physico-chemical Evaluation of different brands of Ashwagandha Churna (powder)

S. No.	Properties	Brand A	Brand B	Brand C	Standard (IP)
1.	Foreign Matter	Nil	Nil	0.4%	NMT 2.0%
2.	pH	5.0	5.6	5.0	-
3.	Loss on Drying/ Moisture Content	4.17%	5.37%	7.07%	NMT 12.0%
4.	Water Soluble Extractive	25.6%	10.4%	20.8%	NLT 15.0%
5.	Alcohol Soluble Extractive	11.2%	6.4%	8.8%	NLT 10.0%
6.	Loss on Ignition	94.54%	94.79%	95.09%	-
7.	Total Ash Value	6.06%	5.52%	5.1%	NMT 7.0%
8.	Acid Insoluble Ash	0.97%	0.84%	0.60%	NMT 1.2%
9.	Water Soluble Ash	0.85%	0.79%	1.60%	-

d) Phytochemical Evaluation

The observations for the phytochemical evaluation of three brands of AshwagandhaChurna (powder) are reported in Table-7.

Table 7: Phytochemical Screening of Ashwagandha Churna (powder)

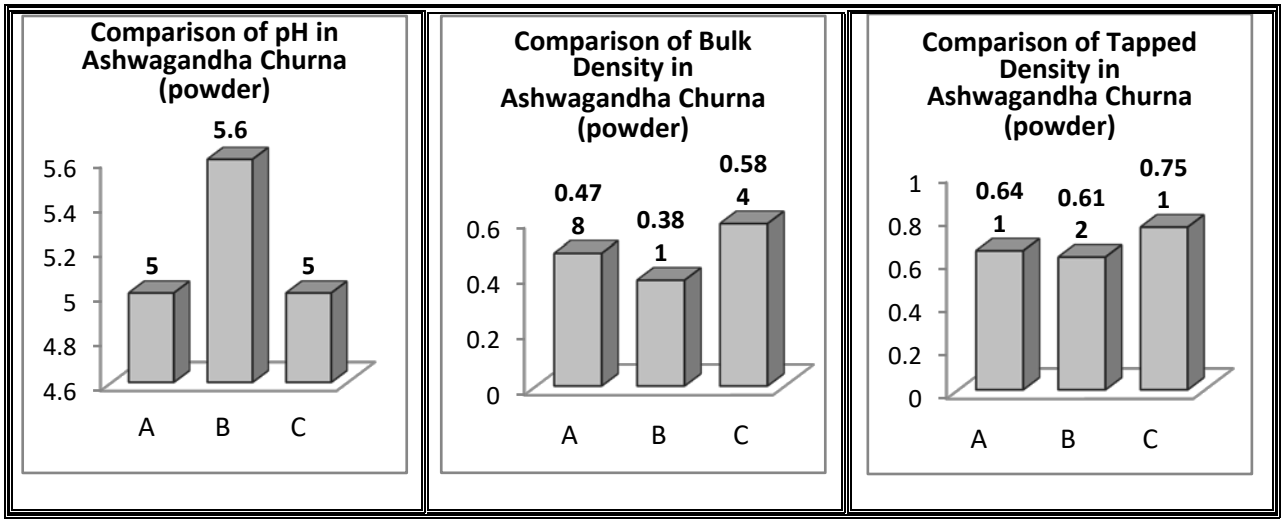
S. No.	Phyto-Constituent	Name of Tests	Brand A		Brand B		Brand C	
			Aq.	Alco.	Aq.	Alco.	Aq.	Alco.
1.	Alkaloids	Hager's test	-	+	-	+	-	+
		Wagner's test	-	+	-	+	-	+
		Mayer's test	-	+	-	+	-	+
2.	Glycosides	Keller Killani's test	+	+	+	+	+	+
3.	Carbohydrates	Molisch's test	+	+	+	+	+	+
4.	Proteins	Biuret's test	-	-	-	-	-	-
		Millon's test	-	-	-	-	-	-
5.	Amino Acids	Ninhydrin' s test	-	-	-	-	-	-
6.	Steroids	Salkowski's test	+	+	+	+	+	+
7.	Flavonoids	Alkaline Reagent test	-	-	-	-	-	-
		Lead acetate test	-	-	-	-	-	-
8.	Terpenoids	Copper Acetate test	+	+	+	+	+	+
9.	Tannins	Ferric Chloride test	-	-	-	-	-	-
10.	Saponins	Foam test	+	-	+	-	+	-
11.	Phenols	Ferric Chloride test	-	-	-	-	-	-
		Lead Acetate test	-	-	-	-	-	-

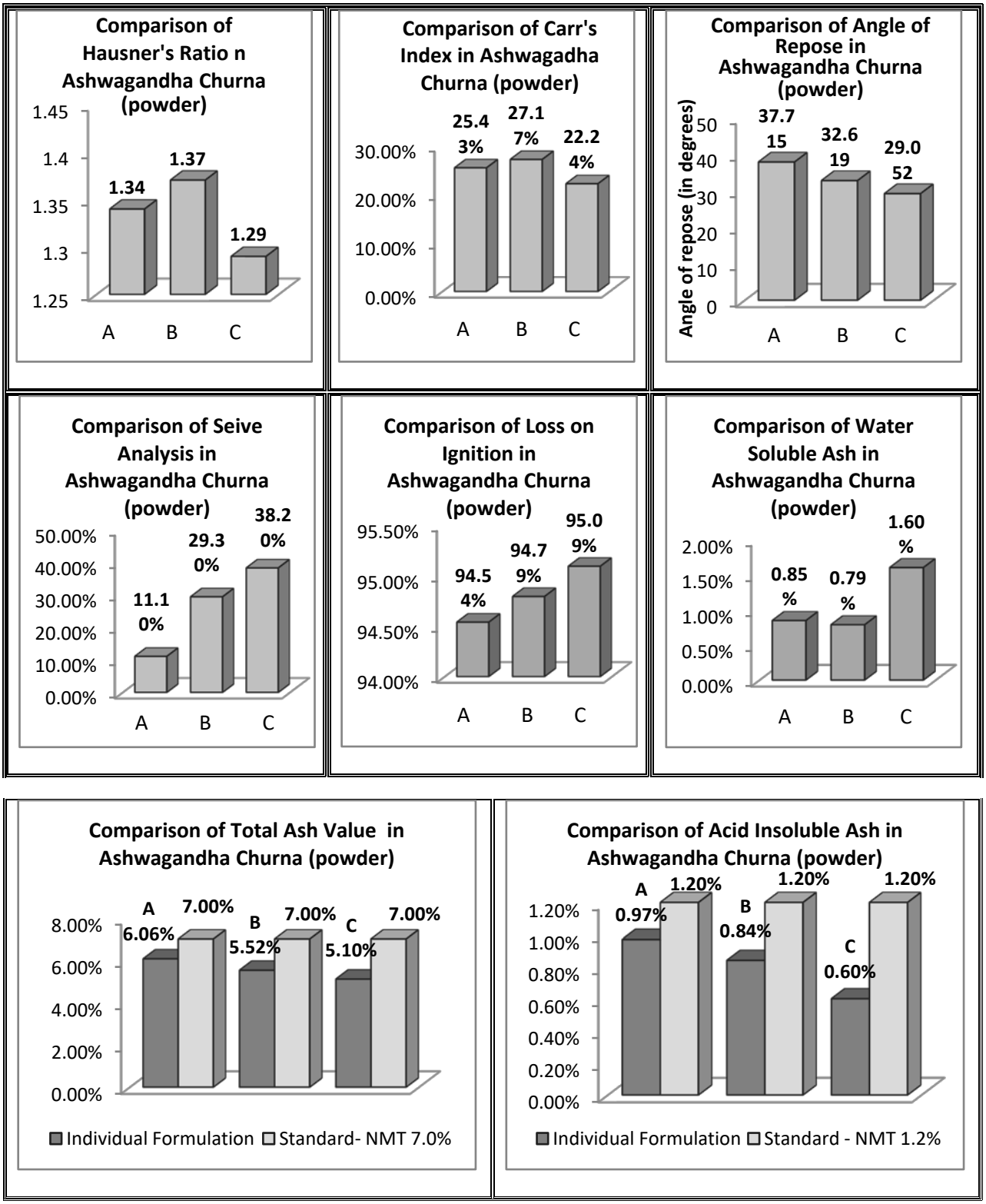
e) Determination of Heavy Metals (Lead And Cadmium)

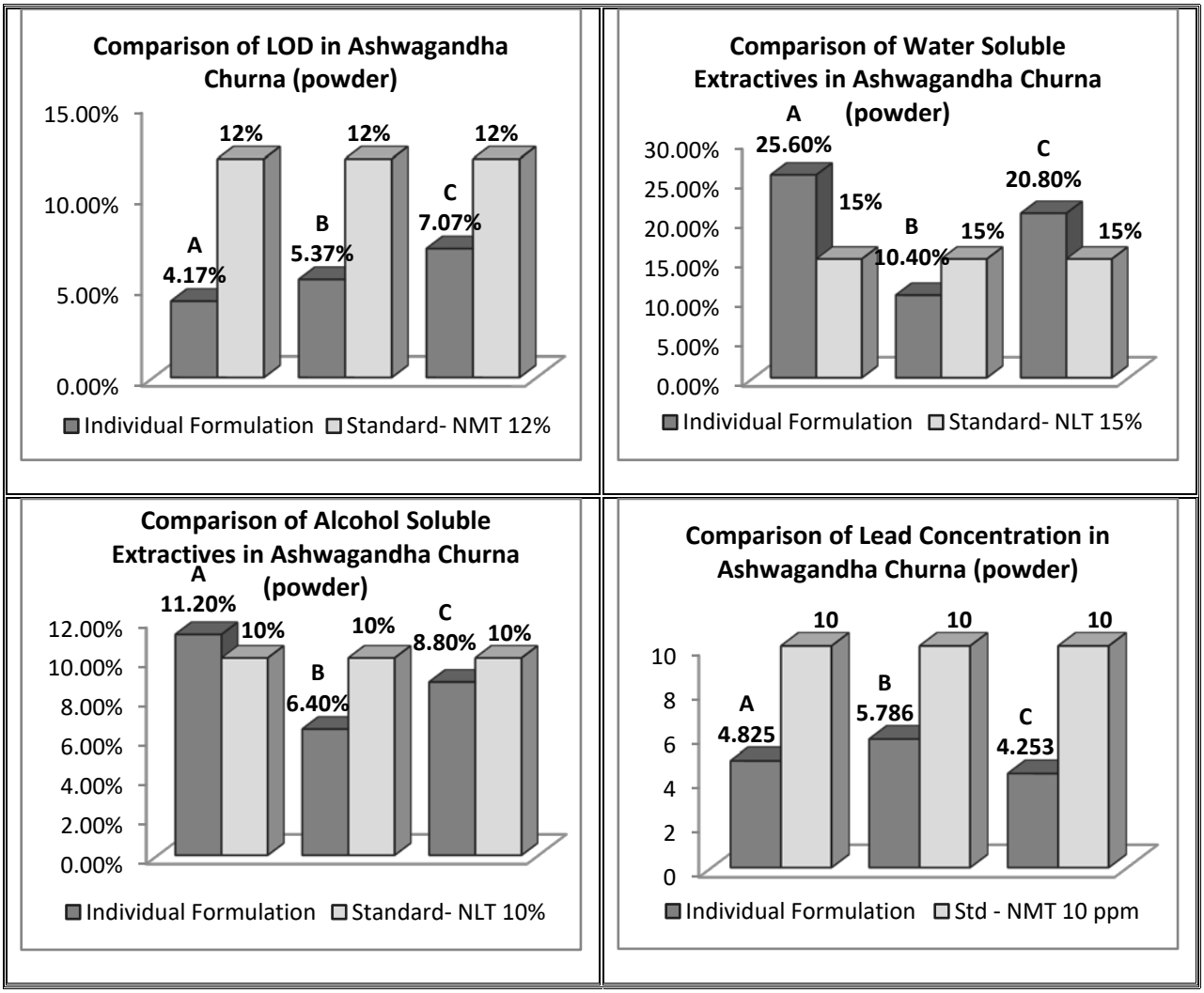
The observations for the Heavy metal determination of three brands of Ashwagandha Churna (powder) are reported in Table-8.

Table 8: Heavy metal analysis of Ashwagandha Churna (powder)

S. No.	Properties	Brand A	Brand B	Brand C	Standard (API)
a.	Lead	4.825	5.786	4.253	10 ppm
b.	Cadmium	0.363	0.325	0.334	0.3 ppm







Graph 1: Graphs for various Pharmaceutical and Physico-chemical parameters of different brands of Ashwagandha Churna (powder)

VIII. Discussion

Ashwagandha churna (powder) of *Brand A* was of the powder form of Creamish color with a characteristic odor and bitter taste. This preparation had pH value of 5.0, and Loss on drying value of 4.17% w/w. Preparation has Alcohol-soluble extractives and Water-soluble extractives values of 11.2% w/w and 25.6% w/w respectively. The bulk density and tapped density of the powder were 0.478 and 0.641 respectively. The powder flow was fair-passable as it had the Carr's Index of 25.43% (Passable), Hausner's ratio of 1.34 (Passable) and Angle of repose of 37.715^0 (Fair). It had Total Ash value of 6.06% w/w, and Acid-insoluble ash and Water-soluble ash value of 0.97% w/w and 0.85% w/w respectively. Loss on ignition was found 94.54% w/w. The concentration for heavy metals Lead and Cadmium were found to be 4.825 and 0.227 respectively of which Lead concentrations were within the prescribed limits and of Cadmium was a little more than the standard value. Phytochemical screening revealed the presence of Glycosides, Carbohydrates, Steroids, and Terpenoids in both the extracts; Alkaloids in alcoholic extract only and Saponins in aqueous extract only.

Ashwagandha churna (powder) of *Brand B* was of the powder form of Yellowish brown color with a characteristic odor and very bitter taste. This preparation had pH value of 5.6, and Loss on drying value of 5.37% w/w. Preparation had Alcohol-soluble extractives and Water-soluble extractives values of 6.4% w/w and 10.4% w/w respectively. The bulk density and tapped density of the powder were 0.381 and 0.612 respectively. The powder flow was poor-good as it had the Carr's Index of 25.43% (Poor), Hausner's ratio of 1.37 (Poor) and Angle of repose of 32.619^0 (Good). It had Total Ash value of 5.52% w/w, and Acid-insoluble ash and Water-soluble ash value of 0.84% w/w and 0.79% w/w respectively. Loss on ignition was found 94.79% w/w. The concentration for heavy metals Lead and Cadmium were found to be 5.786 and 0.363 respectively of which Lead concentrations were within the prescribed limits and of Cadmium was a little more than the standard value. Phytochemical screening revealed the presence of Glycosides, Carbohydrates, Steroids, and Terpenoids in both the extracts; Alkaloids in alcoholic extract only and Saponins in aqueous extract only.

Ashwagandha churna (powder) of *Brand C* was of the powder form of off-white color with a characteristic odor and very bitter taste. This preparation had pH value of 5.0, and Loss on drying value of 7.07% w/w. Preparation had Alcohol-soluble extractives and Water-soluble extractives values of 8.8% w/w and 20.8% w/w respectively. The bulk density and tapped density of the powder were 0.584 and 0.751 respectively. The powder flow was passable-excellent as it had the Carr's Index of 22.24% (Passable), Hausner's ratio of 1.29 (Passable) and Angle of repose of 29.052^0 (Excellent). It had Total Ash value of 5.10% w/w, and Acid-insoluble ash and Water-soluble ash value of 0.6% w/w and 1.60% w/w respectively. Loss on ignition was found 95.09% w/w. The concentration for heavy metals Lead and Cadmium were found to be 4.253 and 0.334 respectively of which Lead concentrations were within the prescribed limits and of Cadmium was a little more than the standard value. Phytochemical screening revealed the presence of Glycosides, Carbohydrates, Steroids, and Terpenoids in both the extracts; Alkaloids in alcoholic extract only and Saponins in aqueous extract only.

IX. Conclusion

Thus, all the parameters of three brands of Ashwagandha Churna (powder) had approximately similar values and were compatible with the standard values mentioned in the Pharmacopoeias except the value of Water-soluble and Alcohol-soluble extractives of Brand B i.e. 10.4% and 6.4% which was lesser than the standard values of 15% and 10% respectively. The pH of the formulation was also higher than the other two with the value of 5.6. There was also a considerable difference between the flow properties of the powder of all three brands. All the three brands were found to contain Cadmium concentration slightly more than the prescribed values.

Hence, it can be concluded that the present study on the pharmaceutical, physicochemical and phytochemical characters can serve as a vital source of information and provide suitable reference standards for the quality control of these formulations for future investigations. It is also emphasized to perform quality checks on every batchto optimize the final product according to the Pharmacopoeial standards.

Abbreviations

API – Ayurvedic Pharmacopoeia of India

IP – Indian Pharmacopoeia

Pb - Lead

Cd - Cadmium

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Pharmacy in Health Care System

By Siniša Franjić

Abstract- The drug is a composition that alleviates the symptoms of some disease, it prevents and heals it. The structure can be of natural or synthetic origin. If taken uncontrolled, it can cause addiction. Regardless of the composition, each drug should have been effective and safe. These are the facts with which each patient should be familiar.

Keywords: *pharmacy, drugs, health care.*

GJMR-B Classification: *NLMC Code: QV 704*

PHARMACYINHEALTHCARESYSTEM

Strictly as per the compliance and regulations of:

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I. Introduction

The pharmaceutical industry is essentially one which supplies the community with what is known technically as "pharmaceutical products" [1]. The latter have for different purposes been defined in different ways, but for any broad discussion some of the existing definitions are likely to prove too narrow and too static.

In the broadest possible sense a pharmaceutical product, known in everyday usage simply as a "medicine" (or less accurately as a "drug") can be defined as a substance or a complex of substances which is administered to man or to animals in order to prevent, diagnose, alleviate or cure a disease, to relieve a symptom, or to modify bodily function in some way.

Traditionally, for many centuries, pharmaceuticals largely comprised herbs or their derivatives or extracts, and less commonly materials of animal or mineral origin. At the present day, most of them are largely based on substances created in the laboratory or mixtures of such substances, only a few were obtained from the plant or animal world. In the foreseeable future, however, a fair part of the market may well be accounted for by substances or tissues prepared by genetic engineering, i.e., by a modification of biological processes in living organisms.

The definition of a pharmaceutical product used here, like some of those to be found in the national law, is also sufficiently broad to include blood products, sera, and vaccines, as well as products meant for veterinary use. It could also be considered to extend to some products used to prevent or treat diseases of plant crops ("phytopharmaceuticals") because at some point they may enter the human system in the form of residues. Some of these groups of products have customarily been dealt with under separate legislation, but that is mainly because rather different types of expertise may be required to deal with them, or because they fall administratively under different government agencies: the legal and ethical issues relating to them are not basically different to those arising when one considers medicines of the most familiar type administered to man.

Pharmaceutical development traditionally involves a linear, sequential series of structured events [2]. This is true on both a macro (program) level as well as a micro (study) level. In both cases, there is an extraordinary amount of highly structured data - a single clinical trial alone may involve several million data points, and a development program may include as many as 30 or more studies. One of the challenging aspects of pharmaceutical development is the fact that this enormous quantity of data must be handled accurately, with accountability from the first place a result was recorded to the final database, along with each change along the way.

II. Drug

In the most general sense, a drug may be defined as any substance that brings about a change in biologic function through its chemical actions [3]. In most cases, the drug molecule interacts as an agonist (activator) or antagonist (inhibitor) with a specific target molecule that plays a regulatory role in the biologic system. This target molecule is called a receptor. In a very small number of cases, drugs are known as chemical antagonists may interact directly with other drugs, whereas a few drugs (osmotic agents) interact almost exclusively with water molecules. Drugs may be synthesized within the body (e.g., hormones) or may be chemicals not synthesized in the body (i.e., xenobiotics). Poisons are drugs that have almost exclusively harmful effects. However, Paracelsus (1493–1541) famously stated that "the dose makes the poison," meaning that any substance can be harmful if taken in the wrong dosage. Toxins are usually defined as poisons of biologic origin, i.e., synthesized by plants or animals, in contrast to inorganic poisons such as lead and arsenic.

Safe drugs, which are consistent with new scientific principles and experience, are extremely important in treating the disease in the best and most efficient way, without the ability to bring the patient to potential danger [4]. To provide the highest possible level of patient safety, accurate and correct information should be available both to the health care team of professionals and to the patient themselves.

The permanent task of all health care professionals is to educate patients.

The most basic information about therapy, doctors and pharmacists must be given to the patients

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themselves to take an active part in their treatment, to understand the importance of the drug and to be familiar with the ability to cure and to make the therapy successful. The patient must be informed about his illness, the drug he or she is taking, his actions, the side effects, the contraindications, the interactions because the real drug is timely, accurate and objective information. The drug information must be independent, exhaustive and best in the patient's interest. The personal interests of doctors and pharmacists should not interfere with informing the patient.

Prescription and medication should not be routine, followed by silence or poorly information or with the type of instructions take this medicine twice a day. The prescribing and issuing of drugs should be individually focused on the best interest of the patient, taking into account of the specifics of each, the economic conditions in which they live, the possibilities for adequate drug use, the physical condition of the patient and numerous other factors.

III. Pharmacogenomics

Pharmacogenomics, the study of genetic factors that underlie variation in drug response, is a modern term for pharmacogenetics [5]. Pharmacogenomics implies a recognition that more than one genetic variant may contribute to variation in drug response. Historically, the field began with observations of severe adverse drug reactions in certain individuals, who were found to harbor genetic variants in drug-metabolizing enzymes. As a scientific field, pharmacogenomics has advanced rapidly since the sequencing of the human genome. In the last decade, powerful genome wide association (GWA) studies, in which hundreds of thousands of genetic variants across the genome are tested for association with drug response, led to the discovery of many other important polymorphisms that underlie variation in both therapeutic and adverse drug response. In addition to polymorphisms in genes that encode drug-metabolizing enzymes, it is now known that polymorphisms in genes that encode transporters, human leukocyte antigen (HLA) loci, cytokines, and various other proteins are also predictive of variation in therapeutic and adverse drug responses. In addition to the discoveries that have been made, the past decade has ushered in “precision medicine,” also known as “stratified or personalized medicine,” in which genetic information is used to guide drug and dosing selection for subgroups of patients or individual patients in medical practice. The Clinical Pharmacogenetics Implementation Consortium (CPIC) published a series of guidelines for using genetic information in selecting medications and in dosing. These highly informative guidelines are being used by practitioners in prescribing drugs to more effectively treat patients. Where appropriate, CPIC recommendations are included to provide information on how to use genetic variant data appropriately in therapeutic medicine.

IV. Quality Control

A pharmaceutical industry quality control laboratory has the important function of testing raw materials, packaging components, materials being processed and finished products for quality [6]. It is important to recognize that quality control plays an important role in the quality assurance of pharmaceuticals all the way from research and development on investigational medicinal products, through to scale-up and commercial manufacture. Key decisions are made from the analytical data generated, and so the reliability of the results is paramount. The safety of patients depends upon the body of knowledge generated by analytical chemists on active pharmaceutical ingredients (APIs) and drug products during product research and development, process validation studies, stability testing, in-process control and finished product testing. When problems occur, the data generated by the quality control laboratory will help to determine the cause and improve process and product quality.

Testing laboratories involved in the generation of data for product development, marketing authorization and batch release of medicinal products face the challenge of undertaking their activities in a heavily regulated environment. Also, as a functional and costly part of the business, testing laboratories must run their operations as efficiently as possible.

Regulatory authorities such as the Medicines and Healthcare products Regulatory Agency (MHRA), the Food and Drug Administration (FDA) or the European Agency for the Evaluation of Medicinal Products (EMEA) enforce national and international regulations. To comply with these, pharmaceutical companies are required to put appropriate quality systems in place. Maintaining the quality system in good working order draws heavily on resources, and costs can be high.

Regulatory compliance versus lean and efficient operational costs can be the dichotomy that every manufacturer faces.

V. Pharmacist

The law imposes duty to take care of a variety of circumstances [7]. As sellers of goods, community pharmacists must take reasonable care to warn customers of any potential dangers arising from them. Quite apart from this general duty on all vendors of goods, there is a special relationship between pharmacists and their customers in respect of transactions involving pharmaceutical knowledge. Reliance is placed upon the special skill and knowledge of the pharmacist when selling, dispensing or prescribing medicinal products. The law would expect him/her to

exercise that degree of competence which the average member of the profession is required to possess. This is known as the 'duty of care.' A pharmacist occupying a special position in any branch of pharmacy would be expected to have a degree of ability commensurate with that position. Pharmacists consistently, and with good reason, press for recognition as experts on drugs and medicines, and for the right to take a greater part in the health services. Every right has its correlative duty, and pharmacists, as they achieve greater recognition, must expect the law to require from them a higher degree of skill. It is probable that they will, as a consequence, be more liable to actions for professional negligence.

Years ago, the pharmacy's main job was the dispensing and compounding of drugs [8]. Because of this relatively limited duty, ethical issues in the workplace were not as prevalent as they are today, and the law or the following of the law was the most important factor to consider. Today, in addition to dispensing and compounding medication, pharmacists counsel patients on proper medication usage, potential side effects, and drug interactions. Pharmacists also must be the mediator if and when questions arise with the patient or the prescriber. Because of the pharmacy professional's close personal contact with the public, problems can arise, and ethical applications may need to be considered.

With high standards firmly in place and competent professionals, the pharmacy profession will continue to excel and live up to its stellar reputation. The profession has proved through changing times that it can rise to the occasion and handle ethical and legal considerations.

Pharmacy is a noble and sacred profession committed to the cause of health care for human beings [9]. The pharmacist is a vital link between the doctor and the patient. He is charged with the responsibility of providing professional services of a high order to the community at large by ensuring production of Quality Medicine and their sale and distribution to the consumers.

The pharmaceutical Ethics encompasses the code of moral principles or the science of morals which is concerned with human character. The pharmacist of today is a drub-maker, drug-dispenser, drug-custodian, patient-counselor, drug-researcher and drug-educator and above all an honest and patriotic citizen. The techno-professional background of the pharmacist gives him / her the confidence of providing services with an ethical approach to the satisfaction of patients. The sacred values are required to be cherished and professed by the pharmacist.

VI. Pharmacy and Health Care

Pharmacy, unlike chemistry or biology, is certainly not a pure science [10]. Rather, it is a profession comprising a wide array of academic and professional disciplines that include basic sciences, business, sociology, and law. Pharmacy practice has changed as rapidly as any other profession in the past few decades. In the not so distant past, a pharmacist's responsibilities were heavily concentrated in compounding and preparing a variety of medicinal dosage forms. A pharmacist would routinely prepare tablets, capsules, suppositories, elixirs, and other medicinal nostrums on the direction of the physician. However, as the pharmaceutical industry expanded, the more commonly compounded prescription products became commercially available. Neighborhood pharmacists were generally seen to augment physicians and became important providers of medical services. By the year 2000, pharmacists were increasingly more involved with therapeutic selection, drug regimen review and monitoring, and patient compliance through education and counseling.

During the last few decades, the pharmacist's new role as a therapeutic advisor and overseer of drug therapy has continued to grow. The role of therapeutic advisor manifests itself primarily in the hospital setting where the opportunity to utilize medical records is presented. The drug therapy overseer role exists in the community by the patient profile that allows the pharmacist to evaluate the multiple medications that more often than not are prescribed by several different physicians. This individual is an "advocacy pharmacist." An advocacy pharmacist assumes a truly patient-oriented role to serve the patient's best interests.

Clinical pharmacy practitioners paved the way for the pharmacist's advocacy role. Because they tended to work very closely with the physician and healthcare team, they prided themselves on exceedingly high professional standards and sophisticated drug knowledge. However, the world of the clinical pharmacist is in the acute care institution and academia. Today, these same precepts have crossed into all pharmacy practice in that pharmacists who practice in the advocacy model put the patient first and discuss the benefits and detriments of medications. They encourage patients to assume responsibility for their medications based on the framework of the patient's life style, values, and environment.

Generally, a pharmacist conducts and is involved in many activities that impact and affect healthcare delivery. The principal functions of a pharmacist are preparing and dispensing of prescription medications and medical devices. Since pharmacists must be certain of the correct medication, dosage form, and directions for use before filling a prescription, a profile of a patient's drug therapy may be crucial to assure that the medication has appropriate instructions and is used correctly. This involvement may include the use of healthcare information. Patient counseling has also become a rapidly growing function of pharmacists because of their specialized training.

These standard guidelines allow the pharmacist to practice pharmaceutical care some different practice settings. This expanded role is supported by the presence of pharmacists practicing pharmaceutical care in the acute care hospitals, ambulatory care and family practice clinics, long term care facilities, and home care programs.

However, the pharmacist of the 21st century cannot practice pharmaceutical care without an intimate knowledge of medication, pharmacy practice, and the laws and regulations that govern them. This paper no has intent to teach the practice of pharmacy. It is designed to assist pharmacists, pharmacy interns, and pharmacy technicians in the practical aspects of their daily professional activities by serving as a handy reference guide to answer fundamental questions of pharmacy practice and the law.

There is still a need to be constantly evaluating what we do and why we do it, to meet the demands of healthcare in the future [11]. There are also new challenges to be faced, such as who the knowledge managers of the future will be. The challenge in community pharmacy is probably greater: the future is likely to belong to those who are willing to develop services, take risks and then seek funding, rather than those with the common attitude of wanting money up front. Current funding mechanisms need to move away from the payment-per-dispensing-item method: greater use will need to be made of technical support and the current practice of having only one pharmacist in each shop almost certainly needs to change.

One thing is sure: whatever is developed will increasingly need to be supported by reliable evidence derived from top-quality research.

Pharmaceutical products play a central role in the prevention and treatment of disease [12]. Making safe and effective pharmaceutical products available and affordable to individuals around the world is a central challenge to the global governance system. There are however myriad obstacles to achieving and maintaining effective worldwide availability of medicines.

Even though people around the world face largely similar challenges from disease, the policy framework for promoting innovation and regulating pharmaceutical supply are remarkably disjointed. Innovation policy, insofar as it is implemented at all, is established on a country-to-country basis with minimal attention to coordination of research and development. Regulatory structures are almost equally fragmented. Each country has its own set of approval standards and regulatory procedures that must be dealt with, and only to a limited extent are there cooperative procedures or systems of mutual recognition. Corporate decisions concerning where to concentrate innovative efforts, what to produce, where to supply it and on what terms are based on the likely impact on profits and capital markets.

VII. Pharmacy and Business

In any form of business enterprise, certain rules exist to govern the behavior of the institution, and those who work in it [1]. The rules are not always clear, and they are not consistently respected, but their existence is evident and the need for some sort of standard is almost universally acknowledged. The majority of the rules are not specific to a particular type of business: they are fundamental in any enterprise because without them the business cannot operate consistently or harmoniously or play a constructive and acceptable role in serving society. These general rules concern the way in which the business operates, both internally and in its environment. Other rules, underlying and complementing these product standards, are activity-related, e.g., specific to the manufacture of goods of a particular type: it is obviously improper (but also unwise) to produce an unsafe bicycle, a glue that adheres only for a short time or a newspaper that does not attempt to tell the truth.

The pharmaceutical industry did not appear overnight [1]. It came into being over many centuries, building on traditions created by others as they served the health needs of the community in their various ways, welding those traditions together and building a new one alongside them. As makers of medicines, the industry inherited much that came from the profession of pharmacy: in its ambition to provide care and instruction for the patient it learned from the tradition of medicine: it absorbed the learning of chemistry, and it brought a dozen newer sciences to fruition. In doing so, it became a new and potent unit of society, which was all the time creating fresh knowledge on the one hand and absorbing new learning on the other, registering achievements and falling into errors, and learning from both experiences.

All these traditions, as well as those of business and industry and the growing concept of human rights in health, were progressively welded together into an industry which acquired a face, a character and a way of working of its own. These things too needed to be defined if the industry was to function as a worthy element of society, capable of enriching it but also willing to heed its needs to serve it.

VIII. Diagnosis

Disease and illness have always challenged human existence, and healthcare has mirrored humanity's social evolution and acquisition of scientific knowledge [13]. As cities grew, populations multiplied, and long-distance travel increased, larger outbreaks of infectious diseases became possible. As our activity level, diet, and longevity have changed, we have increasingly had to treat diseases of the joints, cardiovascular diseases, and cancers. Similarly, our understanding of what causes these and other diseases

has evolved from attributing their origin to demonic forces and the imbalance of elements such as the four bodily senses of humor to today's scientific understandings of microbiology, cell biology, and genetics. With our increased knowledge came vastly improved treatments. The days of bleeding patients to treat fevers are gone. We have vaccines to prevent infections. But as society and science have advanced, we continue to be challenged by new diseases and providing access to healthcare for all people. These are two of today's greatest healthcare challenges focuses on various aspects of how we can be more successful in addressing them.

Physicians usually tackle clinical situations by taking a history (asking questions), performing a physical examination, obtaining selective laboratory and imaging tests, and then formulating a diagnosis [14]. The synthesis of the history, physical examination, and imaging or laboratory tests is called the clinical database. After reaching a diagnosis, a treatment plan is usually initiated, and the patient is followed for clinical response. Rational understanding of disease and plans for treatment are best acquired by learning about the normal human processes on a basic science level: likewise, being aware of how disease alters the normal physiologic processes is also best understood on a basic science level. Pharmacology and therapeutics also require the ability to tailor the correct medication to the patient's situation and awareness of the medication's adverse effect profile. Sometimes, the patient has an adverse reaction to medication as the chief complaint, and the physician must be able to identify the medication as the culprit. An understanding of the underlying basic science allows for more rational analysis and medication choices.

IX. Conclusion

Each drug has its purpose, i.e., each drug is used to treat a specific disease and for other purposes should not be used. Drugs are prescribed by doctors in the form of a prescription, which should include the time to taking in of the drug to the body, the dose and the duration of the treatment. Drugs and other pharmaceutical products such as, for example, fats, creams, solutions, injections, etc. are sometimes used in the treatment of some diseases. All pharmaceutical products must be safe for use, and patients must be familiar with their healing properties. Except for doctors, real advice can be given to patients by pharmacists because, like all other medical professionals, they are active participants in health preservation. This means that activities in promoting health and disease prevention do a significant part of everyday pharmacy practice.

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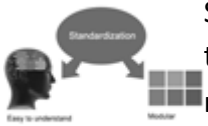

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The corresponding author should mention the name and complete details of all co-authors during submission and in manuscript. We support addition, rearrangement, manipulation, and deletions in authors list till the early view publication of the journal. We expect that corresponding author will notify all co-authors of submission. We follow COPE guidelines for changes in authorship.

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Appealing Decisions

Unless specified in the notification, the Editorial Board's decision on publication of the paper is final and cannot be appealed before making the major change in the manuscript.

Acknowledgments

Contributors to the research other than authors credited should be mentioned in Acknowledgments. The source of funding for the research can be included. Suppliers of resources may be mentioned along with their addresses.

Declaration of funding sources

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Preparing your Manuscript

Authors can submit papers and articles in an acceptable file format: MS Word (doc, docx), LaTeX (.tex, .zip or .rar including all of your files), Adobe PDF (.pdf), rich text format (.rtf), simple text document (.txt), Open Document Text (.odt), and Apple Pages (.pages). Our professional layout editors will format the entire paper according to our official guidelines. This is one of the highlights of publishing with Global Journals—authors should not be concerned about the formatting of their paper. Global Journals accepts articles and manuscripts in every major language, be it Spanish, Chinese, Japanese, Portuguese, Russian, French, German, Dutch, Italian, Greek, or any other national language, but the title, subtitle, and abstract should be in English. This will facilitate indexing and the pre-peer review process.

The following is the official style and template developed for publication of a research paper. Authors are not required to follow this style during the submission of the paper. It is just for reference purposes.

Manuscript Style Instruction (Optional)

- Microsoft Word Document Setting Instructions.
- Font type of all text should be Swis721 Lt BT.
- Page size: 8.27" x 11'", left margin: 0.65, right margin: 0.65, bottom margin: 0.75.
- Paper title should be in one column of font size 24.
- Author name in font size of 11 in one column.
- Abstract: font size 9 with the word "Abstract" in bold italics.
- Main text: font size 10 with two justified columns.
- Two columns with equal column width of 3.38 and spacing of 0.2.
- First character must be three lines drop-capped.
- The paragraph before spacing of 1 pt and after of 0 pt.
- Line spacing of 1 pt.
- Large images must be in one column.
- The names of first main headings (Heading 1) must be in Roman font, capital letters, and font size of 10.
- The names of second main headings (Heading 2) must not include numbers and must be in italics with a font size of 10.

Structure and Format of Manuscript

The recommended size of an original research paper is under 15,000 words and review papers under 7,000 words. Research articles should be less than 10,000 words. Research papers are usually longer than review papers. Review papers are reports of significant research (typically less than 7,000 words, including tables, figures, and references)

A research paper must include:

a) A title which should be relevant to the theme of the paper.
b) A summary, known as an abstract (less than 150 words), containing the major results and conclusions.
c) Up to 10 keywords that precisely identify the paper's subject, purpose, and focus.
d) An introduction, giving fundamental background objectives.
e) Resources and techniques with sufficient complete experimental details (wherever possible by reference) to permit repetition, sources of information must be given, and numerical methods must be specified by reference.
f) Results which should be presented concisely by well-designed tables and figures.
g) Suitable statistical data should also be given.
h) All data must have been gathered with attention to numerical detail in the planning stage.

Design has been recognized to be essential to experiments for a considerable time, and the editor has decided that any paper that appears not to have adequate numerical treatments of the data will be returned unrefereed.

i) Discussion should cover implications and consequences and not just recapitulate the results; conclusions should also be summarized.
j) There should be brief acknowledgments.
k) There ought to be references in the conventional format. Global Journals recommends APA format.

Authors should carefully consider the preparation of papers to ensure that they communicate effectively. Papers are much more likely to be accepted if they are carefully designed and laid out, contain few or no errors, are summarizing, and follow instructions. They will also be published with much fewer delays than those that require much technical and editorial correction.

The Editorial Board reserves the right to make literary corrections and suggestions to improve brevity.

Format Structure

It is necessary that authors take care in submitting a manuscript that is written in simple language and adheres to published guidelines.

All manuscripts submitted to Global Journals should include:

Title

The title page must carry an informative title that reflects the content, a running title (less than 45 characters together with spaces), names of the authors and co-authors, and the place(s) where the work was carried out.

Author details

The full postal address of any related author(s) must be specified.

Abstract

The abstract is the foundation of the research paper. It should be clear and concise and must contain the objective of the paper and inferences drawn. It is advised to not include big mathematical equations or complicated jargon.

Many researchers searching for information online will use search engines such as Google, Yahoo or others. By optimizing your paper for search engines, you will amplify the chance of someone finding it. In turn, this will make it more likely to be viewed and cited in further works. Global Journals has compiled these guidelines to facilitate you to maximize the web-friendliness of the most public part of your paper.

Keywords

A major lynchpin of research work for the writing of research papers is the keyword search, which one will employ to find both library and internet resources. Up to eleven keywords or very brief phrases have to be given to help data retrieval, mining, and indexing.

One must be persistent and creative in using keywords. An effective keyword search requires a strategy: planning of a list of possible keywords and phrases to try.

Choice of the main keywords is the first tool of writing a research paper. Research paper writing is an art. Keyword search should be as strategic as possible.

One should start brainstorming lists of potential keywords before even beginning searching. Think about the most important concepts related to research work. Ask, “What words would a source have to include to be truly valuable in a research paper?” Then consider synonyms for the important words.

It may take the discovery of only one important paper to steer in the right keyword direction because, in most databases, the keywords under which a research paper is abstracted are listed with the paper.

Numerical Methods

Numerical methods used should be transparent and, where appropriate, supported by references.

Abbreviations

Authors must list all the abbreviations used in the paper at the end of the paper or in a separate table before using them.

Formulas and equations

Authors are advised to submit any mathematical equation using either MathJax, KaTeX, or LaTeX, or in a very high-quality image.

Tables, Figures, and Figure Legends

Tables: Tables should be cautiously designed, uncrowned, and include only essential data. Each must have an Arabic number, e.g., Table 4, a self-explanatory caption, and be on a separate sheet. Authors must submit tables in an editable format and not as images. References to these tables (if any) must be mentioned accurately.

Figures

Figures are supposed to be submitted as separate files. Always include a citation in the text for each figure using Arabic numbers, e.g., Fig. 4. Artwork must be submitted online in vector electronic form or by emailing it.

Preparation of Eletronic Figures for Publication

Although low-quality images are sufficient for review purposes, print publication requires high-quality images to prevent the final product being blurred or fuzzy. Submit (possibly by e-mail) EPS (line art) or TIFF (halftone/ photographs) files only. MS PowerPoint and Word Graphics are unsuitable for printed pictures. Avoid using pixel-oriented software. Scans (TIFF only) should have a resolution of at least 350 dpi (halftone) or 700 to 1100 dpi (line drawings). Please give the data for figures in black and white or submit a Color Work Agreement form. EPS files must be saved with fonts embedded (and with a TIFF preview, if possible).

For scanned images, the scanning resolution at final image size ought to be as follows to ensure good reproduction: line art: >650 dpi; halftones (including gel photographs): >350 dpi; figures containing both halftone and line images: >650 dpi.

Color charges: Authors are advised to pay the full cost for the reproduction of their color artwork. Hence, please note that if there is color artwork in your manuscript when it is accepted for publication, we would require you to complete and return a Color Work Agreement form before your paper can be published. Also, you can email your editor to remove the color fee after acceptance of the paper.

Tips for writing a good quality Medical Research Paper

1. Choosing the topic: In most cases, the topic is selected by the interests of the author, but it can also be suggested by the guides. You can have several topics, and then judge which you are most comfortable with. This may be done by asking several questions of yourself, like "Will I be able to carry out a search in this area? Will I find all necessary resources to accomplish the search? Will I be able to find all information in this field area?" If the answer to this type of question is "yes," then you ought to choose that topic. In most cases, you may have to conduct surveys and visit several places. Also, you might have to do a lot of work to find all the rises and falls of the various data on that subject. Sometimes, detailed information plays a vital role, instead of short information. Evaluators are human: The first thing to remember is that evaluators are also human beings. They are not only meant for rejecting a paper. They are here to evaluate your paper. So present your best aspect.

2. Think like evaluators: If you are in confusion or getting demotivated because your paper may not be accepted by the evaluators, then think, and try to evaluate your paper like an evaluator. Try to understand what an evaluator wants in your research paper, and you will automatically have your answer. Make blueprints of paper: The outline is the plan or framework that will help you to arrange your thoughts. It will make your paper logical. But remember that all points of your outline must be related to the topic you have chosen.

3. Ask your guides: If you are having any difficulty with your research, then do not hesitate to share your difficulty with your guide (if you have one). They will surely help you out and resolve your doubts. If you can't clarify what exactly you require for your work, then ask your supervisor to help you with an alternative. He or she might also provide you with a list of essential readings.

4. Use of computer is recommended: As you are doing research in the field of medical research then this point is quite obvious. Use right software: Always use good quality software packages. If you are not capable of judging good software, then you can lose the quality of your paper unknowingly. There are various programs available to help you which you can get through the internet.

5. Use the internet for help: An excellent start for your paper is using Google. It is a wondrous search engine, where you can have your doubts resolved. You may also read some answers for the frequent question of how to write your research paper or find a model research paper. You can download books from the internet. If you have all the required books, place importance on reading, selecting, and analyzing the specified information. Then sketch out your research paper. Use big pictures: You may use encyclopedias like Wikipedia to get pictures with the best resolution. At Global Journals, you should strictly follow here.

6. Bookmarks are useful: When you read any book or magazine, you generally use bookmarks, right? It is a good habit which helps to not lose your continuity. You should always use bookmarks while searching on the internet also, which will make your search easier.

7. Revise what you wrote: When you write anything, always read it, summarize it, and then finalize it.

8. Make every effort: Make every effort to mention what you are going to write in your paper. That means always have a good start. Try to mention everything in the introduction—what is the need for a particular research paper. Polish your work with good writing skills and always give an evaluator what he wants. Make backups: When you are going to do any important thing like making a research paper, you should always have backup copies of it either on your computer or on paper. This protects you from losing any portion of your important data.

9. Produce good diagrams of your own: Always try to include good charts or diagrams in your paper to improve quality. Using several unnecessary diagrams will degrade the quality of your paper by creating a hodgepodge. So always try to include diagrams which were made by you to improve the readability of your paper. Use of direct quotes: When you do research relevant to literature, history, or current affairs, then use of quotes becomes essential, but if the study is relevant to science, use of quotes is not preferable.

10. Use proper verb tense: Use proper verb tenses in your paper. Use past tense to present those events that have happened. Use present tense to indicate events that are going on. Use future tense to indicate events that will happen in the future. Use of wrong tenses will confuse the evaluator. Avoid sentences that are incomplete.

11. Pick a good study spot: Always try to pick a spot for your research which is quiet. Not every spot is good for studying.

12. Know what you know: Always try to know what you know by making objectives, otherwise you will be confused and unable to achieve your target.

13. Use good grammar: Always use good grammar and words that will have a positive impact on the evaluator; use of good vocabulary does not mean using tough words which the evaluator has to find in a dictionary. Do not fragment sentences. Eliminate one-word sentences. Do not ever use a big word when a smaller one would suffice.

Verbs have to be in agreement with their subjects. In a research paper, do not start sentences with conjunctions or finish them with prepositions. When writing formally, it is advisable to never split an infinitive because someone will (wrongly) complain. Avoid clichés like a disease. Always shun irritating alliteration. Use language which is simple and straightforward. Put together a neat summary.

14. Arrangement of information: Each section of the main body should start with an opening sentence, and there should be a changeover at the end of the section. Give only valid and powerful arguments for your topic. You may also maintain your arguments with records.

15. Never start at the last minute: Always allow enough time for research work. Leaving everything to the last minute will degrade your paper and spoil your work.

16. Multitasking in research is not good: Doing several things at the same time is a bad habit in the case of research activity. Research is an area where everything has a particular time slot. Divide your research work into parts, and do a particular part in a particular time slot.

17. Never copy others' work: Never copy others' work and give it your name because if the evaluator has seen it anywhere, you will be in trouble. Take proper rest and food: No matter how many hours you spend on your research activity, if you are not taking care of your health, then all your efforts will have been in vain. For quality research, take proper rest and food.

18. Go to seminars: Attend seminars if the topic is relevant to your research area. Utilize all your resources.

19. Refresh your mind after intervals: Try to give your mind a rest by listening to soft music or sleeping in intervals. This will also improve your memory. Acquire colleagues: Always try to acquire colleagues. No matter how sharp you are, if you acquire colleagues, they can give you ideas which will be helpful to your research.

20. Think technically: Always think technically. If anything happens, search for its reasons, benefits, and demerits. Think and then print: When you go to print your paper, check that tables are not split, headings are not detached from their descriptions, and page sequence is maintained.

21. Adding unnecessary information: Do not add unnecessary information like "I have used MS Excel to draw graphs." Irrelevant and inappropriate material is superfluous. Foreign terminology and phrases are not apropos. One should never take a broad view. Analogy is like feathers on a snake. Use words properly, regardless of how others use them. Remove quotations. Puns are for kids, not grunt readers. Never oversimplify: When adding material to your research paper, never go for oversimplification; this will definitely irritate the evaluator. Be specific. Never use rhythmic redundancies. Contractions shouldn't be used in a research paper. Comparisons are as terrible as clichés. Give up ampersands, abbreviations, and so on. Remove commas that are not necessary. Parenthetical words should be between brackets or commas. Understatement is always the best way to put forward earth-shaking thoughts. Give a detailed literary review.

22. Report concluded results: Use concluded results. From raw data, filter the results, and then conclude your studies based on measurements and observations taken. An appropriate number of decimal places should be used. Parenthetical remarks are prohibited here. Proofread carefully at the final stage. At the end, give an outline to your arguments. Spot perspectives of further study of the subject. Justify your conclusion at the bottom sufficiently, which will probably include examples.

23. Upon conclusion: Once you have concluded your research, the next most important step is to present your findings. Presentation is extremely important as it is the definite medium though which your research is going to be in print for the rest of the crowd. Care should be taken to categorize your thoughts well and present them in a logical and neat manner. A good quality research paper format is essential because it serves to highlight your research paper and bring to light all necessary aspects of your research.

Informal Guidelines of Research Paper Writing

Key points to remember:

- Submit all work in its final form.
- Write your paper in the form which is presented in the guidelines using the template.
- Please note the criteria peer reviewers will use for grading the final paper.

Final points:

One purpose of organizing a research paper is to let people interpret your efforts selectively. The journal requires the following sections, submitted in the order listed, with each section starting on a new page:

The introduction: This will be compiled from reference matter and reflect the design processes or outline of basis that directed you to make a study. As you carry out the process of study, the method and process section will be constructed like that. The results segment will show related statistics in nearly sequential order and direct reviewers to similar intellectual paths throughout the data that you gathered to carry out your study.

The discussion section:

This will provide understanding of the data and projections as to the implications of the results. The use of good quality references throughout the paper will give the effort trustworthiness by representing an alertness to prior workings.

Writing a research paper is not an easy job, no matter how trouble-free the actual research or concept. Practice, excellent preparation, and controlled record-keeping are the only means to make straightforward progression.

General style:

Specific editorial column necessities for compliance of a manuscript will always take over from directions in these general guidelines.

To make a paper clear: Adhere to recommended page limits.

Mistakes to avoid:

- Insertion of a title at the foot of a page with subsequent text on the next page.
- Separating a table, chart, or figure—confine each to a single page.
- Submitting a manuscript with pages out of sequence.
- In every section of your document, use standard writing style, including articles ("a" and "the").
- Keep paying attention to the topic of the paper.
- Use paragraphs to split each significant point (excluding the abstract).
- Align the primary line of each section.
- Present your points in sound order.
- Use present tense to report well-accepted matters.
- Use past tense to describe specific results.
- Do not use familiar wording; don't address the reviewer directly. Don't use slang or superlatives.
- Avoid use of extra pictures—include only those figures essential to presenting results.

Title page:

Choose a revealing title. It should be short and include the name(s) and address(es) of all authors. It should not have acronyms or abbreviations or exceed two printed lines.

Abstract: This summary should be two hundred words or less. It should clearly and briefly explain the key findings reported in the manuscript and must have precise statistics. It should not have acronyms or abbreviations. It should be logical in itself. Do not cite references at this point.

An abstract is a brief, distinct paragraph summary of finished work or work in development. In a minute or less, a reviewer can be taught the foundation behind the study, common approaches to the problem, relevant results, and significant conclusions or new questions.

Write your summary when your paper is completed because how can you write the summary of anything which is not yet written? Wealth of terminology is very essential in abstract. Use comprehensive sentences, and do not sacrifice readability for brevity; you can maintain it succinctly by phrasing sentences so that they provide more than a lone rationale. The author can at this moment go straight to shortening the outcome. Sum up the study with the subsequent elements in any summary. Try to limit the initial two items to no more than one line each.

Reason for writing the article—theory, overall issue, purpose.

- Fundamental goal.
- To-the-point depiction of the research.
- Consequences, including definite statistics—if the consequences are quantitative in nature, account for this; results of any numerical analysis should be reported. Significant conclusions or questions that emerge from the research.

Approach:

- Single section and succinct.
- An outline of the job done is always written in past tense.
- Concentrate on shortening results—limit background information to a verdict or two.
- Exact spelling, clarity of sentences and phrases, and appropriate reporting of quantities (proper units, important statistics) are just as significant in an abstract as they are anywhere else.

Introduction:

The introduction should "introduce" the manuscript. The reviewer should be presented with sufficient background information to be capable of comprehending and calculating the purpose of your study without having to refer to other works. The basis for the study should be offered. Give the most important references, but avoid making a comprehensive appraisal of the topic. Describe the problem visibly. If the problem is not acknowledged in a logical, reasonable way, the reviewer will give no attention to your results. Speak in common terms about techniques used to explain the problem, if needed, but do not present any particulars about the protocols here.

The following approach can create a valuable beginning:

- Explain the value (significance) of the study.
- Defend the model—why did you employ this particular system or method? What is its compensation? Remark upon its appropriateness from an abstract point of view as well as pointing out sensible reasons for using it.
- Present a justification. State your particular theory(-ies) or aim(s), and describe the logic that led you to choose them.
- Briefly explain the study's tentative purpose and how it meets the declared objectives.

Approach:

Use past tense except for when referring to recognized facts. After all, the manuscript will be submitted after the entire job is done. Sort out your thoughts; manufacture one key point for every section. If you make the four points listed above, you will need at least four paragraphs. Present surrounding information only when it is necessary to support a situation. The reviewer does not desire to read everything you know about a topic. Shape the theory specifically—do not take a broad view.

As always, give awareness to spelling, simplicity, and correctness of sentences and phrases.

Procedures (methods and materials):

This part is supposed to be the easiest to carve if you have good skills. A soundly written procedures segment allows a capable scientist to replicate your results. Present precise information about your supplies. The suppliers and clarity of reagents can be helpful bits of information. Present methods in sequential order, but linked methodologies can be grouped as a segment. Be concise when relating the protocols. Attempt to give the least amount of information that would permit another capable scientist to replicate your outcome, but be cautious that vital information is integrated. The use of subheadings is suggested and ought to be synchronized with the results section.

When a technique is used that has been well-described in another section, mention the specific item describing the way, but draw the basic principle while stating the situation. The purpose is to show all particular resources and broad procedures so that another person may use some or all of the methods in one more study or referee the scientific value of your work. It is not to be a step-by-step report of the whole thing you did, nor is a methods section a set of orders.

Materials:

Materials may be reported in part of a section or else they may be recognized along with your measures.

Methods:

- Report the method and not the particulars of each process that engaged the same methodology.
- Describe the method entirely.
- To be succinct, present methods under headings dedicated to specific dealings or groups of measures.
- Simplify—detail how procedures were completed, not how they were performed on a particular day.
- If well-known procedures were used, account for the procedure by name, possibly with a reference, and that's all.

Approach:

It is embarrassing to use vigorous voice when documenting methods without using first person, which would focus the reviewer's interest on the researcher rather than the job. As a result, when writing up the methods, most authors use third person passive voice.

Use standard style in this and every other part of the paper—avoid familiar lists, and use full sentences.

What to keep away from:

- Resources and methods are not a set of information.
- Skip all descriptive information and surroundings—save it for the argument.
- Leave out information that is immaterial to a third party.

Results:

The principle of a results segment is to present and demonstrate your conclusion. Create this part as entirely objective details of the outcome, and save all understanding for the discussion.

The page length of this segment is set by the sum and types of data to be reported. Use statistics and tables, if suitable, to present consequences most efficiently.

You must clearly differentiate material which would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matters should not be submitted at all except if requested by the instructor.

Content:

- Sum up your conclusions in text and demonstrate them, if suitable, with figures and tables.
- In the manuscript, explain each of your consequences, and point the reader to remarks that are most appropriate.
- Present a background, such as by describing the question that was addressed by creation of an exacting study.
- Explain results of control experiments and give remarks that are not accessible in a prescribed figure or table, if appropriate.
- Examine your data, then prepare the analyzed (transformed) data in the form of a figure (graph), table, or manuscript.

What to stay away from:

- Do not discuss or infer your outcome, report surrounding information, or try to explain anything.
- Do not include raw data or intermediate calculations in a research manuscript.
- Do not present similar data more than once.
- A manuscript should complement any figures or tables, not duplicate information.
- Never confuse figures with tables—there is a difference.

Approach:

As always, use past tense when you submit your results, and put the whole thing in a reasonable order.

Put figures and tables, appropriately numbered, in order at the end of the report.

If you desire, you may place your figures and tables properly within the text of your results section.

Figures and tables:

If you put figures and tables at the end of some details, make certain that they are visibly distinguished from any attached appendix materials, such as raw facts. Whatever the position, each table must be titled, numbered one after the other, and include a heading. All figures and tables must be divided from the text.

Discussion:

The discussion is expected to be the trickiest segment to write. A lot of papers submitted to the journal are discarded based on problems with the discussion. There is no rule for how long an argument should be.

Position your understanding of the outcome visibly to lead the reviewer through your conclusions, and then finish the paper with a summing up of the implications of the study. The purpose here is to offer an understanding of your results and support all of your conclusions, using facts from your research and generally accepted information, if suitable. The implication of results should be fully described.

Infer your data in the conversation in suitable depth. This means that when you clarify an observable fact, you must explain mechanisms that may account for the observation. If your results vary from your prospect, make clear why that may have happened. If your results agree, then explain the theory that the proof supported. It is never suitable to just state that the data approved the prospect, and let it drop at that. Make a decision as to whether each premise is supported or discarded or if you cannot make a conclusion with assurance. Do not just dismiss a study or part of a study as "uncertain."

Research papers are not acknowledged if the work is imperfect. Draw what conclusions you can based upon the results that you have, and take care of the study as a finished work.

- You may propose future guidelines, such as how an experiment might be personalized to accomplish a new idea.
- Give details of all of your remarks as much as possible, focusing on mechanisms.
- Make a decision as to whether the tentative design sufficiently addressed the theory and whether or not it was correctly restricted. Try to present substitute explanations if they are sensible alternatives.
- One piece of research will not counter an overall question, so maintain the large picture in mind. Where do you go next? The best studies unlock new avenues of study. What questions remain?
- Recommendations for detailed papers will offer supplementary suggestions.

Approach:

When you refer to information, differentiate data generated by your own studies from other available information. Present work done by specific persons (including you) in past tense.

Describe generally acknowledged facts and main beliefs in present tense.

The Administration Rules

Administration Rules to Be Strictly Followed before Submitting Your Research Paper to Global Journals Inc.

Please read the following rules and regulations carefully before submitting your research paper to Global Journals Inc. to avoid rejection.

Segment draft and final research paper: You have to strictly follow the template of a research paper, failing which your paper may get rejected. You are expected to write each part of the paper wholly on your own. The peer reviewers need to identify your own perspective of the concepts in your own terms. Please do not extract straight from any other source, and do not rephrase someone else's analysis. Do not allow anyone else to proofread your manuscript.

Written material: You may discuss this with your guides and key sources. Do not copy anyone else's paper, even if this is only imitation, otherwise it will be rejected on the grounds of plagiarism, which is illegal. Various methods to avoid plagiarism are strictly applied by us to every paper, and, if found guilty, you may be blacklisted, which could affect your career adversely. To guard yourself and others from possible illegal use, please do not permit anyone to use or even read your paper and file.

Criterion for Grading a Research Paper (Compilation) by Global Journals

Please note that following table is only a Grading of "Paper Compilation" and not on "Performed/Stated Research" whose grading solely depends on Individual Assigned Peer Reviewer and Editorial Board Member. These can be available only on request and after decision of Paper. This report will be the property of Global Journals.

Topics	Grades		
	A-B	**C-D**	**E-F**
Abstract	Clear and concise with appropriate content, Correct format. 200 words or below	Unclear summary and no specific data, Incorrect form Above 200 words	No specific data with ambiguous information Above 250 words
Introduction	Containing all background details with clear goal and appropriate details, flow specification, no grammar and spelling mistake, well organized sentence and paragraph, reference cited	Unclear and confusing data, appropriate format, grammar and spelling errors with unorganized matter	Out of place depth and content, hazy format
Methods and Procedures	Clear and to the point with well arranged paragraph, precision and accuracy of facts and figures, well organized subheads	Difficult to comprehend with embarrassed text, too much explanation but completed	Incorrect and unorganized structure with hazy meaning
Result	Well organized, Clear and specific, Correct units with precision, correct data, well structuring of paragraph, no grammar and spelling mistake	Complete and embarrassed text, difficult to comprehend	Irregular format with wrong facts and figures
Discussion	Well organized, meaningful specification, sound conclusion, logical and concise explanation, highly structured paragraph reference cited	Wordy, unclear conclusion, spurious	Conclusion is not cited, unorganized, difficult to comprehend
References	Complete and correct format, well organized	Beside the point, Incomplete	Wrong format and structuring

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