THE ROLE PLAYED BY THE INDIAN PHARMACOPOEIA COMMISSION IN TODAY'S ERA: A CRITICAL STUDY

Debabrata Basu
Assistant Professor of Law,Hooghly Mohsin College, Government of West Bengal,Chinsurah,West Bengal.

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Abstract

The Indian Pharmacopoeia Commission is a separate, autonomous institution under Ministry of Health and Family Welfare of the Government of India. The Indian Pharmacopoeia Commission was established in 2005 by the Government of India to deal with matter relating to timely publication of the Indian Pharmacopoeia, which is aofficial book of standards for drug included there in, under the Second Schedule of the Drugs and Cosmetics Act, 1940 so as to specify the standards of identify, purity and strength of the drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India.This Commission has become fully operational from 1st January, 2009. In the present day's scenario, this Commission plays very important role.

Keywords: *Indian Constitution, Law, Indian Pharmacopoeia, Monograph, IP Reference Substances.*

The object of Indian Pharmacopoeia Commission is to promote public health by establishing and disseminating officially recognized standards quality for and authoritative information about the use of medicines and health care technologies by health care professionals, patients, and consumers.[1] The main function of this Commission is to review and publish of the Indian Pharmacopoeia and National Formulary of India on a regular basis. It is also the objectives of the Commission to develop comprehensive monographs for drugs to be included in Indian Pharmacopoeia, to accord priority to monographs of drugs included in the National Essential Medicines List and to provide IP Reference Substances and to organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related materials. IP Reference Substances mean the official standards issued by the Indian Pharmacopoeia Commission.[2] Indian Pharmacopoeia contains a collection of authoritative procedures of analysis and specifications for Drugs. A Pharmacopoeia is a book containing directions for the identification of compound medicines and published by the authority of a government.[3] A pharmacopoeia is an official book describing medicines or other pharmacological substances, especially their use, preparation and regulation

[1]Dr. Sanvidhan G Suke, 'Indian Pharmacopoeia Commission: Structure and Role in Formulation of IP and NFI', World Academy of Science, Engineering and Technology International Journal of Pharmacological and Pharmaceutical Sciences Vol:9, No:2, 2015.scholar.waset.org/1307-6892/10001727.

'As per the policy of IPC, IP monographs are not framed to detect all possible impurities. The prescribed tests are designed to determine impurities on which attention are required to be focused, to fix the limits of those that are tolerable to a certain extent, and to indicate methods for ensuring the absence of those, that are undesirable. It is, therefore, not to be presumed that the impurities can be tolerated because they have not been precluded by the prescribed tests.'

[2]http://chromachemie.co.in/indian-pharmacopeia-reference-standards.html, visited 18.05.2020 at 10.41 A.M.

[3]https://en.wikipedia.org/wiki/Pharmacopoeia, visited on 18.05.2020 at 12.16 P.M.

while formulary is a list of available drugs, particularly prescription drugs.[4] A National Formulary contains a list of medicines that are approved for prescription throughout the country.[5]Multiplicity of drugs made it difficult even for a qualified and experienced physician to discriminate the choice of drugs. For the guidance of medical practitioners, medical students and pharmacists in hospitals and in sales departments, National Formulary of India have been formulated. Monograph (till date total numbers of monograph are 2829) usually contains basic chemical information for the ingredients as well as its description and function of drugs. Till date total eight IP editions and their supplements/addendums and 5th edition of National Formulary of India have been published by the Commission.[6]

Rationale and Scope of the Study

The inquisitiveness of the author with respect to know about the importance of the Commission as well as to know the various activities which the Commission is performing compelled the author to go ahead with this direction. The scope of this study is to know about the law sanctioning the establishment of the Commission.

Research Methodology

This study will be partly empirical and partly doctrinal. In Doctrinal part, two types of reference will be used i.e. primary sources and secondary sources. Primary sources consist of statute and legislations and secondary sources are books, journals, articles. In Empirical part, the primary data was obtained by sending the questionnaires through social sites such as mail, phone, skype, face bookmassenger to the common people to assess the knowledge of the common people with respect to this. The samples of 35 persons were taken up for data collection from selected areas by means of opinion survey through questionnaires. Basically the structured questionnaires were asked. Questionnaire method is helpful to collect data from large, diverse and widely scattered people. Accordingly 35 common people were given opinion who were resident of Kolkata Metropolitan Area. The information has been collected on stratified random sampling method. The data obtained through the field survey is processed and presented in appropriate table for deriving conclusions. Simple statistical tools like percentages, is used for deriving inferences and conclusions.

Research Questions: The basic questions which the present study has raised for considerations are: Whether the general masses know about the Indian Pharmacopoeia Commission? What is the role of the Indian Pharmacopoeia Commission? Which law is backing for the establishment of this Commission?Are any changes required for better performance of the Commission?

Hypothesis:The Indian Pharmacopoeia Commission plays an important role in the life of the peoples of India.

Literature Review: In any research, literature review plays an important role. It is not only important but also essential when the author writes about any research report. It is a required homework that ought to have been done carefully. It is a fact finding task and initial step of any research. It depicts the pictures about what research has

[4]https://wikidiff.com/pharmacopoeia/formulary, visited on 18.05.2020 at 3.56 p.m.

[5]https://en.wikipedia.org/wiki/Formulary_(pharmacy), visited on 18.05.2020 at 4.13 p.m.

[6] Supra note 1.

been done in the past of the topic chosen by the author. The main aspect of literature review is that it judge, sums up, compares and contrasts, connects various books, articles, other relevant sources that are very much related to the present topic. It sharpens the focus of the researcher. A comprehensive review of relevant literature is essential as it place the research study in its proper perspective by narrating the amount of work already done in the related area. To build clarity of thought literature review plays a pivotal role. By identifying gaps in the existing literature, the researcher can justify the originality of the proposed research. The analytical features of a literature review might trace the intellectual progression of the field; identify the gaps exist till date. A good number of studies relevant for the present study have been studied.

Origin of Indian Pharmacopoeia:The Bengal Pharmacopoeia and General Conspectus of Medicinal Plants was published in 1844, which mainly listed most of the commonly used indigenous remedies. Thereafter Indian Pharmacopoeia was published in 1868 based on British Pharmacopoeia 1867 covering both the drugs of and indigenous drugs used in India, with a supplement published in 1869 incorporating the vernacular names of indigenous drugs and plants. However, from 1885 the British Pharmacopoeia was made official in India. Afterwards the Indian Pharmacopoeia was published in 1946[7]. After independence, an Indian Pharmacopoeia Committee was constituted in 1948, which prepared the Pharmacopoeia of India in 1955.[8]

Vision and Mission of the Commission:It is the objective of the Commission to promote the highest standards of drugs for use in humans and animals within practical limits of the technologies available for manufacturing and analysis. To promote public health and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients,excipients and dosage forms, used by health professionals, patients and consumers.[9]In a move to strength the Indian Pharmacopoeia further, the Health Ministry in association with the Indian Pharmacopoeia Commission is closely working with other key global pharmaceuticals standard setting bodies to harmonise the IP standards[10].Indian Pharmacopoeia or any part of it, has got legal status under page numbers 37 and 38 of the Second Schedule of the Drugs and Cosmetics Act, 1940. Standards of Drugs included in IP – Standards of Identity, Purity and Strength as specified in the Indian Pharmacopoeia for the time being in force as mandated in Drugs and Cosmetics Rules 1945.[11]

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[7] Supra note 1. After Independence the IP Editions are: First-1955; Second-1966; Third-1985; Fourth-1996; Fifth-2007; Sixth-2010; Seventh-2014; Eighth edition-2018. The supplement to the IP published 1960;1975;1989&1991; 2000,2002,2005;2008; 2012; 2015. 6th edition IP contained total 2000 monographs including 287 new monographs and more than 600 updated monographs.

[8]Jai Prakash et al., 'Current Status of Herbal Drug Standards in the Indian Pharmacopoeia', PHYTOTHERAPY RESEARCH Phytother. Res. (2017) Published online in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/ptr.5933.
https://www.researchgate.net/publication/332268739_Current_Status_of_Herbal_Drug_Standards_in_the_Indian_Pharmacopoeia/link/5cab17d0a6fdcca26d066797/download 17.05.2020 at 12.57 pm

[9]httpswww.pmda.go.jpfiles000214416.pdf visited on 17.05.2020 AT 12.02.P.M.

[10]http://www.pharmabiz.com/NewsDetails.aspx?aid=88331&sid=1 17.05.2020 at 3.44 pm.

[11] https://www.idma-assn.org/pdf/dr-pl-sahu.pdf 17.05.2020 at 2.48 pm

Structure of the Commission:The IPC is a three-tier structure comprising of the General Body (25 members), Governing body (13 members) and Scientific Body (15-23 membersfrom different related scientific fields). The Secretary-cum-Scientific Director of the Commission is the Member Secretary of all three bodies of the Commission as well as the Chief Scientific and Executive Officer of the Commission. The Secretary, Ministry of Health and Family Welfare is the Chairman of the Commission.[12]

The 7th and 8th Edition of Indian Pharmacopoeia:The seventh editions published in accordance with the principles and designed plan decided by the Scientific Body of the Commission. The 7th edition incorporates 2548 monographs.[13]The Indian Pharmacopoeia Commission has released the 8th Edition of Indian Pharmacopoeia on 2018 consisting of 4 Volumes incorporating 220 new monographs [Chemical Monographs (170), Herbal Monographs (15), Blood and Blood related products (10), Vaccines and Immunosera for Human use monographs (02), Radiopharmaceutical monographs (03), Biotechnology Derived Therapeutic Products (06), Veterinary monographs (14)], 366 revised monographs and 7 omissions.[14] The Indian Pharmacopoeia Commission is set to become the first WHO Collaborating Centre for Safety of Medicines and Vaccines in the South-East Asia Region.[15] However, the Pharmacopoeial standards are enforced by the Central, State and Union Territory drug regulatory authorities of India in accordance with the Drugs and Cosmetics Act 1940 and Rules 1945.[16]

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[12] Supra note 1.

[13]Supra note 1.

The 7th edition incorporates 2548 monographs of drugs out of which 577 new monographs, 134 API monographs, 161 formulations monographs, 18 excipient monographs, 43 NDS monographs, 10 antibiotic monographs, 19 anticancer monographs, 11 antiviral monographs are included in this edition. Also 31 herbal monographs, 05 monographs on Vaccine and Immunosera for human use, 06 monographs on insulin products and 07 monographs on biotechnology products are included.

[14]https://www.mondaq.com/india/food-and-drugs-law/671182/indian-pharmacopoeia-commission-ipc-releases-eighth-edition-of-indian-pharmacopoeia-ip visited on 17.05.2020 at 12.34 pm.

"Salient Features of IP-2018 are: Keeping in view the essential requirement for harmonization of analytical methods with those accepted internationally, steps have been taken for monitoring drug standards. General Chemical tests & Thin Layer Chromatography (TLC) for identification of an article have been almost eliminated; and more specific infrared, ultraviolet spectrophotometer and HPLC tests have been emphasized. The concept of relying on published infrared spectra as a basis for identification has been continued. The use of chromatographic methods has been extended to cope with the need for more specificity in assays and in particular, in assessing the nature and extent of impurities in ingredients and products. Most of the existing Assays and Related Substances Test methods have been upgraded by liquid chromatography to harmonize with other International Pharmacopoeias. Pyrogen test has been replaced by Bacterial Endotoxin test (BET) in parenteral preparations and other monographs. For ease of access to make Pharmacopoeia more user-friendly, an Index has been incorporated in Volume-I along with the already existing one in Volume-IV of IP. 53 New Fixed Dose Combination (FDCs) monographs have been included, out of which 25 FDC monographs are not available in any Pharmacopoeia. General Chapters on Volumetric Glassware, Conductivity, Dissolution test, Disintegration test, Dimensions of Hard Gelatin Capsule Shells etc. have been revised."

[15]https://pib.gov.in/newsite/mbErel.aspx?relid=130201 17.05.2020 at 12.42 pm.

[16]Jai Prakash et al., 'Current Status of Herbal Drug Standards in the Indian Pharmacopoeia', PHYTOTHERAPY RESEARCH Phytother. Res. (2017) Published online in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/ptr.5933.

History of Pharmacopoeias: A Global Perspective:According to the latest index of the World Health Organisation, there are 40 Pharmacopoeias published around the world.[17]In the 16th century some city of Europe maintained Pharmacopoeias containing medical prescription for physicians.In the 19th century, there was an emerging focus to standardize the content in the pharmacopoeias. In 1820, the United States Pharmacopeia; in 1858, the British Pharmacopoeia, and in 1953 Chinese Pharmacopoeia were created with an object of providing quality standards for medicines to benefit patients. The other countries published pharmacopoeia in the following year, for example Japanese Pharmacopoeia 1886; the pharmacopoeias in Mexico 1846; Argentina 1898; Brazilian Pharmacopoeia 1929; Korean Pharmacopoeia 1958; the Indonesian Pharmacopoeia in 1962. WHO adopted International Pharmacopoeia in 1951 and the eighth edition of International Pharmacopoeia was published in 2018 to serve as source material for reference or adaptation by any WHO Member State. However, it was recommended that International Pharmacopoeia was not intended to be a legal pharmacopoeia in any country unless adopted by the pharmacopoeial authority of that country.[18]

Kelsen's theory and the Commission:According to Article 245 (1) of the Constitution, Parliament may make laws for the whole or any part of the territory of India, and the Legislature of a State may make laws for the whole or any part of the State. According to Article 246 (1) of the Constitution of India, Parliament has exclusive power to make laws with respect to any of the matters enumerated in the Union List. According to Article 13 (1) of the Constitution of India, 'all laws in force in the territory of India immediately before the commencement of this Constitution, in so far as they are inconsistent with the provisions of this Part, shall, to the extent of such inconsistency, be void'. Therefore it can be said that if that law not violates the provisions of the fundamental rights, then the law is valid. The Drugs and Cosmetics Act, 1940[19] was enacted to regulate the import, manufacture, distribution and sale of drugs. Indian Pharmacopoeia or any part of it, has got legal status under page numbers 37 and 38 of the Second Schedule of the Drugs and Cosmetics Act, 1940 as well as in various provisions of the Drugs and Cosmetics Rules, 1945. In exercise of the powers conferred by Sections 6(2), 12, 33 and 33 N of the Drugs and Cosmetics Act, 1940,

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'Indian Pharmacopoeia (2007a) incorporated for the firsttimeachapteronthegeneralrequirementsofherbs and herbal products standards and a total of 58 specific monographs, including 23 new monographs. The new monographs included were Amalaki, Amra, Arjuna, Artemisia, Bhibhitaki, Bhringraj, Coleus, Gokhru, Gudmar, Guduchi, Haritaki, Kunduru, Kutki, Lasuna, Manjistha, Maricha, Pippali Large, Pippali Small, Punarnava, Sarpagandha, Shatavari, Shati and Tulasi. Indian Pharmacopoeia, Addendum 2008 (2007b) incorporated nine new monographs, namely, Ajwain, Anantmula, Daruharidra Roots, Daruharidra Stems, Kalmegh Dry Extract, Saunf, Senna Dry Extract, Senna Tablets and Yasti Dry Extract'.

[17]J. Mark Wiggins and Joseph A. Albanese, 'A Brief History of Pharmacopoeias: A Global Perspective', Pharmaceutical TechnologyREGULATORYSOURCEBOOKSEPTEMBER2019,Pp.1-6, http://files.alfresco.mjh.group/alfresco_images/pharma//2019/09/25/173bf119-f56e-4e58-ac1d-9ae9d126a800/PTebook0919_PharmacopeiaCompendia_History_watermark.pdf 17.05.2020 at 1.46 pm.

[18]J. Mark Wiggins and Joseph A. Albanese, 'A Brief History of Pharmacopoeias: A Global Perspective', Pharmaceutical TechnologyREGULATORYSOURCEBOOKSEPTEMBER2019,Pp.1-6,

[19]https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf, visited on 18.05.2020 at 11.10 am

the Central Government made the Drugs and Cosmetics Rules, 1945 which contains 169 rules. The Indian Pharmacopoeia Committee (old name) was established by executive orders in 1945 according to the Indian Drugs and Cosmetics Act, 1940[20]. According to the Pure Theory of Law[21], a legal theory, in most cases, takes inspiration from the local legal system. It seeks to give a juristic basis of such legal system and tries to present solution of the problems. The Pure theory of law was propounded by Hans Kelsen. In every legal system there is a fundamental law as the basis of the legal system. The idea of 'Grundnorm' which may be said to be the foundation stone of the 'Pure Theory' and the law may be said as the 'hierarchy of norms'. According to Kelsen, law is a 'normative science'. Law norms are 'Ought' norms. It says, 'if one breaks the law, then he ought to be punished'. The science of law to Kelsen is the knowledge of hierarchy of normative relations. The task of legal theory is to clarify the relations between the fundamental and all lower norms. Every legal norm i.e. Act gains its force from more general norm which backs it. Ultimately that hierarchy relates back to an initial norm i.e. 'Grundnorm' and it is from this norm that all inferior norms derive their force. The 'Grundnorm' is the starting point in a legal system. In India, Indian Constitution is Grundnorm and the Act is inferior norm. Therefore it may be said that the activity of the Commission obtained legal force/sanction from the Drugs and Cosmetics Act, 1940.

Findings of the Empirical Study[22]

Table 1 : Opinion given by the Common People at Kolkata Metropolitan Area(KMA)

Question Number	Questions put to the Respondents *(Total No. of Respondents: 35)*	Answers in %	
1.	Do you know that Indian Constitution is the Supreme Law of the land?	YES	NO
		91.42	8.58
2.	Do you know about the Drugs and Cosmetic Act, 1940?	45.71	54.29
3.	Do you know about the Drugs and Cosmetics Rules, 1945?	37.14	62.86
4.	Do you know about the Indian Pharmacopoeia Commission?	25.71	74.29
5.	Do you ever heard about the term Indian Pharmacopoeia?	22.85	77.15
6.	Do you think that the Indian Pharmacopoeia Commission plays an important role on the life of the people?	31.42	68.58
No. Of Male Respondent: 18		No. Of Female Respondent: 17	
Age wise--Male	From 21-30 years: 08	Age wise--Female	From 21-30 years: 08
	From 31-40 years: 07		From 31-40 years: 05
	From 41-50 years: 02		From 41-50 years: 02
	From 50 and above years: 01		From 50 and above years: 02

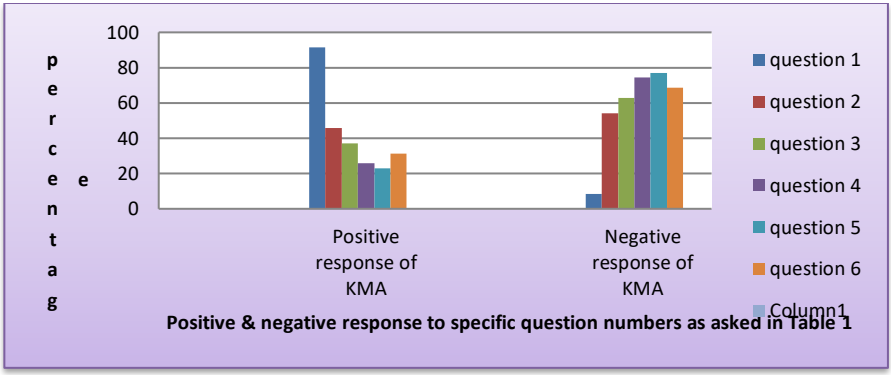
Table No. 1 is the data analysis of the opinion given by the respondent within the study area. The outcome of this Table is further elaborated in the subsequent Columns; pie and Line.

[20]http://www.ias4sure.com/wikiias/prelims/indian-pharmacopoeia-commission-ipc/, visited on 19.05.2020 at 7.03 p.m.

[21] Dr. B. N. Mani Tripathi, 'Jurisprudence, The Legal Theory', Allahabad Law Agency, Faridabad, 19th Edition, 2013

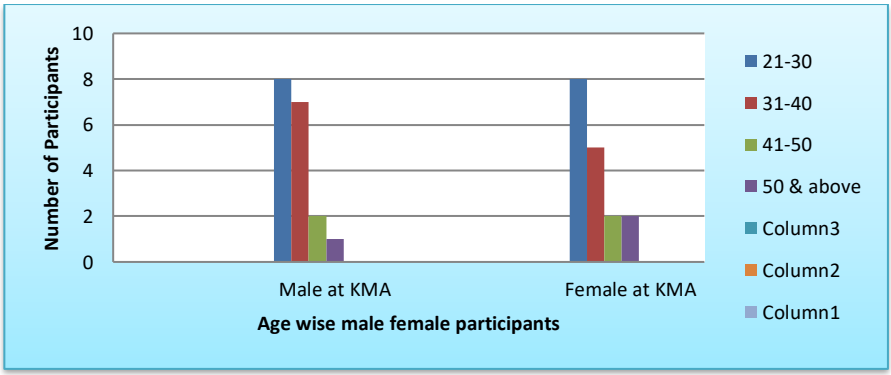
[22]Source: Author

Column No. 1



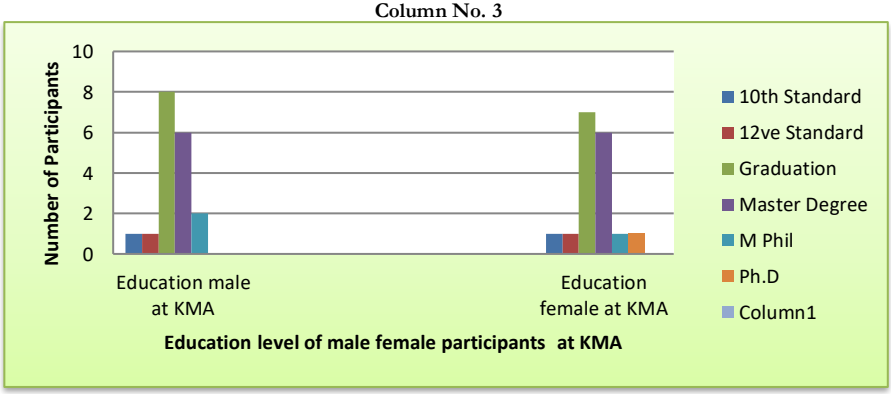
Column No.1 showing the positive and negative response of the respondents with respect to the questions as asked by the author with respect to the Kolkata Metropolitan Area. It is the Column showing the positive and negative percentage of the respondents.

Column No. 2



Column No. 2 showing the actual numbers of the respondents and they are further divided into male and female with a strata of age. The age of the male and female respondents are further divided into 21-30years; 31-40 years; 41-50 years; 50 and above.

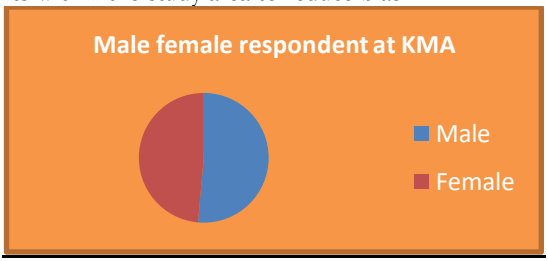
Column No. 3



Column No. 3 showing actual numbers of the education level of male and female respondents within the study area and the education level of the respondents are starting from 10th standard to Ph.d. The various education levelswere chosen to testify the knowledge among different educated people with respect to the Commission.

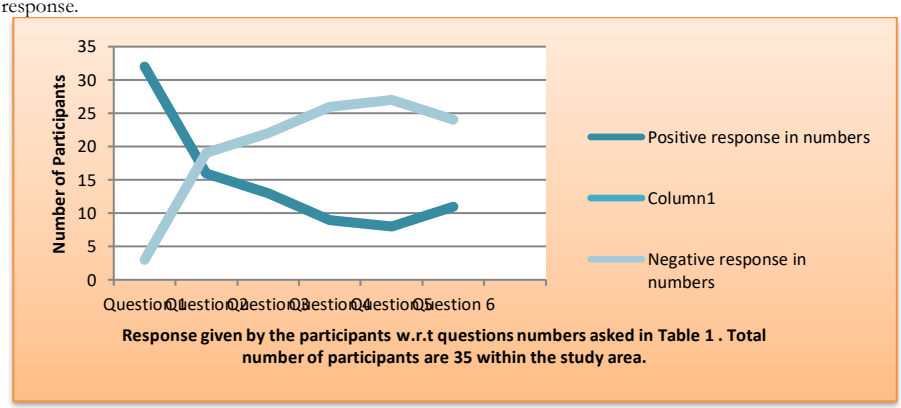
Pie diagram No. 1

The below is the Pie Diagram representing the male and female respondent of the study area i.e. Kolkata Metropolitan Area. The study is conducted with 35 respondents and out of 35 respondents 18 are male respondents and 17 are female respondents. This Pie Diagram showing almost the same numbers of the male and female respondents within the study area to reduce bias.



Line No. 1

This is a graph showing actual numbers of respondents responded with respect to specific questions. The positive response line is decreasing and the negative response line is increasing from question number 1 to question number 6. It is reflecting from the graph that the negative response is prevailing over the positive response.



Conclusion and Suggestions: Most of the people do not know about the Commission and therefore, the basic awareness is highly required in this regard. In the present day, the Commission is performing very important duty. The objective of the Commission is to promote the highest standards of drugs for humans use and to promote public health by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers. The hypothesis, which the author has framed, has been justified. So far as performance of the Commission is concerned, the author is of the view that the Commission is doing excellent job.

Therefore it is suggested that the government create awarenessin collaboration with the Commission among the general masses about the importance of the Commission.

Bibliography

Pandey J.N, (2007) Constitutional Law of India, central law Agency.

Jain M.P,(2008) Indian Constitutional law, Nagpur.

Kumar Narendra, (2007),Constitutional Law of India, Allahabad Law Agency.

Basu, Durga Das,(2002) Introduction to the Constitution of India, Wadhwa and Company law Publishers.

Bakshi,P.M,(2002) The Constitution of India, Universal law Publishing

Seervai, H.M. "*The Constitutional Law of India",* Universal Law Publishing Co. Pvt. Ltd.

Sanvidhan G Suke, 'Indian Pharmacopoeia Commission: Structure and Role in Formulation of IP and NFI', World Academy of Science, Engineering and Technology International Journal of Pharmacological and Pharmaceutical Sciences Vol:9, No:2, 2015. scholar.waset.org/1307-6892/10001727.

http://chromachemie.co.in/indian-pharmacopeia-reference-standards.html,

https://en.wikipedia.org/wiki/Pharmacopoeia,

https://wikidiff.com/pharmacopoeia/formulary,

https://en.wikipedia.org/wiki/Formulary_(pharmacy),

Jai Prakash et al., 'Current Status of Herbal Drug Standards in the Indian Pharmacopoeia', PHYTOTHERAPY RESEARCH Phytother. Res. (2017) Published online in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/ptr.5933.

https://www.researchgate.net/publication/332268739_Current_Status_of_Herbal_Drug_Standards_in_the_Indian_Pharmacopoeia/link/5cab17d0a6fdcca26d066797/download

httpswww.pmda.go.jpfiles000214416.pdf

http://www.pharmabiz.com/NewsDetails.aspx?aid=88331&sid=1

https://www.idma-assn.org/pdf/dr-pl-sahu.pdf

https://www.mondaq.com/india/food-and-drugs-law/671182/indian-pharmacopoeia-commission-ipc-releases-eighth-edition-of-indian-pharmacopoeia-ip

https://pib.gov.in/newsite/mbErel.aspx?relid=130201

J. Mark Wiggins and Joseph A. Albanese, 'A Brief History of Pharmacopoeias: A Global Perspective', PharmaceuticalTechnology REGULATORYSOURCEBOOKSEPTEMBER2019,Pp.1-6, http://files.alfresco.mjh.group/alfresco_images/pharma//2019/09/25/173bf119-f56e-4e58-ac1d-9ae9d126a800/PTebook0919_PharmacopeiaCompendia_History_watermark.pdf

https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf,

http://www.ias4sure.com/wikiias/prelims/indian-pharmacopoeia-commission-ipc/,

Tripathi, B. N. Mani 'Jurisprudence, The Legal Theory', Allahabad Law Agency, Faridabad, 19th Edition, 2013.

http://www.ipc.gov.in/