Pune District Education Association's

Seth Govind Raghunath Sable College of Pharmacy

JOURNAL CLUB ACTIVITY

Department of Pharmaceutical Chemistry

Attendance cum response sheet for Journal Club of Department of Pharmaceutical Chemistry (2021-22)

Date & Time: 29/09/2021, 2.00pm.

Name of the Facilitator: Mr. Amol Kale.

Title of the paper discussed: Development of method for the determination of NDMA impurity in ranitidine drug substance & drug product by LC-MS/MS.

Sr. No.	Name of the member	Signature	Evaluation of today's meeting/suggestions
1.	Dr. R.S. Chavan	RSchavan	Fruitful & effective discussion on LC-MS/MS method.
2.	Dr. S.J. Pawar	Pawar	The LC-MS/MS method development discussion was beneficial.
3.	Mrs. J.R. Jagtap	JRJ	Very informative discussion on LC-MS/MS method development.
4.	Mr. A.P. Kale	APK	very Advanced Technique of LC-MS for impurity profiling
5.	Mr. G.B. Nigade	GBN	Impurity analysis by LC MS was discussed
6.	Ms. Madhuri Kudale	MKudale	Thoughtful discussion

Title 1: Development of method for the determination of NDMA impurity in ranitidine drug substance and drug product by LC-MS/MS.

Title 2: LC-MS/MS method development and validation for estimation of NDMA impurity in ranitidine drug and tablet dosage form.

Abstract:

The main goal of this present study was to look into technique of method development and validation for the impurity N-nitrosodimethylamine (NDMA) in ranitidine (RAN) tablets and drugs. The proposed approach was utilized to determine the amount of NDMA contaminant in RAN or solid dosage pharmaceutical products. This study used a gradient mode HPLC-MS/MS system with a light diode array detector and an electrospray ionization technique. The column utilized was a Thermo Hypersil Gold C_{18} column (4.6 X 100 mm, 3µm) with a column temperature of 40°C. In a gradient mode of separation pattern with a flow rate of 0.6 ml/min, a mixture of solvent A (0.1 % formic acid in water) and solvent B (0.1 % formic acid in methanol) was used as the mobile phase. The total run time for the mobile phase was 14 min. with NDMA retention time of 1.25 min. For NDMA impurity analysis using LC-MS/MS, the MS parameter 78.200/43.300 was used for quantitative analysis and 78.200/58.200 for qualitative analysis. The NDMA estimation range for LC-MS/MS was determined to be 1-50 ng/mL, with a regression value of 0.9999. According to ICH requirements, the method was validated for linearity, accuracy, precision, and robustness. LOD and LOQ were found to be 0.5 ng/mL. NDMA separated from RAN tablet by RP-HPLC and resolution was found to be in acceptable limit.

Introduction:

Ranitidine HCl (RAN) is a regularly prescribed over-the-counter medication for acid reflux and heartburn. N-nitroso-di-methylamine (NDMA) is a carcinogenic chemical impurity identified in pharmaceutical medication products by accident.1 Valsartan, losartan, and RAN were tested for NDMA and other nitroso contaminants by the Food and Drug Administration (FDA) in September 2019. Unacceptably low quantities of NDMA contaminants were discovered during the RAN production process.2,3 According to ongoing research by the US Food and Drug Administration, several common brands of RAN have high levels of NDMA contamination due to high temperature storage or customer exposure to OTC use in the market or production process. Low quantities of NDMA have also been found in foods and water. This low-dose NDMA would not pose a significant cancer risk. However, at large doses, NDMA causes cancer in humans.4 A total of 135 batch samples of RAN were tested by Therapeutic Goods Administration Laboratory for NDMA levels, but no method for the development and validation of NDMA in ranitidine has been reported. It was stated that a concentration of 0.3 ppm or above per 300 mg of RAN was not acceptable for usage as a medication. Different formulations contain various components, increasing the risk of NDMA exposure.5 The degradation products in a solid state were created by photo exposition of RAN.6

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Department of Pharmaceutical Chemistry

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JOURNAL CLUB ACTIVITY

Department of Pharmaceutical Chemistry

Attendance cum response sheet for Journal Club of Department of Pharmaceutical Chemistry (2021-22)

Date & Time: 17/09/2021, 2.02pm.

Name of the Facilitator: Mr. G. B. Nigade.

Title of the paper discussed: HPTLC Method development and validation for Standardization of Ayurvedic formulation: Mahashankh vati

Sr. No.	Name of the member	Signature	Evaluation of today's meeting/suggestions
1.	Dr. R.S. Chavan	Rschavan	Good discussion
2.	Dr. S.J. Pawar	Pawar	Informative & fruitful discussion.
3.	Mrs. J.R. Jagtap	Jj.	Thought provoking useful discussion.
4.	Mr. A.P. Kale		Informative discussion For Validation.
5.	Mr. G.B. Nigade	GN	Discussed on HPTLC method development--
6.	Ms. Madhuri Kudale	MKudale	Good discussion

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HPTLC METHOD DEVELOPMENT AND VALIDATION FOR STANDARDIZATION OF AYURVEDIC FORMULATION: MAHASHANKH VATI

Vineeta Khanvilkar * and Nishigandha Chalak

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Keywords:

Piperine, Umbelliferone, Gallic acid, Standardization, HPTLC, Mahashankhvati

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ABSTRACT: Ayurveda is the primeval complete serving system in medical field. However, one of the barriers in the acceptance of the Ayurvedic formulation is the paucity of standard quality control outline. World health organization (WHO) in 1999 has given a detail procedure for the standardization of herbal drugs comprising of a single content but not for standardization of polyherbal formulations. Mahashankhvati is official in Ayurvedic Formulary of India and is prescribed for treatment of haemorrhoids, malabsorption syndrome, dyspepsia and indigestion. In the proposed work, attempt has been made for standardization of Mahashankh Vati by developing chromatographic method. Piperine from *Piper longum* and *Piper nigrum*, Umbelliferone from *Ferula asafoetida* and Gallic acid from *Terminaliachebula* present in formulation were selected as marker compounds. A new, rapid, simple, precise, selective HPTLC method was developed for marketed preparation of Mahashankhvati. The separation was performed on TLC aluminium plates precoated with silica gel 60 F_{254}, using toluene: ethyl acetate: methanol: formic acid (7:2:2.5:0.5 v/v/v/v) as mobile phase. The densitometric analysis was carried out at the detection wavelength of 290 nm. The R_f values of piperine, umbelliferone and gallic acid was found to be 0.65, 0.52 and 0.32 respectively.The developed method has been validated as per ICH guidelines.

INTRODUCTION: Being resurrecting of interest in natural drugs, especially plants derived, started in the last few decades mainly because of widespread belief that green medicines are healthier and safer than the synthetic once.[1] Standardization of herbal materials and their formulations is essential in order to assess quality of the drugs.

QUICK RESPONSE CODE

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DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.7 (7).3012-20

The quality assessment of herbal formulations is most important in order to justify their acceptability in modern system of medicine. [2] One of the major problems faced by the herbal industry is the deficit of rigid quality control profiles for herbal materials and their formulations.

The World Health Organization (WHO) has appreciated the importance of medicinal plants for public health care in developing nations and has evolved guidelines to support the member states in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation, safety and efficacy.[3] Mahashankh Vati is official in Ayurvedic formulary of India. It is a polyherbal formulation;

Group E:- 41

Pune District Education Association's
Seth Govind Raghunath Sable College of Pharmacy, Saswad.

2021-2022

PBL -1 TRIGGER

Class: Third Year B. Pharm. (Sem-VI)
Subject: Herbal Drug Technology
Date:-

Trigger1

Past and Present Status of Herbal Medicines: Plants and natural products were used by humankind over the years as food and medicines to cure and prevent diseases. It is very difficult to point out an exact time when the use of plants was started as medicine, the carbon dating from ancient Babylon (Iraq) records that plants were cultivated as medicines 60,000 years ago Written materia medica of medicinal herbs go back approximately 5,000 years in India, China and Egypt and at least 2,500 years in Greece and Asia Minor. Neanderthal remains have been found to contain the remnants of medicinal herbs. Ancient Ayurveda was meant essentially to promote health, however, rather than fight disease. Charak Samhita (1000 BC) and Sushnat Samhita (100 AD) are the main text available. Ayurveda materia medica gives detailed descriptions of over 1500 herbs and 10,000 formulations.

Compilation of- Herbal drugs industry: Present scope and future prospects.

Herbal Drug Technology PBL - Trigger.

Date: 05/01/22

Class: Third year B-pharm (sem-VI)

Group Participants. (41-50)

Roll no.	Names.
41	Padher Achal Dattatray
42	Pandit Pratiksha Dnyandeo
43	Parsagle Mahadev shyam
44	Patil Manasi satish
45	Pawar Aditya Ashok
46	Raut Ashish Umesh
47	Rokde Vishalakshi sanjay
48	salunkhe Dhanashri sanjay
49	sarawde Ranjeet Anil
50	sathe Om Vilas

- Present scope of Herbal drug industry:-

- Plant and natural products were used by humankind over the years as food and medicine to cure and prevent disease.
- It is very difficult to point out an exact time when the use of plant was started as medicine, the carbon dating from acient Babylon (Iraq) records that plants were cultivated as medicines 60,000 years ago.
- Written material medica of medicinal herbs go back approximately 5000 years in India, China & Egypt & at least 2500 years in Greece & Asia Minor.
- Neanderthal remains have been found to contain the remnants of medicinal herbs.
- Ancient Ayurveda (40000BC) & Sushrut samhita (100 AD) are the main texts available.
- Ayurveda materia medica gives detailed descriptions of over 1500 herbs & 100000 formulations.
- Currently more than 80% of the world population depends on traditional & plant derived medicine because plants are important sources of medicine & presently about 25% of pharmaceutical prescriptions in the United stated contain at least one plant derived ingredient.
- In the last century, roughly 121 pharmaceutical products were formulated based on the traditional knowledge obtained from various sources.
- In fact, it is now believed that nature contributes up

90% to the new drug molecule.

- Nature has provided many of the effective agent such as dactinomycin, bleomycin, & doxorubicin, vinblastine, irinotecan, topotecan, etoposide, & paclitaxel (anticancer), efloquine, chloroquine, amodiquine, artemisinin, artemether & arteether (anti-malarial), metformin & eventually the other biguanide, harunganin, cyproheptine, maprouneacin (anti-diabetic), calanolide A, curcumin, phenoxidiol (anti-HIV drug,) etc.
- India has around 25,000 effective plant based formulations used traditionally with over 1.5 million practitioner, of tradional medicinal system & 7800 medicinal drug manufacturing units in India, which consume about 2000 tones of herbs annually
- Traditional medicine in most regions of the world taker place after WHO Traditional Medicine strategy 2002 - 2005, state member also developed their own documentation & safety concern.
- The diversity of regulations & regulatory categories for Traditional medicinal products make it difficult to assess the size of the market for products across member states accurately.
- However, available data suggests that the Traditional medicine have significant market in member states.
- Indian herbal market is nearly 50 bilion rupees with 14% annual growth.
- one billion rupees worth of herbal product are being exported.

- The demand for medicinal plants is increasing everyday & WHO has projected that global herbal market will grow up to $ 5 trillion in 2050 from the current level of $ 62 billion.
- India and china produce more than 70% of the global diversity.
- The significant global herbal export market include EU, USA, canada, Australia, singapore. and Japan while Brazil, Argentina, Mexico, China and Indonesia are new emerging market.

Future Prospects of Herbal Medicine:-

- It is estimated that there are about 35000 species of existing plants (including seed plants, bryophytes, and ferns), among which 287 655 speices have been identified as of 2004.
- Relatively small percentages (1 to 10%) of these are used as foods by both humans & other animal species.
- It is possible that even more are used as foods by both humans & other animal species.
- It is possible that even more are used for medicinal purpose.
- WHO has shown great interest in documenting the use of medicinal plants used by tribes from different parts of the world.
- many developing countries have intensified their efforts in documenting the ethno-medicinal data on medicinal plants.
- to find out scientific evidence for claims by

tribal healers on Indian herbs has been intensified.

- Once these local ethano-medicinal preparations are scientifically evaluated & disseminated properly, people will be better informed regarding efficacious drug treatment & improved health status.
- The traditional knowledge system needs to be studied, documented, preserved and used for the benefit of humankind, before it is lost forever.
- This will require a holistic approach, and involvement & participation of local inhabitants.
- The Associated chambers of Commerce and Industry of India (ASSOCHAM) has projected that the market size of herbal industry which is currently estimated at Rs. 7,500 crores (Rs. 75 billion) will double to level at Rs. 15000 crores by 2015 since this industry would be growing at a compounted annual growth rate of over 20% hereafter.
- In a study brought out by ASSOCHAM on herbal industry & global market 2015, it is pointed out that India's rich resource of medicinal plants & traditional treasure of knowledge in this area, its share at present is considered very meager.
- A quick estimate of the potential reveals that India can generate raw stock of around Rs. 300 billion and easily achieve around 150 billion Rs. value added products.

Pune District Education Association's
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Feedback of students on PBL conducted on :

Subject: Herbal Drug Technology

Class: Third Year B. Pharm.

This questionnaire has been designed to understand the opinion of students involved in the PBL activity so that the activity can be improved in the future. The group leader is advised to answer the questions on behalf of all the group members.

Please **tick** the appropriate box:

Trigger	Yes	No	Can't say
Was the trigger provided to you easily understandable?	✓		
Was the trigger interesting?	✓		
Could you relate the trigger to your curriculum?	✓		
Role of facilitator			
Did you find the role of facilitator useful in understanding the problem?	✓		
Did you take the help of the facilitator in identifying the objectives of the problem?	✓		
Resources			
Did you refer to the books available in the library for compiling the data related to your problem?	✓		
Were there sufficient reference books available in the library for researching the problem?	✓		
Did you find the internet facility and online resources adequate?	✓		
Overall activity			
Do you think PBL is enhancing your comprehension and analytical skills?	✓		
Do you think PBL is enhancing your referencing & researching skills?	✓		
Do you think PBL is contributing towards improving your communication and presentation skills?	✓		
Do you think this activity should be continued in future also?	✓		

Suggestions if any,----------

----------Pl. tear from here before submitting----------

Name of the group leader...Patil Manasi.....Signature.....Mpatil.....

Pune District Education Association's

Seth Govind Raghunath Sable College of Pharmacy, Saswad.

FACILITATOR ASSESSMENT FORM

PBL No.: 1

Subject: Herbal Drug Technology

Class:S Third Year B. Pharm **Date:**

Please rate in the 5 point scale: 5- Excellent, 4- Very Good, 3-Good, 2- Satisfactory, 1 - Not satisfactory

Roll No. of the student / Criteria	41	42	43	44	45	46	47	48	49	50
Application of knowledge base										
Applies previous knowledge to clarify and define the problem.	4	4	4	5	4	4	5	4	4	4
Answers questions and shares his/her opinions by applying acquired knowledge.	4	4	5	5	4	4	5	5	4	4
Critical Thinking										
Demonstrate, evidence, critical understanding and critical analysis facts.	3	4	4	5	5	4	5	4	4	4
Is applicable making conclusion and decision regarding the diagnostic / therapeutic approaches?	4	3	5	5	4	3	5	5	4	4
Demonstrates evidence of following a sequential analysis of the problem.	4	4	4	5	4	3	5	4	4	4
Self Directed Learning(Self study)										
Defines learning objectives and learning goals.	3	4	5	5	5	3	5	4	4	4
Demonstrates evidence of accomplishment of learning objectives.	3	4	4	5	4	3	5	5	4	4
If necessary, seeks counseling to orient His/her study and willing to improve	4	4	4	5	5	4	5	4	4	4
Collaborative work	4									
Works towards achievement of the groups learning goals with commitment.	4	4	5	5	4	3	5	4	4	4
Demonstrates effective interpersonal attributes.	4	4	4	5	4	3	5	5	4	4
Accepts feedback with openness.	4	4	4	5	5	3	4	4	4	4
Reacts positively to feedback and criticism.	4	4	5	5	4	3	5	4	4	4
Stands up for his/her points of view.	4	4	4	5	4	4	5	4	4	4
Shows ability to change his/her point of view of new information given/ obtained.	4	4	5	5	4	3	5	4	4	4

Group No : 5/E

Pune District Education Association's
Seth Govind Raghunath Sable College of Pharmacy, Saswad.

2021-2022

PBL

Class: Third Year B pharm (semester-VI)
Subject: Herbal Drug Technology
Date:

Sr. No.	Facilitator's Name	Group	Roll number of the students
1.		A	1-10
2.		B	11-20
3.		C	21-30
4.		D	31-40
5.		E	41-50
6.		F	51-60
7.		G	61-70