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දිනය நிகதி Date 02.10.2020

Secretary

Ministry of Health "Suwasiripaya" Ven Baddegama Wimalawansa Thero Mawatha Colombo 10

Secretary

State Ministry of Production, Supply and Regulation of Pharmaceuticals



#### International Training Programme on "Generic Drugs", 19th November 2020

Please see the attached communication received from the Sri Lanka Permanent Mission in New York, regarding the International training program offered by the Indian Institute of Chemical Technology in Hyderabad for the countries of Non-Aligned Movement (NAM) and the other developing countries under the theme "Generic Drugs" to be convened virtually on 19<sup>th</sup> November 2020.

Given the Sri Lanka's current initiative to manufacture pharmaceutical products within the country, this program would be useful for our experts to gain knowledge and information.

The application must be submitted before 16<sup>th</sup> October 2020 to manstcentre@gmail.com as of the attachment, which gives further details to participate at the training program.

The attachments are forwarded for necessary action please.

Actg.Director / South Asia & SAARC for Secretary

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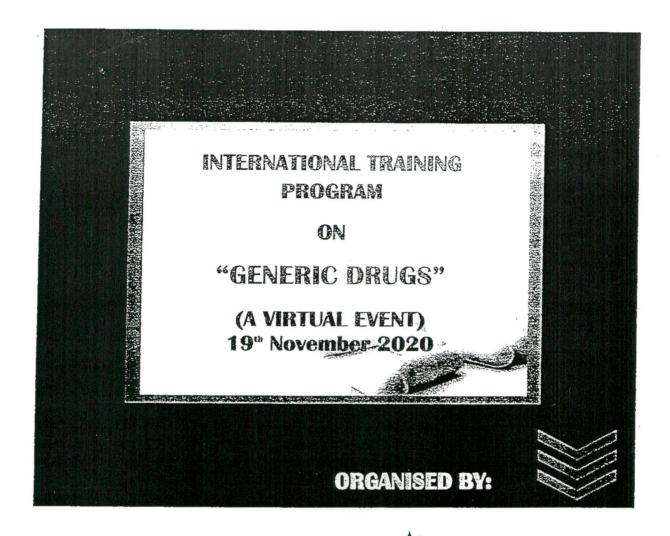
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www.mfa.gov.lk





CSIR-INDIAN INSTITUTE OF CHEMICAL TECHNOLOGY (CSIR-IICT) TARNAKA - UPPAL ROAD, HYDERABAD - 500007 TELANGANA, INDIA



CENTRE FOR SCIENCE & TECHNOLOGY OF THE NON-ALIGNED AND OTHER DEVELOPING COUNTRIES (NAM S&T CENTRE) NEW DELHI, INDIA

#### INTRODUCTION

A generic drug is a pharmaceutical substance that contains the same qualitative and quantitative composition as an Active Pharmaceutical Ingredient (API) which was originally covered in patent by its inventor and whose bioequivalence with the reference drug has already been demonstrated. A generic medicine works in the same way and provides the same clinical benefit as its brand-name version, and may vary only in some aspects such as the process in which they are manufactured, formulations, excipients, color, taste, packaging, etc. In most cases, generic drugs are allowed to be manufactured or sold by other companies after the patent on the original drug expires. Although the profitability of branded generics is undeniable, but it is not the sole reason drug makers have for creating such products - more often, it is to increase the products' recognisability.

Generic pharmaceutical industry plays a key role in the health care of a country by providing affordable medicines. The generic drug industry is involved in development of manufacturing processes at reduced cost thereby increasing the affordability of drugs to common people. The generic drug thus produced should have exact therapeutic efficacy, safety and performance like a branded drug. In other words, this industry helps in managing the health of people under poverty line, which is an important factor for a developing nation. Development of generic industry can effectively reduce the country's dependence on imports, saves foreign exchange, and importantly secures their medicines, especially in medical emergencies and pandemic situations like present COVID, thereby, increasing a country's self reliance on pharmaceuticals, an important factor of National Health Security.

With the increase in spending on health care and rising costs of medicines, there is a need to encourage the use of generics. However, maximizing generic drug use is not possible without the public's positive perception and meeting their informational needs about generic drugs. Thus, improving the public's confidence and knowledge of generic drugs in the market is critical.

Therefore, in order to impart basic knowledge in the area of generic drug industries for scientists and professionals; and to encourage acceptability of generic drugs for facilitating

access to healthcare in NAM and other Developing Countries, the Centre for Science & Technology of the Non-Aligned and Other Developing Countries (NAM S&T Centre), New Delhi, India jointly with the CSIR-Indian Institute of Chemical Technology (CSIR-IICT), Hyderabad, India announces an International Training Program on "Generic Drugs" on 19th August 2020. The event will be hosted by the Department of Organic Synthesis and Process Chemistry, CSIR-IICT and will be organized in Virtual Mode.

#### **OBJECTIVES**

The training program intends to provide its attendees with basic knowledge about the generic drugs and their use as well as different aspects involved in the logistics and manufacturing of generic drugs. The program will cover some key aspects such as challenges involved in manufacturing of generic drugs, quality control, impurity profiling, regulatory aspects, bio-equivalence, formulations, etc. that may help guide policy, education and practice interventions supporting the use of generic drugs.

#### TOPICS TO BE COVERED

- Modalities in Technology Transfer and Establishment of Generic Drug Industry
   Dr. K. V. S. Ram Rao, CEO, PI Industries
- Challenges involved in the Manufacturing of Generic Drugs:
   Dr. T. Rajamannar, Executive Vice President, Sun Pharma Pvt. Ltd & Dr. Veera Reddy, Vice President, Suven Life Sciences
- Formulation/Polymorphism:
  Dr. Srividya Ramakrishnan, Head, API Process Engineering, Dr. Reddy's Laboratory
- Regulatory Aspects
  Dr. A. Kalyan Chakravarthy, Head, Regulatory Affairs, Dr. Reddy's Laboratory
- Key Aspects Pertaining to Generic Drugs Industry Case Studies
   Dr. Srinivas Lanka, Chairman, Elixir Global
- Impurity Profiling
   Dr. C. S. Venkatesan, Senior Vice President, Gland Pharma Ltd.

- Bioequivalence
   Dr. G. Venkata Ramana, Principal Scientist, Drug discovery & Clinical Research,
   NATCO Pharma Ltd
- Role of R & D in Synthesis of API's
   Dr. Ch. Raji Reddy, Senior Principal Scientist, OSPC, CSIR-HCT

#### **IMPORTANT DATES**

Date of the Program	19 <sup>th</sup> November 2020	
Submission of Application Starts	21st September 2020	
Last Date for Submission of Application	16 <sup>th</sup> October 2020	
Confirmation to Selected Applicants	30 <sup>th</sup> October 2020	

#### **PROGRAMME**

A tentative program of the event is given below:

Date of Program: 19th November 2020			
Time Theme of Training Lecture		Resource Person	
1030 – 1100	Inaugural and Introduction	Dr. S. Chandrasekhar /Dr. Amitava Bandopadhyay	
1100 - 1130	Modalities in technology transfer and establishment of generic drug industry	Dr. K. V. S. Ram Rao	
1130 – 1200	Challenges involved in the Manufacturing of Generic Drugs -1	Dr. T. Rajamannar	
1200 - 1230	Challenges involved in the Manufacturing of Generic Drugs -2	Dr. Veera Reddy	
1230 - 1300	Formulation/Polymorphism Dr. Srividya Ramakrishnan		
1300 - 1330	Regulatory Aspects Dr. A. Kalyan Chakravarthy		
1330 - 1430	BREAK		
1500 - 1530	Impurity Profiling/Analytical	Dr. C. S. Venkatesan	
1530 - 1600	Bioequivalence	Dr. G. Venkata Ramana	

Date of Program: 19th November 2020				
Time	Theme of Training Lecture	Resource Person		
1600 - 1630	Key aspects pertaining to Generic Drugs - Case studies	Dr. Srinivas Lanka		
1630 - 1700	Role of R & D in Syntheses of API's	Dr. Ch. Raji Reddy		
1700- 1730	Discussion and Concluding Remarks	Chaired by: Dr. B. V. Rao/ Dr. Prathama Mainkar		
		(Panel of all Speakers)		

The Participants of the Virtual Training Program will receive a Participation Certificate electronically.

#### ABOUT THE ORGANISERS

#### NAM S&T CENTRE

The Centre for Science and Technology of the Non-Aligned and Other Developing Countries (NAM S&T Centre; www.namstct.org) is an Inter-governmental Organisation with a Membership of 47 countries spread over Asia, Africa, Middle East and Latin America. The Centre was set up in 1989 in New Delhi, India to undertake a variety of programmes, including organisation of workshops, symposiums and training courses and implementation of collaborative projects. It also offers short-term Research Fellowships to scientists from developing countries in association with the Centres of Excellence in various countries. The Centre also brings out technical books and other scientific publications in different subjects of interest to developing countries. The Centre's activities provide opportunity for scientist-to-scientist contact and interactions; familiarising participants on the latest developments and techniques in the subject areas; identification of the requirements of training and expert assistance; locating technologies for transfer between the Members and other Developing Countries, and dissemination of S&T information etc. In addition, the Centre encourages Academic-R&D-Industry interactions in the developing countries through its NAM S&T-Industry Network.

#### CSIR-Indian Institute of Chemical Technology (CSIR-IICT)

CSIR-Indian Institute of Chemical Technology, Hyderabad, established in 1944, is a constituent laboratory of the Council of Scientific and Industrial Research (CSIR), New Delhi. With its expertise in chemistry and chemical technology, it provides solutions to challenges faced by Industry, Government Departments and Entrepreneurs through basic and applied research, and process development. It is internationally recognized for its contributions to chemistry research and is an ideal place for taking ideas to commercialization through state of the art research and development.

Vision: To serve society by creating an outstanding knowledge base in chemistry and chemical technology.

Mission: CSIR-IICT will strive towards knowledge intensive translational research in chemistry to meet the country's expectations with novel technologies.

The Organic Synthesis & Process Chemistry (OSPC) Department is a leading research centre in CSIR-IICT with over 50 years experience in the area of synthetic organic chemistry encompassing natural product synthesis and innovative synthetic approaches aimed at offering sustainable chemical solutions and technologies. The department has around 40 personnel including academic experts, specialists and support staff as well as a large number of research students. The department is decorated by professionals with wide spectrum of expertise in organic synthesis such as natural products, carbohydrates, peptides, polymers, heterocycles, etc. The quest for new innovations witnessed the development of several novel technologies. The department is committed to providing safe and sustainable technologies with maximum economical viability and compatibility. Recently, OSPC played a key role in transferring process know-how's on repurposed antiviral API's and intermediates to Indian Pharma companies for mitigation of Covid-19.

#### **PARTICIPANTS**

Young researchers, scientists, government officials and policy makers, and representatives from industry and non-government organizations – who are engaged in pharmaceuties and healthcare sector are invited to participate in this *Virtual Training Program*. The combination of participants from various developing countries will allow for exchange of knowledge, ideas and experiences as well as opportunities for global networking and collaboration.

#### RESOURCE PERSONS

The Training Programme would be designed and coordinated by Dr. D. Shailaja, Chief Scientist, CSIR-IICT. Other resource persons for the Virtual Training Program will comprise eminent experts and professionals from CSIR-IICT and reputed industries from India with expertise in the relevant fields.

#### SUBMISSION OF APPLICATION

Scientists, researchers and other professionals desirous of participating in the Virtual Training Program should submit their filled-in application <u>electronically</u> directly to the NAM S&T Centre (E-Mail: <u>namstcentre@gmail.com</u>) as early as possible, but latest by Friday, 16<sup>th</sup> October 2020.

The following documents must be submitted as e-mail attachments:

- i. Filled in Application Form (Blank form enclosed)
- ii. A short CV (maximum two pages; in MS-Word format) [Format Enclosed]
- iii. Opinion (a short para; in MS-Word format) how you qualify to participate in the Training Program.

#### SELECTION OF APPLICANTS

Selection of applicants will be made based on their academic and professional background, and relevance of their current engagements in the field of pharmaceutical and medical industry. Only a limited number of participants will be selected from various countries in order to ensure organized deliberations and exchange of information and expertise among the participants. Successful applicants will be electronically informed about their selection by 30th October 2020. The details about the *Virtual Platform* that will be used for the Training Program and *log-in details* for joining the program will also be communicated to the selected applicants. Other details and terms & conditions for the participation of scientists from various countries will be given to the individual candidates on receipt of their applications.

#### **CONTACT DETAILS**

#### NAM S&T CENTRE

#### Dr. Amitava Bandopadhyay

Director General

Centre for Science & Technology of the Non-Aligned and other Developing Countries (NAM S&T Centre)

Core - 6A, 2nd Floor, India Habitat Centre, Lodhi Road

New Delhi - 110003, India

Tel: +91-11-24645134, 24644974; Fax: +91-11-24644973

E-mail: namstcentre@gmail.com, namstct@bol.net.in

Website: http://www.namstct.org

#### CSIR-IICT

#### Dr. D. Shailaja

Chief Scientist & Chair, Business Development CSIR-Indian Institute of Chemical Technology Ministry of Science & Technology, Govt. of India, Uppal Road, Tarnaka, Hyderabad – 500 007

Telangana, India

Tel: +91-40-27193992; Fax: +91-40-27160387

Email: sdonempudi@iict.res.in, headbdrm@iict.res.in

Website: http://www.iictindia.org

## Centre for Science and Technology of the Non-Aligned and Other Developing Countries (NAM S&T Centre)

## India Habitat Centre, Lodhi Road New Delhi, India

### Curriculum Vitae

Name: (Prof./Dr./Mr./Mrs./Ms.)	Font Name: Times New Roman

Present Employer: Full Address (Office)

City/State/Province:

Designation: Position Title

1. Personal Details:

Country:

Nationality:

Date of Birth: DD/MM/YYYY

Proficiency in English Language:

Permanent Address: Full Address (Home)

Gender:

Marital Status:

Contact: Mobile:

Telephone Office:

Fax:

E-mail:

Alternative e-mail:

Font Size: 12

2. Academic Qualifications: In chronological order

Qualification Awarded Degree/Diploma/Certificate	Major Subject	University/Institution	Year (From-To)
1.			
2.			
3.			
4.			
5.			

3. Professional Experience: In chronological order

Organisation/Institution	Position Title	Year (From-To)	Nature of duties
1.			
2.			
3.			
4.			
5.			

Total number of years of relevant experience -

4. Research Experience: In chronological order

Research Title	Duration	Status
1.		
2.		
3.		
4.		
5.		

- 5. Administrative Experience: Not more than 100 words
- 6. Experience with respect to the title of the programme:
- 7. Details of Awards/Recognitions (if any):
- 8. Any other information: Not more than 50 words
- 9. Recent Publications: Only five recent publications to be mentioned
- 10. Recent Photograph: A recent passport size colour photo to be attached

# CENTRE FOR SCIENCE AND TECHNOLOGY OF THE NON-ALIGNED AND OTHER DEVELOPING COUNTRIES

(NAM S&T CENTRE)

International Training Program
(A Virtual Conference)

On

## "GENERIC DRUGS"

**19 NOVEMBER 2020** 

#### **REGISTRATION FORM**

PLEASE TYPE OR USE BLOCK CAPITALS; NO COLUMN SHOULD BE LEFT BLANK)

#### SECTION -A

(To be filled in by the nominee)

Please affix your scanned photograph

1	First Name (Prof/Dr/Mr/Mrs/Ms):Last NameLast Name
	(As in Passport)
2.	Father's/Spouse Name:
3	Designation (Position held):
4.	Nationality:
5	Date of Birth: Place of Birth (City) (Country)
6	Name of the Parent Institution (Employer):
	Full Address (Office):
	Phone: Fax:
	E-mail:
7	Full Address (Home):
	Phone: Mobile:
	Fax: E-mail:
8	Educational Qualifications: Highest Degree.
	Year of Award: University:
	Field of Study:
9	Brief Bio data (CV):
	(Maximum two pages, in MSWord; to be attached on separate sheets per attached
	format)

10	What in your opinion qualifies you fo	r participation in this virtual training program?
	(To be attached on separate sheet)	
Date: .		Signature:
SECTIO	DN -B	
ENDOR	RSEMENT BY NOMINATING AUTHORE	ΓY
	•	ne NAM S&T Centre must get the Nomination Form his/her country, if he/she wishes to take advantages
		visit the Centre's website <a href="https://www.namstct.org">www.namstct.org</a> .)
Signatu	re:	
Name (	in full):	
Designa	ation:	
Date:		

#### SEAL

#### **Enclosures**;

- 1. Brief CV (maximum two pages, as per attached format; in MSWord)
- 2. A statement on what qualifies you for participation in this virtual training program.

Font Name: Times New Roman

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## CENTRE FOR SCIENCE AND TECHNOLOGY OF THE NON-ALIGNED AND OTHER DEVELOPING COUNTRIES

#### (NAM S&T CENTRE) INDIA HABITAT CENTRE, LODHI ROAD NEW DELHI, INDIA

#### **CURRICULUM VITAE**

1.	Personal Details:

Name:(Prof./Dr./Mr./Mrs./Ms.)

Designation:Position Title

Present Employer: Full Address (Office)

City/State/Province:

Country:

Nationality:

Date of Birth: DD/MM/YYYY

Proficiency in English Language:

Permanent Address: Full Address (Home)

Gender:

Marital Status:

Contact: Mobile:

Telephone Office:

Fax:

E-mail:

Alternative e-mail:

2. Academic Qualifications: In chronological order

Qualification Awarded  Degree/Diploma/Certificate	Major Subject	University/Institution	Year (From-To)
1.			
2.			
3.			
4.			
5.			

3. Professional Experience: In chronological order

Organisation/Institution	Position Title	Year	Nature of duties
		(From-To)	
1.			
2.			
3.			
4.			
5.			

Total number of years of relevant experience -

4. Research Experience: In chronological order

Research Title	Duration	Status
1.		
2.		
3.		
4.		
5.		

- 5. Administrative Experience: Not more than 100 words
- 6. Experience with respect to the title of the conference:
- 7. Details of Awards/Recognitions (if any):
- 8. Any other information: Not more than 50 words
- 9. Recent Publications: Only five recent publications to be mentioned
- 10. Recent Photograph: A recent passport size colour photo to be attached

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