



Pharmaceuticals and Nutraceuticals from Development to Commercialisation: An IIUM Experience

Keynote Speaker presentation USTC, 4th August 2022

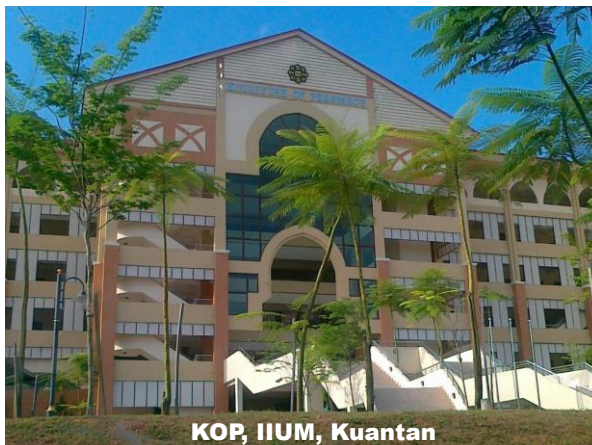
Assoc. Prof. Dr. A. B. M. Helal Uddin

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Faculty of Pharmacy
International Islamic University Malaysia (IIUM)
Malaysia



INTRODUCTION

- Kulliyah of Pharmacy (KOP) at IIUM was established in the year 2000 with the vision of becoming leading Faculty with continuous solutions for academic and research in health care sectors.
- Main focus was in Pharmaceuticals but the success in herbal, nutraceuticals and cosmeceuticals sections are also increased with the demand from the different sections of customers and industries.



KOP, IIUM, Kuantan

Contd..

- Considering the future need of the health care sectors KOP has taken a **diverse approach** towards **teaching and research**.
- Continuous **updating the curriculum** and **reorientation of the research** towards current updates of science and technology are the major steps to achieve such objectives.
- Besides, **academic-industry partnership** and **academic-society partnership** were major way forward to sustain the consistency of the development of the profession.

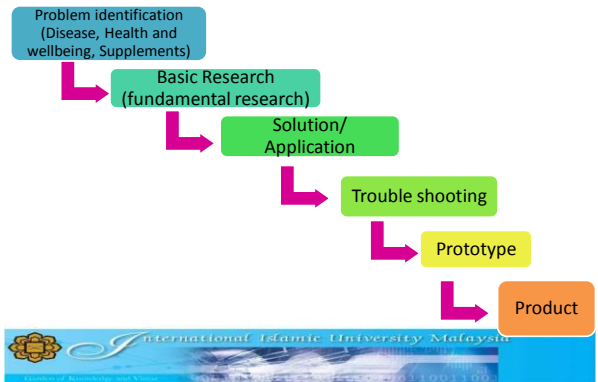


KOP Research Activities

- Research is an **obligatory part** of the Academic activities. It is mainly divided according to the different stream of Pharmacy and other relevant fields:
- Pharmaceutical Chemistry, Technology, Basic Medical Sciences, Clinical Sciences, Quality Management Systems, UN Sustainable Development Goals (SDG)



Research to Product



Research and Practice

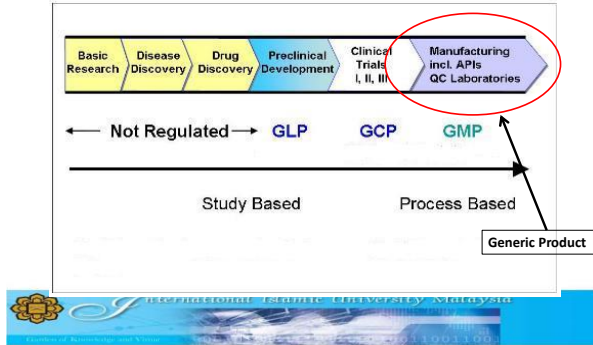
- **Drug Development** (Generic and Internal Patent)
- **Medicinal Plants and herbs**
- **Toxicity Analysis**
- QMS implementation (**PICS GMP**, **HALAL**, **ISO 9001**, **ISO 17025**)



DRUG DEVELOPMENT

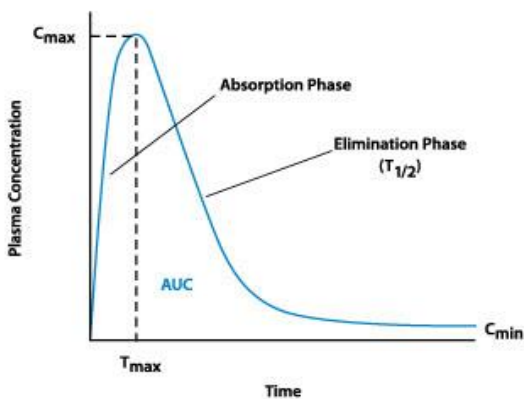


Patented vs Generic



Bioanalysis

- Bioanalysis is defined as quantitative measurement of drugs in biological system (plasma, urine, and tissues).
- Bio analysis is very important in the field of drug development and generic formulation such as:
 - ❖ preclinical studies for new drugs
 - ❖ clinical studies in human plasma
 - ❖ therapeutic and toxicological concentrations.
 - ❖ pharmacokinetic studies for drugs
 - ❖ Bio equivalence of generic formulation

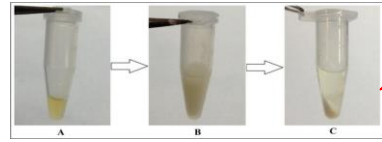


Choice of Drugs

RANK	ATC	THERAPEUTIC GROUP	PUBLIC	PRIVATE	TOTAL
1	A10	Drugs used in diabetes	42.0556	6.9074	48.9630
2	CC	Calcium channel blockers	20.4728	10.6096	31.0823
3	C09	Agents acting on the renin-angiotensin system	19.7722	4.4640	24.2362
4	C07	Beta blocking agents	17.6028	2.5778	20.1806
5	C03	Diuretics	14.6048	4.3189	18.9237
6	M01	Antiinflammatory and antirheumatic products	3.0869	11.9973	15.0843
7	C10	Lipid modifying agents	8.6305	4.6590	13.2895
8	J01	Antibacterials for systemic use	4.7513	7.9885	12.7398
9	R06	Antihistamines for systemic use	4.3263	7.9234	12.2497
10	H02	Corticosteroids for systemic use	3.6126	8.1238	11.7364

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RANK	ATC	THERAPEUTIC GROUP	PUBLIC	PRIVATE	TOTAL
1	C08C A01	Amlodipine	26.7411	2.9817	29.7228
2	A10B B04	Gliclazide	23.7710	1.9930	25.7640
3	C09A A04	Perindopril	13.7130	0.6026	14.3156
4	A10B A02	Metformin	13.1892	1.1200	14.3092
5	C08C A05	Nifedipine	10.0114	1.5413	11.5527
6	C03A A03	Hydrochlorothiazide	10.6896	0.2586	10.9482
7	G03C A57	Conjugated estrogens	3.6887	6.9684	10.6570
8	C07A B02	Metoprolol	9.8532	0.1297	9.9829
9	C07A B03	Atenolol	7.9423	1.2049	9.1472
10	A10B B01	Glibenclamide	7.6174	0.8190	8.4364



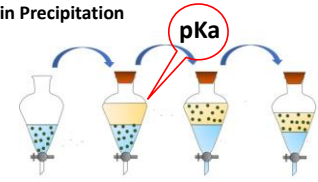
Solvent Strength

Affinity

Protein Precipitation



SPE, Solid Phase Extraction

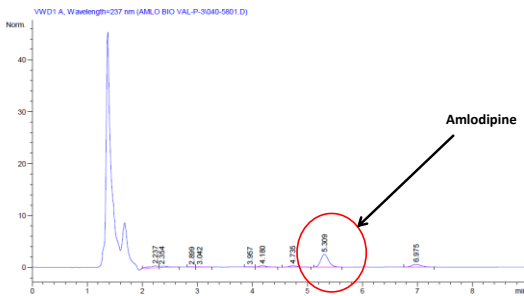


pKa

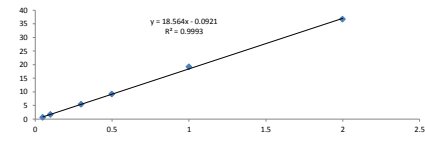
Solvent Extraction



Amlodipine



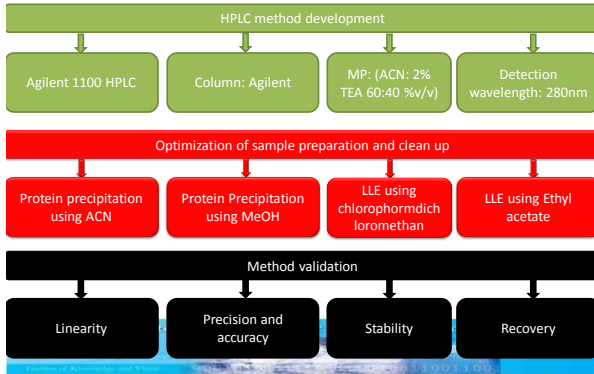
Amlodipine method validation



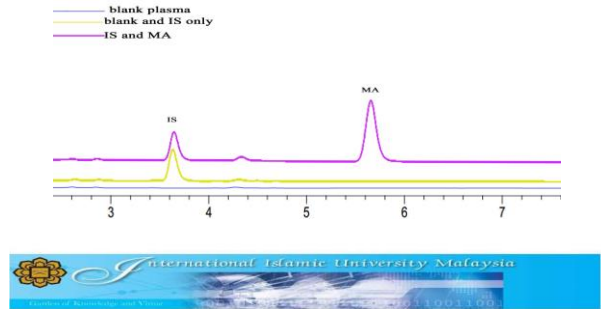
	Accuracy		Precision	
	Intra day	Inter day	Intra day CV	Inter day CV
LOQ and LQC, MQC and HQC	109.1%	102.8%	8.3	8.9



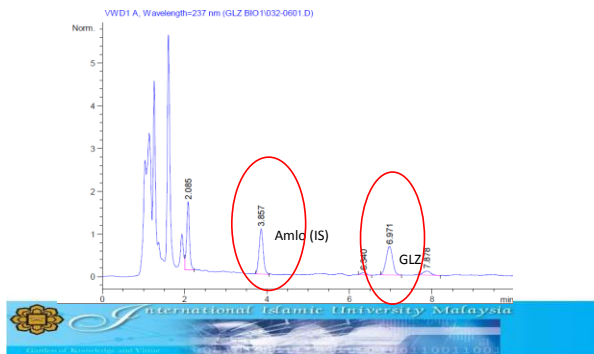
Mefenamic acid analysis in Plasma



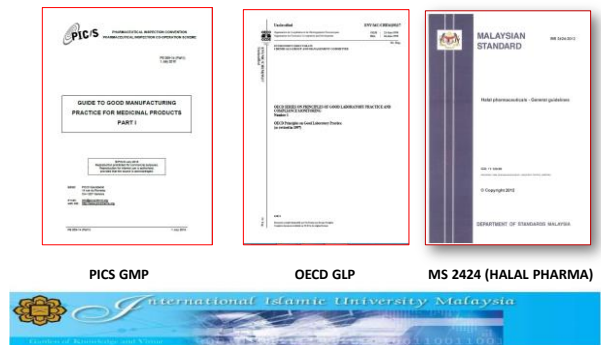
Mefenamic Acid



Gliclazide Analysis



REGULATORY



IP/PATENT

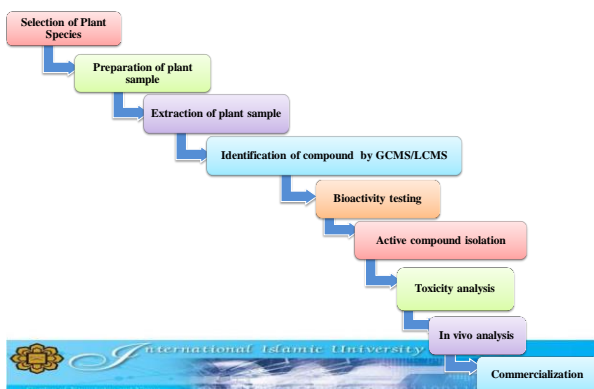
- Composition of a transdermal film for protein- and peptide-based therapeutic drug delivery in a non-invasive way. September 2021, **German patent**. Patent Number/ID: DE202021105304U1
- Hepatoprotective and Antioxidant activity of Novel active herbal agent against Non-Alcoholic fatty liver disease. **Australian Patent** No: 2021104915.
- A Formulation For Synthesis Of Silymarin Conjugated Gold Nanoparticle To Heal Wound And A Method Thereof. **South African Patent** Filed No: 2022/00148.
- Synthesis of coagulant material from tropical peat soil. PI20023170, 2002, **Malaysian patent**.



MEDICINAL/HERBAL PLANT RESEARCH



Plant Selection to Commercialization

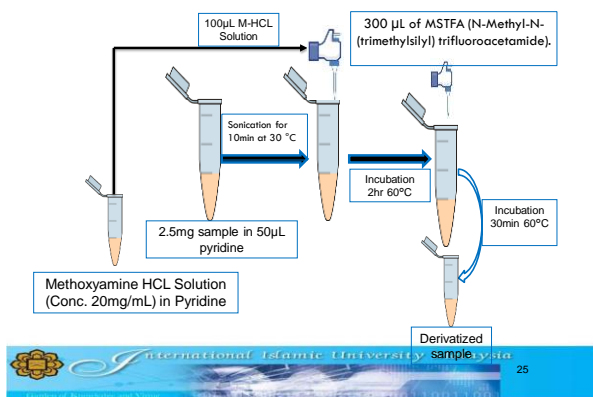


Bioactivity Testing

- Selection of **appropriate bioactivity test**
- Develop **protocol** for biological test
- Analyze **in vitro** bioactivity
- Determine **type and level** of bioactivity



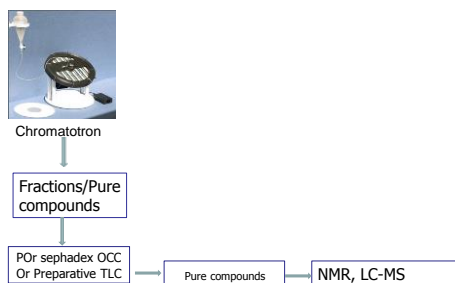
Sample derivatization for GC-MS identification¹⁸ (Robinson et al 2005)



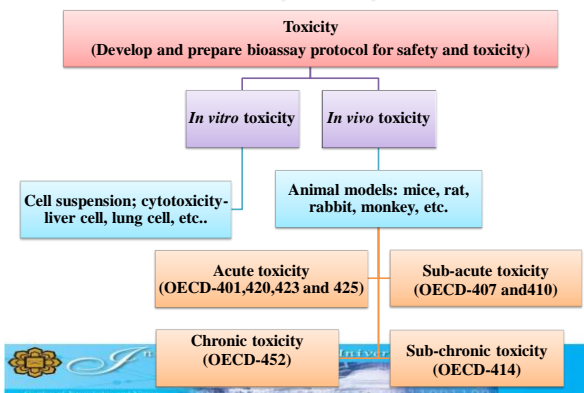
Isolating Active Compounds

- Isolation and characterization of compounds responsible for observed biological activity.
- Evaluation of active pure compound and in combination with others to explore existence of activity and /or synergy of biological effect.

ISOLATION (Centrifugal thin layer chromatography)



Toxicity Analysis



In vivo analysis

- ❖ Use animal model for specific bioactivity analysis for active compounds and or extracts
- ❖ Conduct human studies

Commercialization

- **Develop appropriate dose delivery system**
- **Analyze cost effectiveness**
- **Sustainable industrial production**



NUTRACEUTICALS

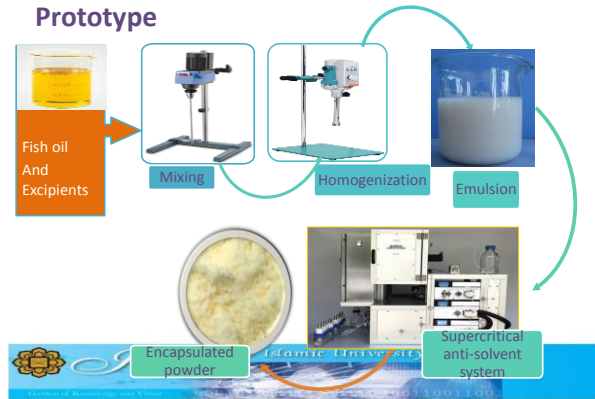
Nutraceuticals, Fish Oil

Solidified Fish Oil

- ✓ High stability
- ✓ Good taste
- ✓ High nutritional value
- ✓ High content of omega-3
- ✓ High encapsulation efficiency
- ✓ Shari'ah compliance for Halal product



Fish Oil Powder Production



SFO Stability

Organoleptic Characteristics				
Parameters	Appearance	Color	Odor	Moisture content (% w/w)
0 Months	Powder	Off white	Odorless	3.60±0.06
1	Powder	Off white	Odorless	3.58±0.05
3	Powder	Off white	Odorless	3.59±0.03
6	Powder	Off white	Odorless	3.61±0.02
12	Powder	Off white	Odorless	3.62±0.02
18	Powder	Off white	Odorless	3.59±0.03
24	Powder	Off white	Odorless	3.58±0.04
30	Powder	Off white	Odorless	3.61±0.04
36	Powder	Off white	Odorless	3.62±0.06
42	Powder	Off white	Odorless	3.59±0.03
48	Powder	Off white	Odorless	3.62±0.05

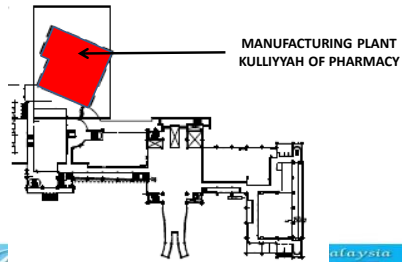
REGULATORY

BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)
 Juga dikenali sebagai Biro Pengendalian Farmasetikal Kebangsaan (BPFK)
 NATIONAL PHARMACEUTICAL REGULATORY AGENCY (KEMENTERIAN KESIHATAN MALAYSIA)

GMP – TM and Supplements **Stability – TM and Supplements** **QMS- HALAL**

ACDEMIC INDUSTRY PARTNERSHIP

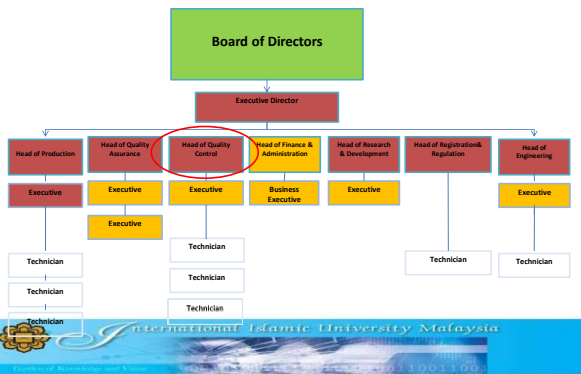
Location of Manufacturing Plant
(Behind the Kulliyah of Pharmacy)



PICS-GMP APPROVAL



ORGANISATION CHART- IKOP



IIUM Pharmaceutical Manufacturing Plant - IKOP



Main Office

Production Entrance

QC Lab



ACADEMIC SOCIETY PARTNERSHIP



Kampung Alor Batu, Jabor



Hygiene and healthy well being drive from KOP during first wave of COVID 19 to the residence of Adopted Kampung (village) Alor Batu.



Contd..



Home medication review, Experiential learning for Pharmacy students from KOP to the Adopted Kampung (village) Alor Batu.



RIVER OF LIFE



Kampung Sungai (River) Lembing, Experiential Learning of IIUM students with KCROL team.



THANK YOU





Dr. A.B. M Helal Uddin,

Assoc. Professor
Department of Pharmaceutical Chemistry
Kulliyah (Faculty) of Pharmacy,
International Islamic University Malaysia (IIUM)
25200 Kuantan, Pahang, Malaysia.

Dear Sir,

We are delighted by having the opportunity to invite you as a Keynote Speaker in Our Faculty Special Seminar to enlighten our Faculties and Students regarding the subjects as mentioned below on August 04, 2022 at 7:30 pm. They will be honored to have been able to share your experiences and opinions.

We hope you will accept our request for this invitation and also help our faculties and students to gather knowledge.

Thank you for your consideration

Professor Dr. Nurul Absar

Dean,
Faculty of Basic Medical and Pharmaceutical Sciences,
University of Science and Technology (USTC),
Foy's Lake, Chittagong – 4202, Bangladesh

Topics o the Seminar:

- 1) Current research and research based commercial product output,
- 2) Field of potential research collaboration and
- 3) Opportunity for Postgraduate studies.



University of Science and Technology Chittagong (USTC)
Department of Biochemistry and Biotechnology



Speaker

Dr. A.B.M. Helal Uddin

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Department of Pharmaceutical Chemistry
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25200 Kuantan, Pahang,
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Seminar On

**"Pharmaceuticals and Nutraceuticals from development
to commercialisation: An IIUM experience"**



4th August, 2022

Time: 07:30 PM



Session ID: 67263999538

Organized by
Department of Biochemistry and Biotechnology
University of Science and Technology Chittagong (USTC)