Proposed Syllabus For

Post Graduate Diploma in Toxicology

(PGDT)

As an

Add on Course

DEPARTMENT OF BIOSCIENCES

VEERNARMADSOUTHGUJARATUNIVERSITY

SURAT, GUJARAT – 395 007

Preamble:

South Gujarat region starting from Vapi to Bharuch is industrially well developed often referred to as golden corridor. It is dominated by Pharmaceutical industries, pesticide manufacturers, synthetic yarn production, textile processing houses and dying units. Surat in particular is dominated by textile industry and diamond cutting industry. Nearly 30 million meters of raw fabric and 25 million meters of processed fabric is produced in Surat daily.

The Textile industries are very complex in nature as far as varieties of products, process and raw materials are concerned. The wastewater of the industry is highly alkaline in nature and contains high concentration of BOD, COD, TDS and alkalinity, chloride, sulphide, heavy metals, organic solvents and carcinogenic dyes. It can cause environmental problems unless it is properly treated before disposal. Diamond industry doesn't produce effluents, however the workers are exposed to toxic chemicals during the process. Most of these agents have shown to have adverse effects on human health. Sustainable industrial development has two key phases, ecofriendly and economic approaches.

This entire industrial corridor has been identified as most polluted region in the country, Ministry of environment and Forestry has put a ban on expansion of existing and on new chemical industries in most of these GIDCs. As result of the governments policy many CEPTs have come up in the region, there are many private pollution analysis labs in this region and all the industries need technically qualified people to monitor their effluents, All the pharmaceutical companies need manpower to evaluate the toxicity of their products, there are several Contract Research Organizations in need of manpower trained in toxicology. This proposed diploma aims to produce the trained manpower to the needs of the industry in the field of toxicology.

This program is proposed as an add on degree where the Post-graduate students, Research Scholars can pursue along with their regular courses, to facilitate this provision the course will be conducted as evening course after the regular teaching of the University (Tentatively proposed timing is 5.00 pm to 9.00 pm)

Proposed Course Structure for PG Diploma in Toxicology (PGDT)

Semester -I

Paper	Title	Credits
PGDT-101	Principles of Toxicology	3
PGDT-102	Principles of Ecotoxicology	3
PGDT-103	Environmental Toxicology	3
PGDT-104	Analytical Methods & Instrumentation	3
PGDT-105	Practical based on PGDT-101 to 104	6
PGDT-106	Field work	2

Semester -II

PGDT-201	Genetic Toxicology & In-vitro Methods	3
PGDT-202	Food Safety and Nutritional Toxicology	3
PGDT-203	Biostatistica and Risk Assessment	2
PGDT-204	Regulations and Quality systems	2
PGDT-205	Practicals based on PGDT-201-203	6
PGDT-206	Industrial Training	4

SEMESTER-I

PGDT-101- Principles of Toxicology

Sr. No.	Title	Individual Units Hours	Total Hours
1	**Introduction & History**		**2**
2	**Principles of Toxicology**		**6**
2.1	Classes of Toxicants	2	
2.1.1	Metals		
2.1.2	Agricultural Chemicals		
2.1.3	Food Additives & Contaminants		
2.1.4	Toxins		
2.1.5	Solvents		
2.1.6	Therapeutic Drugs		
2.1.7	Drugs of Abuse		
2.2	Dose Response Relationship	2	
2.2.1	Individual dose response relationships		
2.2.2	Graded dose response relationships		
2.2.3	Quantal dose response relationships		
2.2.4	Shape of the dose response curve		
2.3	Evaluating dose response relationship	2	
2.3.1	Comparison of dos eresponses		
2.3.2	Therapeutic index		
2.3.3	Margin of safety & exposure		
2.3.4	Potency versus efficacy		

3.0	Route of exposure & animal toxicity tests		15
3.1	Routes of exposure	1	
3.1.1	Oral (Gavage & Dietary)		
3.1.2	Subcutaneous (S.C.)		
3.1.3	Intravenous (I.V.)		
3.1.4	Intraperitoneal (I.P.)		
3.1.5	Inhalation		
3.1.6	Sublingual		
3.1.7	Dermal		
3.2	Short term toxicity tests	2	
3.2.1	Acute toxicity testing		
3.2.2	Skin & Eye irritation		
3.2.3	Sensitization test		
3.3	Long term toxicity test	3	
3.3.1	Subacute (14/28/90 Days)		
3.3.2	Subchronic		
3.3.3	Chronic		
3.4	Specialized toxicity tests	6	
3.4.1	Developmental & Teratology		
3.4.2	Reproduction		
3.4.3	Mutagenicity		
3.4.4	Oncogenicity		
3.4.5	Neurotoxicity		
3.4.6	Immunotoxicity		
3.5	Test Species	3	
3.5.1	Housing		

3.5.2	Space		
3.5.3	Health monitoring		
3.5.4	Ethics		
3.5.5	IAEC / CPCSEA		
4.0	Mechanism of toxicity		5
4.1	Absorbtion	1	
4.2	Distribution	1	
4.3	Metabolism	1	
4.4	Excretion	1	
4.5	Cellular disregulation	1	

PGDT-102-Principles of Ecotoxicology

Sr. No.	Title	Individual Units Hours	Total Hours
1.0	Introduction, History & Principles of Ecotoxicology		3
2.0	Test species & environmental conditions		6
2.1	Terrestrial	3	
2.1.1	Earthworm: (*Eiseniafoetida, Eisenia Andrei*)		
2.1.2	Honey bee : (*Apismellifera*)		
2.1.3	Birds : Japanses quail *Coturnix japonica* (*Galliform*) Mallard Duck *Anasplatyrhynchos*(*Anseriform*) Feral pigeon (*Columba livia*(*Collumbiform*)		
2.1.4	Plants: Dicot - Methi (Digonella), Tuver (Phasiolas) Monocot – Rice (*Oriza sativa*), Onion (*Allium cepa*)		
2.2	Aquatic	3	
2.2.1	Algae:*Pseudokirchneriellasubcapitata*&*Desmodesmus subspicatus*		
2.2.2	LemnaSpp.*Lemnagibba*, *Lemna minor*		
2.2.3	Daphnia Spp. *Daphnia magna*		
2.2.4	Fish : Common carp – Cyprinuscarpio Rainbow trout – Oncorhynchusmykiss Zebra fish – Brachydaniorerio Guppy – Poeciliareticulate		
3.0	Route of exposure & tests		7
3.1	Water, Soil, Diet	1	
3.2	Short Term / Acute Toxicity Tests	6	
3.2.1	AGIT – Algal Growth Inhibition Test		
3.2.2	*Lemna Spp.* Toxicity Test		
3.2.3	AIT – Acute Immobilization Test		
3.2.4	AFT – Acute Fish Toxicity Test		
3.2.5	AET – Earthworm, Acute Toxicity Test		

3.2.6	HBOT – Honey, Acute Oral Toxicity Test		
3.2.7	HBCT – Honey, Acute Contact Toxicity Test		
3.2.8	AAOT – Avian Acute Oral Toxicity Test		
3.2.9	ADT – Avian Dietary Toxicity Test		
3.2.10	Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test		
4.0	Mechanism of toxicity		4
4.1	Absorbtion – Aquatic & Terrestrial Organisms		
4.2	Distribution – Aquatic & Terrestrial Organisms		
4.3	Metabolism – Aquatic & Terrestrial Organisms		
4.4	Excretion – Aquatic & Terrestrial Organisms		

PGDT-103-Environmental Toxicology

Sr. No.	Title	Individual Units Hours	Total Hours
1.0	Basics & Specific Histroy of Environmental Toxicology		2
2.0	Occupational Toxicology & Routes of Exposure		4
2.1	Respiratory		
2.2	Allergic Response		
2.3	Nephrotoxins		
2.4	Hepatotoxins		
2.5	Other Toxic Responses		
2.6	Histo techniques for evaluation of Organ Specific Toxicities		
3.0	Air, Water, Land & Atmospheric Pollution		12
3.1	Air Pollution	3	
3.1.1	Pollutant Cycles		
3.1.2	Urban Pollutants		
3.1.3	Trends & Present Status of Air Quality		
3.1.4	Pollution by Motor Vehicles		
3.1.5	Pollution by Incinerators		
3.1.6	Pollution by Industrial Chemicals		
3.1.7	Tall Stacks & their role in transport of pollutants		
3.1.8	Indoor Air pollution		
3.2	Water Pollution	3	
3.2.1	Nitrogen Overload		
3.2.2	Transport of Water Pollutants		
3.2.3	Urban Pollutants		
3.2.4	Lead Pollution		
3.2.5	Soil Erosion		
3.2.6	Wet Lands & Estuaries Pollution		
3.2.7	Pollution of Ground Water		

3.3	Land Pollution	3	
3.3.1	Nutrients & Pesticides		
3.3.2	Genetically Modified Crops		
3.3.3	Industrial Pollutants		
3.3.4	Airborne Water & Land Pollution		
3.4	Atmospheric Pollution	3	
3.4.1	Earth's Atmosphere		
3.4.2	Formation & Sustenance of Stratospheric Ozone		
3.4.3	Depletion of Stratospheric Ozone		
3.4.4	Emission of CO_2		
3.4.5	Current Developments		
4.0	Radioactive Pollution		5
4.1	Ionizing Radiation		
4.2	Measurement of Radioactivity		
4.3	Source of Radiation		
4.4	Health & Biological Effects of Radiation		
4.5	Nuclear Energy		

PGDT- 104-Analytical Methods & Instrumentation

Sr. No.	Title	Individual Units Hours	Total Hours
1.0	Basics of Analytical Methods		4
1.1	Chemical Equilibrium in Solutions		
1.2	Qualitative Chemical Analysis		
1.3	Quantitative Chemical Analysis		
1.4	Titration		
1.4.1	Acid Base Titration		
1.4.2	Complexation Titrations		
1.5	Gravimetric – Measurements based on Mass		
1.6	Electrochemical Methods		
1.6.1	pH Measurements		
1.6.2	Ion Sensitive Electrodes		
2.0	Sampling, Preservation, Handling, Storage & Transportation of Samples		3
2.1	Soil		
2.2	Water		
2.3	Air		
2.4	Blood		
2.5	Tissues		
2.6	Diet		
2.7	Dose Formulation		
3.0	Instrumentation		17
3.1	Balances		
3.2	pH Meter		
3.3	Multiport Meters (pH, Dissolve Oxygen, Temperature, Conductivity, Salinity Meter)		
3.4	Incubators (COD, BOD)		

3.5	Temperature Monitoring Devices (Thermometers, Sensors)		
3.6	Centrifuges (Simple, High Speed, Cooling)		
3.7	HPLC		
3.8	GC		
3.9	GCMS		
3.10	LCMS		
3.11	AAS		
3.12	Spectrophotometers		
3.13	Microtome's		
3.14	Tissue Processors (Manual & Automatic)		
3.15	Air Quality Analyzers		
3.16	Radio Active Monitoring Devices		
4.0	Method Development & Validation		4
4.1	Important Terminoly of Development	2	
4.1.1	Accuracy		
4.1.2	Precision		
4.1.3	Specificity		
4.1.4	Detection Limit		
4.1.5	Quantitation Limit		
4.1.6	Linearity		
4.1.7	Range		
4.1.8	Robustness		
4.2	Elements of Validation	2	
4.2.1	Approaches to Validation		
4.2.2	Timing of Validation		
4.2.3	Criteria for Validation		
4.2.4	Repeatability		
4.2.5	Reproducibility		

SEMESTER-II

PGDT-201-Genetic Toxicology & In-vitro Methods

Sr. No.	Title	Individual Units Hours	Total Hours
1.0	Basics & History of Genetic Toxicology		2
2.0	Test Systems		4
2.1	Bacterial Strains	2	
2.1.1	*S. typhimurium*TA1535		
2.1.2	*S. typhimurium*TA1537, TA97 or TA97a		
2.1.3	*S.* typhimurium TA98		
2.1.4	*S.* typhimurium TA100		
2.1.5	*S. typhimurium*TA102		
2.1.6	*E. coli* WP2 uvrA, WP2 uvrA (pKM101)		
2.2	Cell Lines	2	
2.2.1	Chinese Hamster Fibroblasts (CHO)		
2.2.2	Human Lymphocytes		
2.2.3	Mouse Lymphoma		
2.2.4	CACO II / Rat / Mice		

3.0	Assays		10
3.1	Bacterial Reverse Mutation Test (AMES)		
3.2	HLCA		
3.3	Rat & Mice Chromosomal Aberration (CA)		
3.4	In-vitro Mammalian Chromosomal Aberration		
3.5	Rat & Mice Micro Nucleus Test (MNT)		
4.0	Assays		10
4.1	Comet Assay		
4.2	Micro Arrays		
4.3	Cell Gene Mutations		
4.4	Skin Sensitization		
4.5	Skin Irritation (TER)		
4.6	Application of Assays		

PGDT-202-Food Safety and Nutritional Toxicology

Sr. No.	Title	Individual Units Hours	Total Hours
1.0	Definition of Terms		6
1.1	Food & Nutritional Toxicology		
1.2	Toxicants in food		
1.3	Effects of Toxicants in food on Nutrition		
1.4	Natural Toxicants		
1.5	Food Additive Contamination		
2.0	Factors Influencing Toxicity		6
2.1	Effects of Macronutrients Changes		
2.1.1	Carbohydrates		
2.1.2	Proteins		
2.1.3	Lipids		
2.2	Effects of Micronutrients Changes		
2.2.1	Vitamins		
2.2.2	Minerals		
2.3	Allergy and Food Intolerance		
2.3.1	Allergy and Types of Hypersenstivity		
2.3.2	Primary Food Sensitivity		
2.3.3	Non Immunological Sensitivities		
2.3.4	Secondary Sensitivities		
2.3.5	Symptoms & Diagnosis		
3.0	Toxicants in Food		8
3.1	Bacterial – Mode of action & Clinical Signs		
3.1.1	*Bacillus cereus*		
3.1.2	*Clostridium botulinum*		
3.1.3	*Staphylococci*		
3.1.4	*Salmonella*		

3.1.5	*Campylobacter jejuni*		
3.1.6	*Clostridium perfringens*		
3.1.7	*Escherichia coli*		
3.2	Marine Animals & Plants - Mode of action & Clinical Signs		
	Tetrodotoxin		
	Saxitoxin		
	Ciguatoxin		
	Goitrogens		
	Cyanogenic Glycosides		
	Phenolic Substances		
	Cholinesterase Inhibitors		
3.3	Fungal Mycotoxins - Mode of action & Clinical Signs		
3.3.1	Aflatoxin		
3.3.2	Trichothecenes		
3.3.3	PenicilliaMycotoxins Rubratoxin Patulin Yellow Rice Toxins		
4.0	Food Residues		8
4.1	Insecticides DDT (1,1'-(2,2,2-Trichloroethylidene)bis(4-Chlorobenzene) Organophosphates Carbamates Cyclodiene Insecticides		
4.2	Herbicides Chlorophenoxy Acid Esters (Phenoxyalipatic Acids) Bipyridyliums		
4.3	Fungicides		
4.4	Industrial and Environmental Contaminants Halogenated Hydrocarbons Polychlorinated Biphenyls Dioxins		
4.5	Risk management in relation to food and its components		
4.6	Setting toxicological standards for food safety		

PGDT-203-Biostatistics, Risk Assessment,

Sr. No.	Title	Individual Units Hours	Total Hours
1.0	Statistics		
	Chi square Test		
	Students t Distribution		
	F Distribution		
	Correlations		
	Two Independent Correlations		
	Regression		
	Analysis of Variance		
2.0	Risk Assessment		
	Human Pharmaceuticals		
	Medical Devices		
	Biomaterials		
	Food Additives		
	Agricultural Chemicals		
	Industrial Chemicals		

PGDT-204-Regulations & Quality Systems

Sr. No.	Title	Individual Units Hours	Total Hours
1.0	Regulatory Gudelines - National		
	National		
	DCGI / CDSCO Guidelines		
	FSSAI		
	GOTS		
	CPCB / GPCB		
2.0	Regulatory Gudelines - International		
	US FDA		
	OECD Guidelines		
	US EPA		
3.0	National - Quality Standards		
	NABL		
4.0	International – Quality Standards		
	OECD GLP		
	ISO		

Reference Books

1) A guide to practical toxicology – Evaluation, Prediction & Risk) – Adam Woolley
2) Food & Nutritional Toxicology – Stanley T Omaye
3) Experimental Toxicology – The Basic Issues – D Anderson & DM Conning
4) Environmental Toxicology – David A Wright & Pamela Welbourn
5) Predictive Toxicology – ChristophHelma
6) Principles of Toxicology (Environmental & Industrial Applications)\
7) Casarett&Douls's Toxicology
8) Hayes Toxicology
9) Environmental Toxicology – Sigmunel F Zakrzenski

VEER NARMAD SOUTH GUJARAT UNIVERSITY
PG Diploma in Toxicology (PGDT)
Proposed Teaching and Evaluation Scheme for PGDT
Semester-I

Paper No.	Paper title	Teaching schedule (hrs./wk)		University Exam Theory/ Practical		Internal Exam. Theory/ Pract.	Total Theory/ pract.
		Lecture	Pract.	Duration	Marks	Marks	Marks
PGDT-101	Principles of Toxicology	3		3	70	30	100
PGDT-102	Principles of Ecotoxicology	3		3	70	30	100
PGDT-103	Environmental Toxicology	3		3	70	30	100
PGDT-104	Analytical Methods & Instrumentation	3		3	70	30	100
PGDT-105	Practicals		12	5 x2	140	60	200
PGDT- 106	Field Work					100	100
	TOTAL	**12**	**12**		**490**	**210**	**700**

Semester-II

Paper No.	Paper title	Teaching schedule (hrs./wk)		University Exam Theory/ Practical		Internal Exam. Theory/ Pract.	Total Theory/ pract.
		Lecture	Pract.	Duration	Marks	Marks	Marks
PGDT-201	Genetic Toxicology & In-vitro Methods	3		3	70	30	100
PGDT-202	Food Safety and Nutritional Toxicology	3		3	70	30	100
PGDT-203	Biostatistica and Risk Assessment	2		3	70	30	100
PGDT-204	Regulations and Quality systems	2		3	70	30	100
PGDT-205	Practicals		12	5 x 2	140	60	200
PGDT-206	Industrial training				100		100
	TOTAL	10	12		550	150	700