

Gopal Narayan Singh University
Faculty of Pharmacy
Impurities Profiling in Pharmaceuticals

Course code: BPHVA2

Objective: With ever increasing the emphasis with stringent regulatory guidelines globally on quality of pharmaceuticals, impurities in active pharmaceutical ingredients, stability, and profiling of degradation products in the formulations, identification and assessment of their toxicity in general and genotoxicity in particular has become valuable and necessary expertise.

Unit I	6 hours
Regulatory status, ICH guidelines	
Concerned authorities, certifications	
Limits prescribed, methodology, toxicity guidelines and prescribed tests	
Unit II	6 hours
Impurity: Separation, isolation, and characterization	
Unit III	6 hours
Potential toxicity assessment using QSAR and other computational techniques	
Unit IV	6 hours
Toxicology: methods of evaluation of toxicity	
Genotoxicity, animal studies and other approaches	
Unit V	6 hours
Case studies	


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