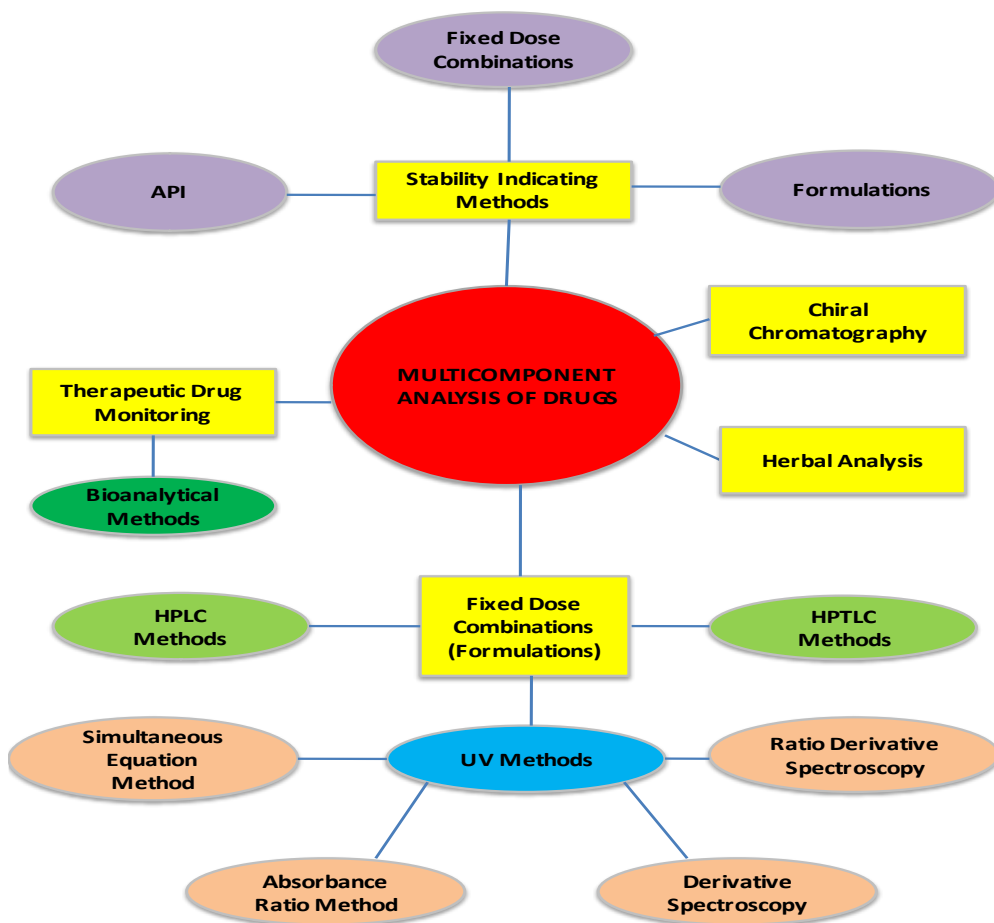


SUMMARY OF MAJOR RESEARCH GRANT  
**MULTICOMPONENT ANALYSIS OF DRUGS**  
SANCTIONED BY UGC

The executive summary of the report, research documents, monograph, academic papers provided under Major Research Project of University Grants Commission (UGC) posted on website as required by UGC

1. Name of the Principal Investigator: **Dr Krishnapriya Mohanraj**  
Professor of Pharmaceutical Analysis  
Bombay College of Pharmacy, Mumbai
2. UGC approval number and date: **F. No. 41-721/2012(SR) dated 23<sup>rd</sup> July 2012**
3. Title of research project: **MULTICOMPONENT ANALYSIS OF DRUGS**
4. Effective period of project: 3<sup>rd</sup> October 2012- 31<sup>st</sup> December 2015
5. Amount Sanctioned: Rs 835000/- + Rs 13557 (Interest on Fixed Deposit)  
= Rs 848557
6. Amount Utilised: Rs. 848559/-
7. Summary of report



Work carried out under each objective is summarized below

**Objectives A & B: Development of Analytical methods for Fixed Dose Combination (FDC)s and Stability indicating methods for Active Pharmaceutical Ingredients (API) or FDCs using different techniques**

**Work done:** Multicomponent Analytical techniques for various APIs and FDCs were developed, validated and the methods were applied for assay of API in marketed formulations. Impurity profiling by LC-MS-MS and prediction of degradation pathway and fragmentation pattern in mass spectrometry was postulated for 4 APIs

Technique	Drugs	Method Developed & Validated
UV Spectroscopy	Tolperisone Hydrochloride and Diclofenac Sodium	Simultaneous equation method Absorbance ratio method
	Metformin Hydrochloride and Gliclazide	First order derivative spectroscopy
HPLC	1. Fenoxazoline, 2. Dapoxetine, 3. Tapentadol, 4. Sodium picosulfate	Stability indicating assay methods for four APIs (Collaboration with School of Science, NMIMS University, Mumbai, <b>4 papers published</b> )
	Terbinafine HCl and Mometasone Furoate	Stability indicating assay method for FDC
	Tolperisone Hydrochloride and Diclofenac Sodium	Stability indicating assay method for FDC
HPTLC	Terbinafine HCl and Mometasone Furoate	Assay method for FDC

**Objective C: Development and validation of Bioanalytical methods using reverse phase HPLC for therapeutic drug monitoring**

**Work done:** Bioanalytical RP-HPLC method using ion pair reagent for **risperidone (Atypical antipsychotic)** and its major active metabolite **9-hydroxy-risperidone** was developed and validated as per CDER guidelines. The method was applied to therapeutic drug monitoring of psychiatry patients of Nair Hospital (Collaboration: Dr. Renuka Munshi, Department of Clinical Pharmacology, TN Medical College & B.Y.L. Nair Charitable Hospital, Mumbai).

**Objective D: Herbal analysis by HPTLC**

**Work done:** Successive Soxhlet extraction of 4 crude drugs was done using hexane, chloroform, methanol and water. HPTLC analysis of various herbal extracts with their marker compound was performed

1. Lavang extracts and Eugenol
3. Maiphall extracts and Gallic acid

2. Daruharidra extracts and Berberine
4. Bael extracts and Marmeolsin

**Objective E: Development and validation of chiral chromatography for a chiral drug.**

**Work done:** Chiral chromatographic method using chiral mobile phase additive and achiral HPLC column (C<sub>8</sub>) was developed and validated and applied for assay of API (single enantiomer) in marketed formulations for following chiral drugs

1. Milnacipran hydrochloride (Anti-depressant)
2. Cetirizine (Anti-histaminic)
3. Citalopram (Anti-depressant)
4. Cloperastine (Anti-tussive)

Sulphated Betacyclodextrin was synthesized and used as chiral mobile phase additive. It was found to give better resolution than the marketed sulphated beta cyclodextrin. Effect of sulphated Beta cyclodextrin concentration in mobile phase, pH and buffer type and concentration on retention time and resolution were studied for 2, 3 and 4. (2,3 and 4 were done in collaboration with School of Science, NMIMS University; **2 publications**)

