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Department of Pharmaceutical Analysis and Quality Assurance (PA & QA)

Quality Assurance Technique (QAT)

1. Introduction: Basic need of any business is to satisfy the customers, which is rationally possible only through quality services and products; therefore quality should be built in the product. Central role of **Quality Assurance (**QA) is to assure the quality through well planned activities and not just by testing the quality of final product. Quality Assurance act as caretaker of the Pharmaceutical Quality System (PQS) which are necessary to build quality in to the services and products which means QA is essential for better business plans and progression. QA work as gate keeper of Quality of Pharmaceuticals with deep understanding of all stages of product design and development (F&D), analytical development (ADL), manufacturing operations (GMP), process validation & controls, etc [1, 2].

Quality Assurance is the action of giving proof required to set up quality in work, required for all those planned or systematic actions essential to provide sufficient assurance that a product or service will fulfill the offered requirements for quality. Quality Assurance presents the guidelines which are 'fit for function' and 'do it right the first time'. It can be obtained by presenting suitable standards and standard operating procedures (SOPs) in-house [3].

The pharmaceutical industry is the most regulated among all other industries. Each country has well established drug regulatory authorities controlling all regulatory aspects (research, manufacturing, transport, sales, safe disposal, etc.) of pharmaceuticals, medical devices and diagnostics and other health care needs viz. specialized foods articles and dietary supplements, etc [4].

In the globalized era and increased export-import (Exim) trade, health care articles moving internationally needs to comply standards of all the nations involved in Exim operations. QA plays pivotal role in meeting compliance to the regulations and standards. QA personals play central role to ensure that National (viz. USFDA, TGA, MHRA, etc.) regional (ASEAN, CIS, GCC, PANDRH, ENVISA, etc.) and global (WHO, ICH, PICs, etc.) regulations relevant to the concerned product are complied. In nutshell Pharmaceutical Quality Assurance section must ensure that the drug manufacturing process complies with government regulations and stringent manufacturing standards so that drugs are safe, effective and work as promised.

National, regional and global regulatory authorities have their own set of regulations in the form of drug laws, good laboratory practice (GLP), good clinical practice (GCP), good manufacture practice (GMP), current GPM (cGMP), etc. combined together called GXPs. GXPs lay down

requirements for high quality systems to ensure the availability of the pharmaceuticals with desired quality, purity, safety and efficacy. In this view QA personnel are playing very vital role in drugs, biologics, medical devices, diagnostics and other health care (specialized foods articles and dietary supplements) quality aspects as it is the only effective link among all the pharmaceutical organization sections such as production, packing, QC, R&D (F&D, ADL, bulk, etc.), purchase, sales, warehouse & logistics, regulatory affairs, etc. In short QA plays vital role for pharmaceutical organization for it to be anticipating organization rather than reactive to situations. This is also true in view of current trend of continues changes in the existing regulation and introduction of new one e. g. herbal technology related regulations (global herbal perspective) by EMEA (herbal) and USFDA (Botanicals) guidelines as well as chines herbal medicine (CHM) and Japanese herbal regulations [5-8].

Quality unit (QA and QC) in each organization is concerned with quality of the services and product to protect the interest of the manufacturer and the user. QA plays vial role in these activities as it is caretaker of the Pharmaceutical Quality System (PQS) i. e. Quality Management System (QMS).

2. Responsibilities of the Pharmaceutical Quality Unit are: Top 10 responsibilities[9]

i. To establish the quality system (QMS) to ensure compliance to GXPs and keep in current with good industry practices, as applicable to the mission.
ii. To audit compliance to the quality system and report on the performance of the QMS.
iii. To establish procedures (SOPs,), documents (formats), specifications for inhouse and contract organizations and for vendor validation.
iv. To review and approve or reject all things relevant to cGMP requirements such as procedures, protocols, test methods, and specifications—including changes to these documents, production batch records and make the final decision to release a product lot into commerce.
v. To ensure investigation of nonconformance and enforcement of emerging quality assurance tools (CAPA, PAT, cGMP, QRM, etc.) to avoid any out of specification (OOS) incidents. To report relevant investigations to FDA if it is serious and unexpected and to keep management informed.
vi. Liaison with Research & Development, New Product Introduction and process.
vii. To establish manufacturing controls and to perform laboratory tests or examinations.
viii. To describe responsibilities in writing to establish complete and compliant procedure
ix. To remain independent to avoid conflict of interest between regulatory responsibilities and actual daily activities. It is Independent reviewer and approver for all others departments.
x. Regulatory Compliance Duties: QA holds primary responsibility for regulatory, validation, compliance and must educate the QA employees and other key personnel about relevant national, international and regional regulations and alert them for changes in these documents in organisations internal depts.

The obvious assumption would be that the establishment of an effective PQS belongs to the duties of a QA department or a QA Unit. All these activities and functions needs to be customized to each organization, because no pharmaceutical organizations function in the same way.

3.0 QA subjects

Table 1: Partial list of subjects relevant to QA as per semester pattern

Class	Subjects
S.Y.B. Pharm	Pharmaceutical Analysis I
T.Y.B. Pharm	Pharmaceutical Analysis II and Pharmaceutical Analysis III
Final Year B. Pharm	Pharmaceutical Analysis IV and Pharmaceutical Analysis V
M. Pharm. 1st year a. First semester	1. Quality Assurance Techniques (cGMP and documentation) 2. Advanced analytical Techniques 3. Sterile Product Technology and 4. Research Methodology
M. Pharm. 1st year b. Second Semester	1. Pharmaceutical Validation 2. Drug Regulatory Affairs 3. Cosmetology 4. Quality planning & Analysis
M. Pharm. 2nd year	**Minor and Major Research Projects** Each student must submit at the end of second year one minor and one major research based projects**.** **Research Projects in Industry:** One of the research based project can be completed in the industry with written permission of research guide and principal of the institute. At least one research project should be completed in the institute.

As QAT is a perfect combination of Pharmaceutics and Pharmaceutical chemistry. The core subjects of both the branches at UG level are already explored by QA aspiring students in keeping career focus. Few selected subjects of special interest are listed below	
Pharmaceutics subjects	**Pharmaceutical Chemistry & other subjects**
Pharmaceutical Engineering	Pharmaceutical Organic Chemistry I and II
Physical Pharmacy	Pharmaceutical Medicinal Chemistry I and II
Pharmaceutical Microbiology	Pharmacology I and II
Pharmaceutics–I, II and III	Pharma Biotechnology
Pharmaceutical Business Management	
Bio-pharmaceutics and Pharmacokinetics	
Pharmaceutical Jurisprudence	

The QA manages all aspects of plants quality control systems, including documentation of quality control, and monitoring the activities of material suppliers from outside of the company. QA take care of training and education of work force, executives and officers for its own dept. as well as form other dept. also about quality management processes.

Quality Assurance is dynamic, versatile and most inclusive branch in the Pharmaceutical and health care field which offers wide carrier opportunities to the aspirants. It is the pervasive and indispensable component of any pharmaceutical and health care organization. Person planning carrier in QA needs to imbibe itself with technical and other skills so to become immediately indispensible entity of the organization.

4.0 Career Enrichment at MIP:

MIP QAT aspirants need to take closer look of abilities, strengths and weaknesses. Decide area to excel and work accordingly, individually and in association with colleagues, teachers, guardian teacher, HOD and allotted research guide.

At national and International level new opportunities are created and new challenges are posed, some students may desire to make carrier in such area. In this view following additional subjects are offered at institute level to students interested to enhance knowledge, skills and make carrier in particular field. At present these subject includes -

1. Pharmaceutical plant design and operations
2. Herbal drug technology and regulations
3. Proteomics and pharmacogenomics
4. Novel Drug Delivery System (NDDS)

Well educated and skilled QAT student have ample opportunities to make carrier based on its interest. Available carrier options are - Quality assurance (QA) and Corporate Quality assurance (CQA), Analytical development (ADL), Quality control (QC) , Documentation, Validation, Regulatory affairs, etc. in various pharmaceutical organization. Other opportunities include carrier in Education field (Chemistry and Pharmaceutics branches), Clinical trial management, Pharmacovigilance, Formulation Research and Development, IPR professionals, etc.

Further close guidance is available in the institute for achieving mental alertness, intellectual sharpness and to achieve elevated awareness through proper guidance on yoga, pranayama, Universal Vishwashanti Prayaer and other techniques relevant to subject.

5.0 Research Projects: M. Pharm. QAT students in the institute can undertake "Research Projects" in the following areas:

Students are advised to work on multidisciplinary projects as the QAT branch has widest scope to select research topics. As per curriculum research work is to be carried out in second year. There is component of research in 2nd sem. syllabus of first year and you are expected to crystallize your research project and start experimenting in 1st year only and experience seedlings of research. In view to complete major and minor projects in 3rd and 4th sem. through literature survey and initial experimentation in second semester is very essential. Partial list of research avenues in the institute is provided below -

a. ***Formulations development*** [10-11]: Solubility enhancement, drug diffusion studies, dissolution studies, novel drug delivery systems (NDDS) Viz. Floating Drug Delivery System, Oregano-gel, Pulsatile Drug Delivery System, Mouth Dissolving Tablet, Matrix release Drug Delivery System, Transdermal Drug Delivery System, Buccal Drug Delivery System , Microencapsulation, Herbal Drug formulation, Nanoparticualte DDS, Etc.
b. ***Analytical Method Development*** [12-13]: Analytical method development, impurity profile study, stability indicating method development.
c. ***Herbal Standardization*** [14-15]: Finger printing method development, marker based herbal and polyherbal formulation standardization,
d. ***Industrial process development and validation*** [16-17]: Manufacturing process of immediate, controlled and modified release tablets, liquid orals, external preparations, coating process etc.).
e. ***Chemical Synthesis*** [18-19]: Design and synthesis of bioactive compound such as pro-drug, mutual drugs and their activity evaluation. Activity of synthesized compound can be evaluated by cell line study, animal study. Predictive evaluation of the bioactive compounds can be achieved by using various software to predict the ADME and PK/PD and cellular disposition in various biological systems.
f. ***Molecular Docking Study For Analogs*** [18, 20-22]: Available analogs of the known bioactive compounds can be searched and docked for particular bioactivity. Evaluation Challenging activity in animal &/or cell line is achieved.
g. ***Polymer Study*** [23-24]: Polymer evaluation for its properties related to safety, drug release, enteric coating ability, release control ability, penetration, conjugate/complex formation, polymer carrier/ substrate study, dissolution studies using the well-established drug molecule. Exploratory polymer study for parenteral and other pharmaceutical uses.
h. ***Ayurvedic And Herbal Formulation:*** Design and evaluation of Ayurvedic, herbal, polyherbal drug and cosmetics and its evaluation.
i. ***Molecular Level Mechanism*** [25]: Projects to know the changes in biomarker level in the biological system by administering designed herbal formulation, synthesized bioactive compound etc.
j. ***Homoeopathy*** [26 -27] : Formulation and evaluation of activity and molecular level mechanism.
k. ***Drug – Drug Interaction animal Study*** [28-29]: Interaction of herbal and synthetic drugs proposed for concurrent administration for the treatment or prevention of health complication and new analytical evaluation of the same.

l. ***Regulatory Compliance Projects*** [30- 31]: IVIVC study, tablet weight and surface area ratio for bio wavier, RFIDs in SODFs, etc.
m. ***Dietary supplements/ Probiotic*** [32-34]**:** Need based development of formulation and its evaluation.
n. ***Patentable Technology*** [35-36]: Patent in the formulation, herbal, polymer, NDDS, new technology in addition to the academic research projects.

6.0 Equipments, software and facilities available in the PA and QA department

a. Equipment available in the PA and QA Dept.

Table 2: List of equipments available in the PA and QA Dept.

Chromatography Instruments	Waters Binary Gradient HPLC system with PDA detector, Column Oven and Auto Sampler	
	Combiflash - Flash Chromatography	
Bio Analytical Sample Processing	Solid Phase Extraction Vacuum Manifold Nitrogen purging assembly and Nitrogen cylinder	
Spectroscopy Instruments	Double Beam UV-VIS Spectrophotometer- Varian -Cary -100	
	Double Beam UV-VIS Spectrophotometer with cell holders - Lab India	
	Fourier Transform Infrared Spectrophotometer (FTIR)	
Important analytic Instruments	Microprocessor based pH meter	Flame photometer
	Refractometer with temperature sensor	Polarimeter
	Microprocessor based conductivity meter	Flame photometer
Support Utilities and sample preparation and treatment equipment	All Glass Double Distillation Unit Capacity 2.5 Lit /hr	Vortes mixer
	All Glass single Distillation Unit Capacity 5 Lit /hr	UV Chamber
	Oil free vacuum pump	Centrifuge
	Magnetic stirrer	Cooling centrifuge
	Ultasonicator	
	Schimadzu AWD 220 Dual Range Electronic Balance	
Packaging Material Testing equipments	Ubique Tensile Strength Tester	Ubique Subastence Tester
	Ubique Bursting Strength Tester	Caton Drop Tester
	Ubique Puncture Resistance Tester	Ubique Cobb Tester

b. **Analytical Software**: 1. Chemometric

c. Equipments available for sharing from other section in the Institute

Table 3: QAT students have access to the following equipments and instruments in the Institute working on the relevant research projects

A. Formulation development and Processing related equipments	
Tablet and Capsule (EHG) Processing apparatus	**Testing and Evaluation Equipments**
Tablet Compression Machine- **Remake** Mini Press 8 station	Tablet dissolution tester model TDT-08L-Electrolab
Kalweka Main Drive Unit and following Attachment For :	Brookfield Viscometer
Dry granulator Powder mixer	Humidity Control Oven
Homogeniser Pelletizer	Sterility Testing Unit
Planetory mixer Wet granulator	Digital Colony counter
Pan coating machine	Antibiotic zone reader
Digital Tray Dryer	BOD incubator
Hand operated EHG capsule filling Machine	Tap/Bulk Density apparatus
Spray Dryer –Lab Ultima	Diffusion cell

B. Synthesis and molecular modeling, Docking related equipments, Soft wares, etc.		
QSAR Software	Scientific Microwave	Rotary Evaporator
High Precision Water Bath	Electrophoresis Unit	Vacuum Oven

C. Herbal Processing and activity Evaluation Facility and Equipments		
Clinical Chemistry Analyser - Model C61, Make- Bensepra		
Tail flick Analgesiometer	Open field Apparatus	Hot plate
Digital rotating drum	Persolt's Apparatus	Radial Maze
Electroconvulsiometer	Plethysmometer	Rota Rod
Elevated plus maze apparatus	Student's organ bath	Spirometer
Histamine chamber	Pole climbing model	Metabolic cages
Kymograph drum	Student physiograph	Actophotomete
Microtome machine	Morris water apparatus	Refrigerated centrifuge
Soxhlet apparatus	Clevenger apparatus	

Microtome for TS	Optic Digital Microscope with camera & PC
D. Cell Line Study	
Fluorescence microscope	Micro plate reader (96 well)

New arrivals for research and development activity in the institute

A. **Following equipments are in the process of procurement :**
   - Differential scanning calorimeter

B. **Facility under development:** Cell line testing facility

7.0 Certificate courses offered

Table 4: Institute level certificate courses offered by the QA Dept. in the institute:

Sr. No.	Certificate Course Title	Course Duration	Recommended to Students	Registration Period	Course type
1.	Hands on Analytical Instruments (**HAS**)	3 months (Sept. - Nov.)	Third & Final Year B. Pharm.	August	Teaching & practical
2.	Health Care Regulatory Affairs **(HCRA)**	1 year (August to July)	B. Pharm and M. Pharm.	August	Correspondence
3.	Pharmaceutical Validation **(PV)**	6 months (February to July)	All M. Pharm. (except QAT)	December	Correspondence/ teaching

8.0 Consultancy / Testing activities carried out in the department:

- HPLC Analytical method development and validation
- Impurity profiling and Stability indicating method development and validation
- Dissolution study projects
- Herbal formulation development
- Stability studies
- Conductometric and potentiometric measurements, refractive index determination, polaroimetric measurements.

9.0 Academic and sponsored/funded research projects in the dept.

Table 5: Competed funded and consultancy projects in the dept.

Sr. No.	Project title, Academic year and Principal investigator	Funding agency	Sanctioned Funds (Rs)
1.	Analytical method development, validation and stability indicating studies on finasteride and tamsulosin hydrochloride, 2008-10, Dr. V. P. Choudhari	BCUD	2,00,000/-
2.	Development and validation of analytical methods for antihypertensive drugs, 2009-12, Dr. B.S. Kuchekar	BCUD	3,00,000/-
3.	- Development and validation of stability indicating HPLC method and bioanalytical for some drugs, 2009-12, Prof. A. S. Sutar.	BCUD	2,00,000/-
4.	Analytical method development of some drugs. 2012-14, Prof. Y. A. Shete.	BCUD	2,00,000/-
5.	Development and validation of stability indicating HPLC method for API and formulations as per ICH guidelines, 2011-13, Dr. V. P. Choudhari	M/s Shivaji Scientific	20,000/-

Table 6: Ongoing Funded projects and consultancy projects undertaken in the dept.

Sr. No.	Project title, Academic year and Principal investigator	Funding agency	Sanctioned Funds (Rs)
1.	Stability indicating, impurity profile study of Pharmaceuticals and synthesis, isolation and characterisation of important related impurities", 2014-16, Prof. G. B. Choudhari	BCUD	1,60,000
2.	Fingerprint and stability method development for poyherbal formulation containing Piperine, Zingiberene, eugenol and gallic acid/embelin in single ayurvedic proprietary formulation. 2013-15, Dr. V. P. Choudhari	BCUD	2,30,000
3.	A study of hazardous chemicals in personal care (cosmetics) products, 2013-15, Prof A. S. Sutar.	BCUD	2,30,000
4.	Isolation and Characterization of impurities from tablet dosage form, 2013-15, Dr. B.S. Kuchekar	BCUD	1,90,000/-
5.	Herbal – Synthetic antidiabetic drug - drug interaction study, 2014-15 Dr. V. P. Choudhari	M/s Tate Remedies	50,000/-
6.	Development and validation of stability indicating HPLC method for API and formulations as per ICH guidelines Development and validation of impurity profiling HPLC method for API as per ICH guidelines 2014-16, Dr. V. P. Choudhari	M/s Shivaji Scientific	40,000/-

Table 7: Ongoing Academic Research projects in the PA & QA dept. during 2014-15

Sr. No.	Project title
1.	Preparation and characterization of ibuprofen cocrystals
2.	Chromatographic method development for polyherbal formulation containing piperine, zingiberene, eugenol and gallic acid in ayurvedic proprietary formulation.
3.	Development and validation of RP-HPLC method for ofloxacin, clotrimazole, beclomethasone dipropionate and lignocaine in combined dosage form by using DOE
4.	Design and evaluation of a novel drug delivery system for esomeprazole
5.	Spectroscopic studies of some drug molecules with aid of Chemometric.
6.	Development and validation of analytical method for prolonged release antidepressant drug in bulk and formulation
7.	Development and validation of RP-HPLC method for pyridoxine and folic acid in combined formulation and dissolution study.
8.	Synthesis of biodegradable polymeric nanoparticles with chlorhexidine for antimicrobial applications.
9.	Method development and validation for betamethasone valerate, miconazole nitrate and chlorocresol in cream and cleaning validation of chlorocresol by HPLC.
10.	Study of beta cyclodextrin complex and bio-polymer mediated drug release
11.	Study of inclusion complex of model drug with conducting polymers.
12.	Implimenting quality by design : A methodical approach in fabrication of dexamethasone immediate release tablet.
13.	Formulation and evaluation of thermoreversible in-situ nasal gel of timolol maleate
14.	Development and evaluation of self-micro-emulsifying floating drug delivery system for prochlorperazine maleate
15.	Chemometric assisted spectroscopic determination of some APIs in bulk and in formulation
16.	Development & validation of stability indicating RP-HPLC assay method for API

Table 8: Partial list of academic research projects completed in the department and in collaboration with industry since 2008.

Sr. No.	Research Project Title
1.	Development and validation of analytical methods for some drugs by chemometrics.
2.	Formulation development and evaluation of stable fixed dose combination
3.	Development and validation of RP - HPLC methods for antibiotic and SI - RP - HPLC method for NSAID combined drug formulations.
4.	Development, optimization & evaluation of norfloxacin emulgel for topical drug delivery.
5.	Layer by layer tempelating for drug release.
6.	Study of cyclodextrin drug complexation .
7.	Development and validation of analytical methods for simultaneous determination of salbustamol and ambroxol in pharmaceutical and bulk dosage form.
8.	Formulation development and evaluation of antihypertensive immediate release tablet.
9.	Development and validation of dissolution method for Albendazole tablets
10.	Analytical method development and method validation of antiretroviral drugs in combined tablet dosage form by RP - HPLC for Assay method.
11.	Synthesis and characterization of Bis {Quercetinato} decavanadium {V} conjugate and its evaluation for antidiabetic and antihyperlipidemic activity in wistar rat.
12.	Solubility enhancement of a poorly Aqueous soluble drug by usingmicrowave technique
13.	Development and validation of dissolution method for mebendazole tablets.
14.	Method development and validation of HPLC Assay and dissolution methods for antigout drug.
15.	Development and Validation of Analytical Methods for Simultaneous Estimation of Sildenafil Citrate and Dapoxetine Hydrochloride in Combined Dosage form, collaborative project at Gen Paharma International Pvt. Ltd., Bhosari, Pune
16.	Analytical method development validation for 1) Estimation of unknown impurities in Atorvastatin ezetimibe tablet formulation. 2) Metformin Hcl-Glicazide tablet by HPLC & stability study of simvastatin collaborative project at Manisha Analytical Labortories, Mumbai.
17.	Optimization study of degree of actvation of meningococcal serogroup c polysaccharide for men c l conjugate vaccine, collaborative project at Serum Institute of India, Hadapsar, Pune
18.	Development & validation of stability indicating RP-HPLC methods for estimation of dicyclomine hydrochloride and mefenamic acid in tablet dosage form and application for formulation stability study, collaborative project at Plethico, Indore
19.	Development & validation of analytical methods for estimation of Eszopiclone and its related substances in bulk and HPLC, collaborative project at Sun Pharmaceutical , Ahmednagar
20.	Development and validation of analytical methods for simultaneous estimation of tapentalol dosage form, collaborative project at Wanbury Pharmaceuticals, Mumbai
21.	Development & validation of analytical methods for simultaneous estimation of Lafutidine & Domperidone in tablet dosage form collaborative project at Emcure Pharmaceuticals, Pune.
22.	Isolation of impurities from Digoxin, collaborative project at Natioanl Chemical Laboratory, Pune
23.	A Novel method for the synthesis of Losartan Potassium using [2'(N-trityltetrazol-5-yl)biphenyl-4-yl]methylbromide (TTBB), a key intermediate used for the synthesis of Angiotensin Receptor Blockers collaborative project at Unichem Lab. Ltd., Mumbai
24.	Development & validation of analytical methods for simultaneous estimation of

	cardiovascular pharmaceuticals collaborative project at Lupin Ltd., Aurangabad.
25.	Development & validation of analytical methods for simultaneous estimation of olmesartan medoximil and metoprolol succinate incombined dosage form, collaborative project at Cadial Pharama, Ahmedabad
26.	Impurity profiling of Diclofenac sodium in tablet dosage form, collaborative project at Abbot, Mumbai
27.	Analytical method development and validation of single component tablet by using RP-HPLC for dissolution and related substances, collaborative project at Macleods Pharmaceuticals, Mumbai
28.	Formulation and evaluation of solid Lipid Nanoparticles Betamethasone dipropionate for skin targeting collaborative project at CEMET, DIT, GOT of India, Pune
29.	A Quality by design (QBD) approach : Product knowledge and process understanding for immediate release dosage form of antiemetic agents collaborative project at Lupin Resarch Park, Pune
30.	Solubility enhancement and formulation of Buccal patches of Ramipril
31.	Analytical method development and validation of rasagiline mesylate by HPLC and GC, collaborative project at Macleods Pharmaceuticals, Mumbai
32.	Development of insitu gel for magnolol loaded poly(lactide co- glycoside, PLGA) nanoparticles, collaborative project at Natioanl Chemical Laboratory, Pune
33.	Design, Development and evaluation of taste masked rapid disintegrating tablet collaborative project at Emcure Pharmaceuticals, Pune.
34.	Ant diabetic Immediate release tablet: Pharmaceutical Quality by design approach collaborative project at Lupin Resarch Park, Pune
35.	Formulation and Development of Immediate Release tablet of an Antihypertensive drug collaborative project at Cadilapharamceuticals, Ahmedabad
36.	Application Of Design Of Experiments For Optimizing Aqueous Film Coating Process For Ciprofloxacin HCL Tablets, collaborative project at GlaxoSmithKline, Nashik
37.	Development And Validation Of UV And HPLC Methods For Anti-Asthamatic And Anti-Histaminic Drugs In Pharmaceutical Formulation, collaborative project at Glenmark Pharmaceuticals, Sinner, Nashik
38.	Formulation development and evaluation of polyblend thermo sensitive nanofibres for wound healing application, collaborative project at Natioanl Chemical Laboratory, Pune
39.	Development of Analytical Method for Milnacipran & its related substances by HPLC, collaborative project at Glenmark Research Centre, Mumbai
40.	Development & validation Of Analytical Method for Simultaneous estimation of GABA Antagonist & Antihistaminic drugs in Pharmaceutical Dosage Form, collaborative project at Pfizer Pharmaceutical, Mumbai.
41.	Development and evaluation of time based rupturable pulsatile drug delivery system of montelukast sodium, collaborative project at Elder, Mumbai
42.	Formulation and Development of Osmotic drug delivery system of theophylline, collaborative project at JPCL, Jalgaon
43.	Formulation development & analysis of topical dosage form for halobetasol propionate and fusidic acid, collaborative project at Glenmerk, Nashik
44.	Formulation, Development and Evaluation of Floating Pulsatile drug delivery system of Atenolol, collaborative project at JPCL, Jalgaon.
45.	Pharmaceutical Development and Evaluation of Parenteral Lyophilized Formulation collaborative project at Emcure Pharmaceuticals, Pune.
46.	Effect of binders in the development of gabapentin tablet and it's evaluation, collaborative

	project at Alkem laboratories Ltd., Mumbai.
47.	Formulation and Evaluation of Floating Drug Delivery system of Propranolol Hydrochloride, collaborative project at Nulife Pharmaceuticals, Pune
48.	Analytical Method Development ,validation and stability indicating studies on Dutasteride and Tamsulosin Hydrochloride in pharmaceutical dosage forms, collaborative project at NAFARI, Pune
49.	HPLC method development & validation for paracetamol, domperidone in combination in tablet dosage form collaborative project at Wockhrdt Pharmaceuticals Aurangabad
50.	Effect of Superdisintegrants on various Drugs, Nicholas, Mumbai
51.	Formulation Development and Evaluation of orodispersible tablets of mosapride Citrate Dihydrate, collaborative project at Concept Pharmaceuticals, Aurangabad
52.	Analytical Method Development ,validation and stability indicating studies on Finasteride and Tamsulosin Hydrochloride in pharmaceutical dosage forms
53.	Six Sigma of Pharmaceutical dosage form tablet includes process understanding control capability Measurement system Analysis change in coating reconstitution level, collaborative project at GlaxoSmithKline, Nashik
54.	Development of methodology for analysis of triphala and is constituents by integrating TLC, IR and HPTLC techniques, Highteck Laboratory, Pune
55.	HPCL method development for some hypertensive drugs, collaborative project at NARI, Pune
56.	Stabilization & Evaluation of a Glucocorticoid Steroidal solution and formulation of its dispersible tablet, collaborative project at Nicholas, Mumbai
57.	Process Validation of Proton Pump Inhibitor Drug 'A' Delayed Release Capsule (Pellets)
58.	Design, Development and Evaluation of 6-Mercaptopurine Tablet for Colon Targeting.
59.	Development of Pluronic Lecithin Oganogel for Transdermal Delivery of Tapentadol
60.	Design, Development and Evaluation of Matrix type Transdermal patch of Pravastain Sodium.
61.	Press coated technology based floating Pulsatile drug delivery of sumatriptan Succinate
62.	Development and Evaluation of Pulsatile Drug Delivery System of rizatriptan Benzoate
63.	Formulation and Evaluation of Mouth Dissolving Tablet of Atenolol and chlorthalidone.
64.	Design and Evaluation studies on Floating tablet of troxipide for the Treatment of H. Pylori infection.
65.	Assay method development and validation of an antipsychotic drug by RP-HPLC
66.	Formulation development and in-vitro evaluation of generic quetiapine fumarate ER tablets 200 mg and 50 mg.
67.	Preparation, evaluation and in-vitro characterisation of isoniazid loaded polyethylene glycol(PEG)- poly caprolactone(PCL) copolymer nanoparticles and formulation as dry powder inhalation.
68.	Preparation, evaluation and in-vitro charecterization of calcium alginate beads
69.	Design , development and evaluation of oral strip of eletriptan HBr
70.	Solubility enhancement of dronedarone by solid dispersion techniques
71.	Formulation and development of immediatef release tablet of anti-diarrhael drug by solubility enhancement
72.	Formulation, evaluation of bilayer tablet for binary drug combination
73.	Formulation, development and evaluation of er pellets in capsules containing

	antimuscarinic agent
74.	Formulation And evaluation of mometasone furoate hydrotropic gel
75.	Application of surface response methodology for separation of anti cold drug combination by HPLC
76.	Application of surface response methodology for separation of anti hypertensive drug combination by HPLC.
77.	Application of surface response methodology for separation of preservatives in cosmetic drug preparations HPLC
78.	Impurity profiling of Lornoxicam by LC-MS and MALDI TOF, collaborative project at NCL, Pune.
79.	Method development and validation of stroncium ranilate and related substance, collaborative project at Glenmerck , Mumbai
80.	Formulation development and evaluation of topical drug delivery for halobetasol propionate and fusidic acid.
81.	Solid state characterization dissolution profile of inclusion complexes of nifedipine with cyclodextrins and formulation of fast dissolving tablet.
82.	Development and validation of analytical methods for simultaneous estimation of drota verine combinations in pharmaceutical formulations and LC – SIAM Study
83.	Formulation and evaluation of gastro retentive drug delivery system of tramadol hydrochloride using response surface methodology
84.	Solid state characterization dissolution profile of inclusion complexes of nifedipine with cyclodextrins and formulation of fast dissolving tablet.
85.	Preparation, physicochemical characterization & evaluation of mouth dissolving tablet of clonazepam solid dispersion
86.	Improvement of dissolution rate of chlrzoxazone by solid dispersion technique and development of buccal patch.
87.	Solubility enhancement of darifenacin using cyclodextrin and formulation of buccal drug delivery system.
88.	In - situ inclusion complexation of nebivolol hydrochloride with cyclodextrins and its host guest physicochemical characterization
89.	Development and validation of analytical methods for simultaneous estimation of gaba antagonist ant antihistaminic drugs in pharmaceutical dosage forms.
90.	Development and validation of computer system and UV Spectrophotometric baseline manipulation method.
91.	Optimization study of degree of activation of meningococcal serogroup 'C' polysaccharide for men c conjugate vaccine.
92.	Isolation of impurity from digoxin by HPLC Method
93.	A Quality by design {QBD} approach : product knowledge & process understanding for immediate release dosage form of antiemetic agent.
94.	Design, development and evaluation of taste masked rapid disintegrating tablet.
95.	Design and development of immediate release tablet of an anti - diarrheal drug
96.	Solubility enhancement of dronedarone HCL by solid dispersion techniques.
97.	Press coated technology based floating pulsatile drug delivery of sumatriptan succinate
98.	Development and evaluation of pulsatile drug delivery system of rizatriptan benzoate.
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