

# Pharmacy Practice Communicator



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# MEDICATION RECONCILIATION A VITAL ACTIVITY IN PHARMACEUTICAL CARE

Mr. Bejoy Thomas\*

## Introduction

Medication reconciliation is a formal process for creating the most complete and accurate list possible of a patient's current medications and comparing the list to those in the patient record or medication orders according to the Joint Commission International.<sup>[1]</sup>

It includes the process of comparing a patient's medication orders to all the medications that the patient has been taking with the objective to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. It should be done at every transition of care in which new medications are ordered or existing orders are rewritten. Transitions in care include changes in setting, service, practitioner, or level of care. Points of transition that require special attention are:<sup>[2]</sup>

- Admission to hospital
- Transfer from the Emergency Department to other care areas (wards, Intensive Care, or home)
- Transfer from the Intensive Care Unit to the ward
- From the hospital to home, residential aged care facilities or to another hospital.

And it includes the following steps <sup>[3,4,5]</sup>:

1. Develop a list of current medications from Best Medication History possible (BMHP) which includes the OTC drugs, nutritional supplements, herbal medicines etc
2. Develop a list of drugs to be prescribed and compare the medications with the above mentioned list.
3. The discrepancy in the list should be resolved after discussions with the various stake holders (the prescriber, nurse, pharmacist and other health care professionals)

This reconciliation is a continuous process and should be in continuum at all transitions of care by restarting, continuing, discontinuing or modifying of the medications so the patients receive only appropriate medications. At the time of discharge, the reconciliation should be done for the medications that the patients were taking prior to the admission and those initiated at the hospital to those with the discharge medications. This also includes the development of a Best Possible Medication Discharge Plan (BPMDP). After the development of BPMDP, the same should be communicated to the community pharmacist, primary care physician and the patient.

## Medication Reconciliation: an accreditation requirement

Medication reconciliation was recognized as a vital activity in pharmaceutical care in 2005, The Joint Commission on Accreditation of Healthcare Organizations, currently known as The Joint Commission International, designated it National Patient Safety Goal (NPSG) under the chapter Management of Medication and Use (MMU). They subsequently revised its requirements for medication reconciliation under NPSG 03.06.01, which became effective from July 1, 2011.<sup>[6]</sup> Later, with the implementation of the 4th edition of National Accreditation Board for Hospitals (NABH), which became effective from July, 2016, medication reconciliation is a mandatory activity to be ensured under the chapter of Management of Medication (MOM).<sup>[7]</sup>

As with all activities of pharmaceutical care and as required by the regulations for the accreditation by the national and international bodies, medication reconciliation aims in the effective and rational use of medications while at the same time preventing or minimizing the medication related problems.

### **Medication Reconciliation: Indian Scenario**

With more and more health care organizations signing up for the accreditation process with JCI and/or NABH, it is becoming a cardinal activity expected to be performed by the clinical pharmacist. It would be highly recommended that such skill sets are acquired by the aspiring clinical pharmacist, which will make them more employable.

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# ROLE OF PHARMACIST IN RATIONAL USE OF DRUGS

Dr. Chinju Susan Chacko\*

It has been estimated that more than half of the medicines used worldwide are prescribed, dispensed or sold inappropriately and that more than half of the patients do not take their medication as prescribed by the doctor.<sup>[1]</sup> The irrational use of drugs is a serious phenomenon and needs to be taken a serious note. Rational use of medicine has been defined by the World Health Organization (WHO) as “patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at lowest cost to them and their community”. In other words we describe rational drug use as “prescribing right drug in adequate dose for the sufficient duration appropriate to the patient, at lowest cost”.<sup>[2]</sup> The common type of irrational drug use occurs when there is polypharmacy, inappropriate use of antibiotics often in inadequate dosage or the use of antibiotics for non-bacterial infections like viral infections, over use of injections when the oral route would be more appropriate, inappropriate self-medication, failure to prescribe in accordance with clinical guidelines. The causative reasons for irrational drug use are lack of knowledge, influenced by others, negative attitudes, own prescriptions, difficult or complicated regimens.<sup>[1]</sup> As we know, medicines are foreign substance to human body and if not used with utmost care they can harm our normal physiological system. The potential hazards that occur due to irrational drug prescribing are wastage of health and economy resources, inappropriate patient demand, serious adverse drug reactions, increased antibacterial resistance, increased drug related morbidity and mortality.<sup>[3]</sup>

Promoting the rational use of medicines will result in improved quality and increased accessibility of drugs leading to better quality of life. A pharmacist is one of the inevitable members of healthcare team who can help in achieving the goal of rational use of drugs by following good pharmacy benefit-risk of drug use. The pre-requisites of rational drug use which include critical assessment and evaluation of benefit-risk of drug use and comparing the advantages, disadvantages, safety & cost of the new drug with an existing drug for the same indication. In the health care profession physicians and pharmacists can play a key role in promoting the rational use of drugs. For promoting the rational drug use objective information and continuing educational training in pharmacology must be available along with well organized drug regulatory authority and supply of drugs.<sup>[2]</sup>

To assess drug use problems in a health care facility, WHO defines certain core drug indicators into three types: a) Patient indicators which include average consultation time, average dispensing time, percentage of drugs actually dispensed and percentage of drugs adequately labelled and patient knowledge of correct dosage; b) Facility indicators: availability of copy of essential drug lists or formulary and the availability of key drugs; and c) Prescribing indicators: average number of drugs per prescription, percentage of drugs prescribed by generic name, percentage of drugs with antibiotic prescribed and percentage of drugs with injections. The pharmacist can use these indicators to check the rationality of the prescription. It is essential for pharmacist to evaluate the completeness of the issued prescriptions to assess patient care and eliminate some aspects of irrational use of medicines. An ideal prescription should have all necessary information including; 1) patient information i.e. name of the patient, age, sex, weight and contact information; 2) pharmaceutical product information i.e. name, strength, dose, frequency of administration, duration and number of refills if needed; 3) Prescriber information; name, address, signature, contact information, specialty and medical license number.<sup>[3]</sup>

## Role of Pharmacist in Rational Drug Use

Pharmacist can play a lead role in rational drug use since they have great knowledge about all types of drugs and the amount to be taken and the reason why they are given. The pharmacist is now no longer a supplier of medicines but also a coordinator between different members of healthcare team and the patients. Pharmacists help in achieving the goal of rational use of drugs by following good pharmacy practice. By promoting the rational drug use and counselling about medications, pharmacist improve the quality of life. Pharmacists have more opportunity to interact closely with the prescriber and therefore, to promote the rational prescribing and use of drugs. Clinical Pharmacist are in a better position to educate other health professionals about the rational use of drugs. By having access to medical records, the pharmacist is in a position to influence the selection of drugs, dosage regimens, to monitor patient compliance and therapeutic response of drugs and to recognize and report adverse drug reactions there. Pharmacist can control hospital manufacture and procurement of drugs to ensure the supply of high quality products. Pharmacist can play a multidisciplinary approach for the promotion of rational drug use by providing proper information and instruction regarding the ADRs, dosage schedule of drugs to patients and warning them about the unwanted effects of medicine and monitoring the ill effects. In collaboration with other healthcare professionals pharmacist can educate the patients about the potential hazards of self-medication and complications of over usage of medications. [2, 4]

To promote the rational use of medications, pharmacists can implement different programs with the involvement of academia, regulatory authorities and other organisations working to address the existing problem of irrational use of medicines. Rational use of drugs is an important tool in the safe and effective treatment of patients. In coordination with healthcare team, pharmacists can establish a common approach to the rational use of drugs by giving advice and information to patient regarding the proper use of drugs. This may help to reduce the irrational drug use which leads us to a better quality of life.

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# BEDAQUILINE FOR THE TREATMENT OF MULTI DRUG RESISTANT TUBERCULOSIS

Dr. Vinay BC\*

Bedaquiline Fumarate drug has shown ability in treating patients that are infected with *Mycobacterium tuberculosis* especially for the drug-resistant tuberculosis (TB) variety.

**Mechanism of Action:** Bedaquiline, a diarylquinoline, inhibits mycobacterial ATP synthase which is an enzyme required for the generation of energy in *Mycobacterium tuberculosis*.

## Spectrum of Activity

Bedaquiline has demonstrated activity against most *Mycobacterium tuberculosis* isolates. It is however not effective in extra-pulmonary TB (e.g., CNS) or for latent TB infections.

## Indications and Dosage:

### Multidrug resistant tuberculosis, in combination with at least 3 other agents

**Usual dosage:** Initial, 400 mg orally once daily for 2 weeks, then 200 mg orally 3 times weekly (at least 48 hours gap doses) for 22 weeks. Give all doses with food under direct observation; tablets should be swallowed whole.

## Administration

Oral route

Administer Bedaquiline fumarate by direct observation therapy and in combination with at least 3 other effective agents. Take the tablet with food and swallow whole with a glass of water.

**Missed dose:** If a dose is missed during the initial 2 weeks of treatment, do not administer the missed dose (skip that dose and then resume the daily dosing regimen). If a dose is missed from week 3 onwards, administer the missed dose as soon as possible and resume the 3 times per week dosing regimen.

## Pharmacokinetics:

**Absorption:** Tmax, Oral: 5 hours, Effects of food: bioavailability increased by 2-fold.

**Distribution:** Protein binding: greater than 99.9%, Vd: 164 L

**Metabolism:** Hepatic

**Excretion:** Fecal: extensive, Renal: less than 0.001%, Renal clearance: insignificant, Dialyzable: No (hemodialysis); No (peritoneal dialysis)

**Elimination Half Life:** 5.5 months

## Dosage in Renal Failure:

- Mild to moderate impairment: No adjustment necessary.
- Severe impairment or ESRD requiring hemodialysis or peritoneal dialysis: Use with caution.

## Dosage in Hepatic Insufficiency:

- Mild to moderate impairment: No adjustment necessary.
- New or worsening liver function (aminotransferase and total bilirubin greater than 2 times ULN, elevations greater than 8 times ULN, elevations greater than 5 times ULN and persist for longer than 2 weeks): Discontinue therapy.
- Severe impairment: Use not recommended unless benefit outweighs risk.

### **Paediatric Dosing:**

- Safety and efficacy not established in paediatric patients

### **Contraindications**

- Specific contraindications have not been determined.

### **Adverse Effects:**

Cardiovascular Effects: Chest pain, Prolonged QT interval.

Dermatologic Effects: Rash

Gastrointestinal Effects: Loss of appetite, Nausea, Serum amylase raised

Hepatic Effects: Increased liver enzymes

Musculoskeletal Effects: Arthralgia

Neurologic Effects: Headache

Respiratory Effects: Hemoptysis

### **Monitoring**

#### 1) Therapeutic

##### a) Laboratory Parameters

- 1) Obtain sputum for mycobacterial culture and susceptibility testing prior to the initiation of therapy as well as during treatment to monitor therapeutic response.

#### 2) Toxic

##### a) Laboratory Parameters

- 1) Measure serum calcium, magnesium, and potassium at baseline.
- 2) Monitor liver function tests (ALT, AST, alkaline phosphatase, and bilirubin) at baseline and monthly during treatment, and as needed.

##### b) Physical Findings

- 1) Obtain ECGs before initiation, and at least 2, 12, and 24 weeks after initiation of treatment. Monitor ECGs more closely in patients at risk for QT prolongation.
- 2) Monitor symptoms of liver dysfunction (e.g., fatigue, jaundice, liver tenderness, and hepatomegaly) at baseline and monthly during treatment, and as needed.

### **Black Box Warning:**

Only use bedaquiline when effective treatment regimen cannot be provided due to an increased risk of unexplained death in bedaquiline treated patients when compared with placebo in a controlled trial. QT prolongation has been reported with concomitant use of other QT-prolonging drugs, in patients with low serum calcium, magnesium or potassium levels.

### **Information on Bedaquiline for Patients:**

#### **How do you take bedaquiline?**

- It is in the form of a tablet and is easy to swallow.
- You will receive bedaquiline for 24 weeks (6 months) for treatment of MDR-TB.

### **What are the most common side effects?**

- Headache, common cold and sore throat, feeling an irregular, fast or slow heartbeat, heart rhythm may change, dizziness, fainting, light-headedness, nausea, vomiting.

### **Benefits:**

- There is a greater chance that you will be cured of tuberculosis.
- You will possibly become better very much sooner than if you only took the standard medicines for treatment of resistant TB.
- Also, it is probably less likely that the drugs you are taking will develop resistance if you are taking bedaquiline.

### **What do I do when I have problems?**

- You should tell your health-care provider immediately about any side-effect that you experience while taking bedaquiline.

### **What do women need to know?**

- All women must avoid getting pregnant while taking bedaquiline.

### **What do I do in case of pregnancy during treatment?**

- Inform the health care provider immediately.
- After evaluation in consultation with Obstetrician/ gynaecologist you may be required to either terminate the pregnancy, get modified regimen with bedaquiline. You and the baby both may be evaluated for longer duration post treatment.

### **What do men need to know?**

- All men should avoid fathering a child while on treatment with bedaquiline.

### **What should I avoid while taking bedaquiline?**

- You should not drink alcohol while taking bedaquiline.
- There are some medications that cannot be taken safely with bedaquiline.
- Make sure to inform your doctor if you are taking medicines or if medicines are recommended to you by health-care practitioner for some other illness while you are on treatment for TB with bedaquiline.
- If you do not know the medicines please ensure that you show the prescriptions to the TB doctor.

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# NEW DRUGS APPROVED BY USA FOOD AND DRUG ADMINISTRATION (FDA) (JULY – SEPTEMBER 2017)

Ms. Reshma Elsa R Tom\*

Specialty	Drug Name	Brand Name	Company Name	Uses	Approved (Month, Year)
<b>Dermatology</b>	Guselkumab	Tremfya	Janssen Biotech	Treatment of moderate-to-severe plaque psoriasis	July 2017
<b>Hematology</b>	Copanlisib	Aliqopa	Bayer	Treatment of follicular lymphoma	September 2017
<b>Neurology</b>	Inotuzumab ozogamicin	Besponsa	Pfizer	Treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia	August 2017
	Enasidenib	IDHIFA	Celgene	Treatment of relapsed or refractory acute myeloid leukemia with IDH2 mutation	August 2017
	Tisagenlecleucel	Kymriah	Novartis	Treatment of refractory B-cell precursor acute lymphoblastic leukemia	August 2017
	Daunorubicin and cytarabine	Vyxeos	Jazz Pharma	Treatment of newly-diagnosed therapy-related AML or AML with myelodysplasia-related changes	August 2017
	L-glutamine oral powder	Endari	Emmaus Life Sciences	Treatment of sickle cell disease	July 2017
<b>Neurology</b>	Amantadine	Gocovri	Adamas Pharmaceuticals	Treatment of Parkinson's disease dyskinesia	August 2017
<b>Oncology</b>	Neratinib	Nerlynx	Puma Biotech	Treatment of HER2 breast cancer	July 2017
<b>Immunology</b>	Tocilizumab	Actemra	Genentech	Treatment of CAR T cell-induced severe or life-threatening cytokine release syndrome	September 2017
<b>Infections and Infectious Diseases</b>	Secnidazole	Solosec	Symbiomix Therapeutics	Treatment of bacterial vaginosis	September 2017
	Benznidazole	Benznidazole	Chemo Group	Treatment of Chagas disease	August 2017
	Rabies Immune Globulin (Human)	KedRab	Kedrion Biopharma	For the post-exposure prophylaxis of rabies infection	August 2017
	Meropenem and vaborbactam	Vabomere	The Medicines Company	Treatment of complicated urinary tract infections	August 2017
<b>Obstetrics/ Gynecology</b>	Abemaciclib	Verzenio	Eli Lilly	Treatment of HR+, HER2-breast cancer	September 2017

<b>Hepatology</b>	Glecaprevir and pibrentasvir	Mavyret	AbbVie	Treatment of chronic HCV genotype 1, 2, 3, 4, 5 or 6	August 2017
	Sofosbuvir, velpatasvir, and voxilaprevir	Vosevi	Gilead	Treatment of hepatitis C	July 2017
<b>Internal Medicine</b>	Lesinurad and allopurinol	Duzallo	Ardea Biosciences	Treatment of hyperuricemia associated with gout	August 2017

Reference: <http://www.centerwatch.com/drug-information/fda-approved-drugs/>. (Last accessed on 01 Oct, 2017)

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## NEW DRUGS APPROVED BY CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO), India (JULY – SEPTEMBER 2017)

Mr. Shabeer Ahammed\*

Drug Name	Strength	Indication	Date of issue
Prucalopride (Prucalopride Succinate)	1mg/2mg Tablet	Treatment of chronic idiopathic constipation in adults in whom laxatives fail to provide adequate relief	13 <sup>th</sup> April 2017
Pomalidomide	1mg/2mg/3mg/4mg Capsules	In combination with dexamethasone, for patient with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.	01 <sup>st</sup> May 2017
Sofosbuvir	400 mg +Velpatasvir 100 mg Tablet & Bulk	Treatment of adult patients with -chronic Hepatitis C virus, Genotype 1,2,3,4,5 or 6 infection.-Without cirrhosis or with compensated cirrhosis-With decompensated with chronic for use in combination with Ribavirin	04 <sup>th</sup> May 2017
Osimertinib (Osimertinib Mesylate)	40 mg/80 mg Film coated Tablets	Treatment of patient with metastatic epidermal growth factor receptor (EGFR) T790 M mutation-positive non-small cell lung cancer (NSCLC), as detected by an appropriate test, whose disease has progressed on or after EGFR TKI therapy.	29 <sup>th</sup> May 2017
Argatroban Hydrate	Injection 250 mg/2.5 ml	For prophylaxis or treatment of thrombosis in adult patients with Heparin induced thrombocytopenia (HIT). As an anticoagulant in adults patients with or at risk for heparin-induced thrombocytopenia undergoing percutaneous coronary intervention (PCI)	30 <sup>th</sup> May 2017

Reference: <http://www.cdsc0.nic.in/forms/list.aspx?lid=2034&ld=11>. (Last accessed on 1 Oct, 2017)

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## DEPARTMENT OF PHARMACY PRACTICE NEWS

### World Pharmacists Day Celebration

“From Research to Healthcare: Your Pharmacist is at Your Service” the theme for this year’s **World Pharmacists Day**, emphasizes the growing need for assistance by pharmacists sought by the health care delivery system indicating that the pharmacists role is complementary to the medical profession and not in competition. To drive home this message to the public, a rally was organized by NGSMIPS, Deralakatte, Mangaluru on 25 September, 2017. Over 700 students participated in the rally which was flagged off by the principal Dr. C.S. Shastry.



Presiding the function, Dr. Ramanand Shetty, Vice Chancellor, Nitte University informed the students that there is a huge scope for research in the field of pharmaceutical science and advised the students to develop a keen interest to pursue the field of research targeted towards wellness of the society. Dr. C.S. Shastry, Principal, NGSMIPS briefed the significance of the Pharmacist Day. Shri Ramakanth Kunte, Asst. Drugs Controller I, Mangalore and Shri Shankara Naik, Asst. Drugs Controller II, Mangalore, Major (Dr.) Shivakumar Hiremath, Medical Superintendent, K.S. Hegde Hospital were the Guests of Honour. Shri Kunte and Shri Naik gave an account of the functioning of drug administration and the steps taken by the government to eradicate the spurious drugs from the market. Eminent pharmacists Shri. Manohar S. Shetty, CMD Sai Radha Groups and Shri. Panduranga Rao, Senior Pharmacist, Mangaluru were felicitated on this occasion for their exemplary social and professional contribution made by them. Dr. R. Narayana Charyulu, Vice Principal, NGSMIPS, proposed the vote of thanks.



Shri Kunte and Shri Naik gave an account of the functioning of drug administration and the steps taken by the government to eradicate the spurious drugs from the market. Eminent pharmacists Shri. Manohar S. Shetty, CMD Sai Radha Groups and Shri. Panduranga Rao, Senior Pharmacist, Mangaluru were felicitated on this occasion for their exemplary social and professional contribution made by them. Dr. R. Narayana Charyulu, Vice Principal, NGSMIPS, proposed the vote of thanks.

### What's New?

The Dept. of Pharmacy Practice, NGSMIPS has initiated a new learning program for updating the students as well as the faculty members regarding the current activities such as ADR monitoring, drug interactions, new interventions and new drug updates. This learning program will be updated once in a month.



### Invited Speaker at National Conferences

**Dr. Uday Venkat Mateti**, Asst. Professor & HOD, Dept. of Pharmacy Practice, NGSMIPS, Nitte University delivered a talk on “**Patient Reported Outcomes**” as Speaker at the “**1<sup>st</sup> Health Net India Meet**” held from September 2-3, 2017, Bengaluru, Karnataka, organized by ISPOR India Andhra Pradesh, ISPOR India Karnataka, ACPI-KSPOR and ANN Pharmicare.

**Dr. Uday Venkat Mateti**, Asst. Professor & HOD, Dept. of Pharmacy Practice, NGSMIPS, Nitte University delivered a talk on “**Role of Clinical Pharmacist in Evidence Based Practice**” as Speaker at the DST Sponsored Two Days National Seminar on “**Recent Advances In Pharmacovigilance and Pharmacoepidemiology in India (RAPPI-2017)**” held from September 11-12, 2017, organized by Vaageswari College of Pharmacy (WN), Karimnagar, Telangana Sate.

# NGSM Institute of Pharmaceutical Sciences



## Nitte Institutions

### Health Science Institutions, Hospitals and Research Centres

1. K.S. Hegde Medical Academy, Mangaluru
2. A.B. Shetty Memorial Institute of Dental Sciences, Mangaluru
3. Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, Mangaluru
4. Nitte Usha Institute of Nursing Sciences, Mangaluru
5. Nitte Institute of Physiotherapy, Mangaluru
6. Nitte Institute of Medical Laboratory Sciences, Mangaluru
7. Nitte Institute of Speech and Hearing, Mangaluru
8. Justice K. S. Hegde Charitable Hospital, Mangaluru
9. Nitte Meenakshi Institute of Craniofacial Surgery, Mangaluru
10. Leela Narayana Shetty Memorial Cancer Institute, Mangaluru
11. Nitte-Gajria Hospital, Karkala
12. Kshema-IVF: Fertility & Reproductive Medicine Centre, Mangaluru
13. Nitte Rural Psychiatry Centre, Nitte.
14. Kowdoor Gopal Hegde & Smt. Manorama Hegde Hospital, Bailur.
15. Nitte University Centre for Science Education & Research (NUCSER), Mangaluru
16. Nitte University Centre for Animal Research & Experimentation (NUCARE), Mangaluru
17. Nitte University Centre for Stemcell Research & Regenerative Medicine (NUCSReM), Mangaluru

### Engineering Institutions

18. Nitte Mahalinga Adyanthaya Memorial Institute of Technology, Nitte
19. Nitte Meenakshi Institute of Technology, Bengaluru
20. Nitte Institute of Architecture, Mangaluru

### Management Institutions

21. Justice K. S. Hegde Institute of Management (Dept. of Management Studies, NMAMIT, Nitte), Nitte
22. Nitte School of Management, Bengaluru
23. Sarosh Institute of Hotel Administration, Mangaluru
24. Nitte Institute of Banking & Finance, Mangaluru
25. Nitte Institute Communication, Mangaluru

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### Schools

33. Dr. Nitte Shankara Adyanthaya Memorial Senior Secondary School, Nitte
34. Dr. Mundkur Ramanna Shetty Memorial English Medium High School, Thokur
35. Nitte International School, Bengaluru
36. Dr. Nitte Shankara Adyanthaya Memorial Higher Primary School, Bolakodi

### Satellite Health Centres:

Bailur | Bellikoth | Bengre | Dabbekatte | Farangipet | Hejamadikodi | Kadri  
| Karkala | Mangalagangothri | Madikeri | Mukka | Mulki | Mundkur | Nada  
| Nitte | Sasihithlu | Sringeri | Subrahmanya | Thalipadi