For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Rx Cilnidipine & Telmisartan Tablets
CILACAR® T

COMPOSITION
Each film coated tablet contains:
Cilnidipine IP.....10 mg
Telmisartan IP.....40 mg
Colour: Titanium Dioxide IP

DOSAGE FORM
Film Coated Tablet

INDICATIONS
Treatment of essential hypertension in adults.
Cilacar T is indicated in adults whose Blood Pressure (BP) is not adequately controlled on Cilnidipine or Telmisartan monotherapy.

DOSAGE AND METHOD OF ADMINISTRATION
The recommended adult oral dosage of Cilacar T is one tablet per day.
Cilacar T 40 may be administered in patients whose Blood Pressure (BP) is not adequately controlled with Cilnidipine 10 mg or Telmisartan 40 mg alone.
Cilacar T 80 may be administered in patients whose Blood Pressure (BP) is not adequately controlled with Cilnidipine 10 mg or Telmisartan 80 mg alone.
Cilacar T tablets are for once-daily oral administration and should be taken with liquid, with or without food.

USE IN SPECIAL POPULATIONS
Pregnancy and Lactation
The FDC of Cilacar T should not be initiated during pregnancy and lactation.
Cilnidipine:
There are no human clinical or animal data concerning the safety of Cilnidipine during pregnancy. Until data are available, administration of Cilnidipine during pregnancy should be avoided.
Nursing mothers should consult a physician before taking Cilnidipine.
Telmisartan:
The use of angiotensin II receptor antagonists is not recommended during the first trimester of pregnancy. The use of angiotensin II receptor antagonists is contraindicated during the second and third trimesters of pregnancy. There are no adequate data from the use of Telmisartan in pregnant women. Studies in animals have shown reproductive toxicity.
Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk with angiotensin II receptor antagonists, similar risks may exist for this class of drugs. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.
Exposure to angiotensin II receptor antagonist therapy during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia).
Should exposure to angiotensin II receptor antagonists have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended.
Infants whose mothers have taken angiotensin II receptor antagonists should be closely observed for hypotension.
Because no information is available regarding the use of Telmisartan during breast-feeding, Telmisartan is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.
Renal impairment-
Cilnidipine:
Dose adjustment is not needed in patients with impaired renal function. Cilnidipine at a dose of 10 mg once a day for 7 days in patients with impaired renal function caused no differences in the pharmacokinetic profile compared with that in patients with normal renal function.
Telmisartan:
Patients with renal impairment: Limited experience is available in patients with severe renal impairment or haemodialysis. A lower starting dose of 20 mg is recommended in these patients.
No posology adjustment is required for patients with mild to moderate renal impairment.

Hepatic impairment
FDC of Cilnidipine and Telmisartan is contraindicated in patients with Severe Hepatic impairment.
Cilnidipine:
Dosage recommendations have not been established in patients with mild to moderate hepatic impairment; therefore dose selection should be cautious and should start at the lower end of the dosing range. Transient and generally clinically insignificant elevations in SGOT, SGPT, alkaline phosphatase, and serum bilirubin have been reported during calcium antagonist therapy in less than 1% of patients.
Telmisartan:
Telmisartan is contraindicated in patients with severe hepatic impairment.
In patients with mild to moderate hepatic impairment, the posology should not exceed 40 mg once daily.

Paediatric population: The safety and efficacy of FDC of Cilnidipine and Telmisartan in children and adolescents aged below 18 years have not been established.

CONTRAINDICATIONS
FDC of Cilnidipine and Telmisartan is contraindicated in:
- Hypersensitivity to the active substance, other calcium channel antagonist or to any of the excipients listed
- Advanced Aortic stenosis
- Second and third trimesters of pregnancy
- Biliary obstructive disorders
- Severe hepatic impairment

The concomitant use of Telmisartan and Cilnidipine with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m^2)

WARNINGS & PRECAUTIONS
Telmisartan
Pregnancy: Angiotensin II receptor antagonists should not be initiated during pregnancy. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.
Hepatic impairment: Telmisartan is not to be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairment, since Telmisartan is mostly eliminated with the bile. These patients can be expected to have reduced hepatic clearance for Telmisartan. Telmisartan should be used only with caution in patients with mild to moderate hepatic impairment.
Renovascular hypertension: There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the reninangiotensin- aldosterone system.
Renal impairment and kidney transplantation: When Telmisartan is used in patients with impaired renal function, periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of Telmisartan in patients with recent kidney transplantation.
Intravascular hypovolaemia: Symptomatic hypotension, especially after the first dose of Telmisartan, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea, or vomiting. Such conditions should be corrected before the administration of Telmisartan. Volume and/or sodium depletion should be corrected prior to administration of Telmisartan.
Dual blockade of the renin-angiotensin-aldosterone system (RAAS): There is evidence that the concomitant use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren increases the risk of hypotension, hyperkalaemia and decreased renal function (including acute renal failure). Dual blockade of RAAS through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is therefore not recommended**.** If dual blockade therapy is considered absolutely necessary, this should only occur under specialist supervision and subject to frequent close monitoring of renal function, electrolytes and blood pressure. ACE-inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy.
Other conditions with stimulation of the renin-angiotensin-aldosterone system: In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with medicinal products that affect this system such as Telmisartan has been associated with acute hypotension, hyperazotaemia, oliguria, or rarely acute renal failure.
Primary aldosteronism: Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Therefore, the use of Telmisartan is not recommended.

Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy: As with other vasodilators, special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy.

Diabetic patients treated with insulin or antidiabetics: In these patients hypoglycaemia may occur under Telmisartan treatment. Therefore, in these patients an appropriate blood glucose monitoring should be considered; a dose adjustment of insulin or antidiabetics may be required, when indicated.

Hyperkalaemia
The use of medicinal products that affect the renin-angiotensin-aldosterone system may cause hyperkalaemia.
In the elderly, in patients with renal insufficiency, in diabetic patients, in patients concomitantly treated with other medicinal products that may increase potassium levels, and/or in patients with intercurrent events, hyperkalaemia may be fatal.
Before considering the concomitant use of medicinal products that affect the renin-angiotensin-aldosterone system, the benefit risk ratio should be evaluated.
The main risk factors for hyperkalaemia to be considered are:
- Diabetes mellitus, renal impairment, age (>70 years)
- Combination with one or more other medicinal products that affect the renin-angiotensin-aldosterone system and/or potassium supplements. Medicinal products or therapeutic classes of medicinal products that may provoke hyperkalaemia are salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim.
- Intercurrent events, in particular dehydratation, acute cardiac decompensation, metabolic acidosis, worsening of renal function, sudden worsening of the renal condition (e.g. infectious diseases), cellular lysis (e.g. acute limb ischemia, rhabdomyolysis, extend trauma).

Close monitoring of serum potassium in at risk patients is recommended.

Ethnic differences: As observed for angiotensin converting enzyme inhibitors, Telmisartan and the other angiotensin II receptor antagonists are apparently less effective in lowering blood pressure in black people than in non-blacks, possibly because of higher prevalence of low-renin states in the black hypertensive population.

Other: As with any antihypertensive agent, excessive reduction of blood pressure in patients with ischaemic cardiopathy or ischaemic cardiovascular disease could result in a myocardial infarction or stroke.

Cilnidipine
Cilnidipine should be used carefully in patients with Angina, Chronic renal insufficiency, Congestive heart failure, Hypotension, Liver dysfunction, or elevated liver enzymes and Peripheral edema (confounding physical findings in congestive failure)

DRUG INTERACTIONS
Cilnidipine
Cilnidipine can interact with aldesleukin, quinidine, phenytoin, rifampicin, erythromycin, other anti-hypertensive drugs and anti-psychotic drugs.

Telmisartan
Digoxin: When Telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49%) and in trough concentration (20%) were observed. When initiating, adjusting, and discontinuing Telmisartan, monitor digoxin levels in order to maintain levels within the therapeutic range.
As with other medicinal products acting on the renin-angiotensin-aldosterone system, Telmisartan may provoke hyperkalaemia. The risk may increase in case of treatment combination with other medicinal products that may also provoke hyperkalaemia (salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim).
The occurrence of hyperkalaemia depends on associated risk factors. The risk is increased in case of the abovementioned treatment combinations. The risk is particularly high in combination with potassium sparing-diuretics, and when combined with salt substitutes containing potassium. A combination with ACE inhibitors or NSAIDs, for example, presents a lesser risk provided that precautions for use are strictly followed.
Concomitant use not recommended.
Potassium sparing diuretics or potassium supplements: Angiotensin II receptor antagonists such as Telmisartan, attenuate diuretic induced potassium loss. Potassium sparing
diuretics e.g. spirinolactone, eplerenone, triamterene, or amiloride, potassium supplements, or potassium-containing salt substitutes may lead to a significant increase in serum potassium. If concomitant use is indicated because of documented hypokalemia they should be used with caution and with frequent monitoring of serum potassium.

Lithium: Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors, and with angiotensin II receptor antagonists, including Telmisartan. If use of the combination proves necessary, careful monitoring of serum lithium levels is recommended. Concomitant use requiring caution
Non-steroidal anti-inflammatory medicinal products: NSAIDs (i.e. acetylsalicylic acid at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) may reduce the antihypertensive effect of angiotensin II receptor antagonists. In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function), the co-administration of angiotensin II receptor antagonists and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter.
In one study the co-administration of Telmisartan and ramipril led to an increase of up to 2.5 fold in the AUC_{0-24} and C_{max} of ramipril and ramiprilat. The clinical relevance of this observation is not known.
Diuretics (thiazide or loop diuretics): Prior treatment with high dose diuretics such as furosemide (loop diuretic) and hydrochlorothiazide (thiazide diuretic) may result in volume depletion and in a risk of hypotension when initiating therapy with Telmisartan.
To be taken into account with concomitant use
Other antihypertensive agents: The blood pressure lowering effect of Telmisartan can be increased by concomitant use of other antihypertensive medicinal products. Clinical trial data has shown that dual blockade of the renin-angiotensin-aldosterone-system (RAAS) through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is associated with a higher frequency of adverse events such as hypotension, hyperkalaemia and decreased renal function (including acute renal failure) compared to the use of a single RAAS-acting agent. Based on their pharmacological properties it can be expected that the following medicinal products may potentiate the hypotensive effects of all antihypertensives including Telmisartan: Baclofen, amifostine. Furthermore, orthostatic hypotension may be aggravated by alcohol, barbiturates, narcotics or antidepressants**.**
Corticosteroids (systemic route): Reduction of the antihypertensive effect.

UNDESIRABLE EFFECTS
Cilnidipine
Dizziness, headache, peripheral edema, flushing, rash and gingival hyperplasia are the most common adverse events seen with the dihydropyridine derivative calcium channel antagonists. Headache, Flushing was reported in 3.7 & 4.5% of 764 subjects receiving Cilnidipine respectively.

Telmisartan:
Serious adverse drug reactions include anaphylactic reaction and angioedema which may occur rarely (≥1/10,000 to <1/1,000), and acute renal failure.
Tabulated summary of adverse reactions:
The adverse reactions reported with Telmisartan are as mentioned in table below.
Adverse reactions have been ranked under headings of frequency using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Infections and infestations	**Uncommon:** Urinary tract infection including cystitis, upper respiratory tract infection including pharyngitis and sinusitis **Rare:** Sepsis including fatal outcome
Blood and the lymphatic system disorders	**Uncommon:** Anaemia **Rare:** Eosinophilia, thrombocytopenia
Immune system disorders	**Rare:** Anaphylactic reaction, hypersensitivity
Metabolism and nutrition disorders	**Uncommon:** Hyperkalaemia **Rare:** Hypoglycemia (in diabetic patients)
Psychiatric disorders	**Uncommon:** Insomnia, depression **Rare:** Anxiety
Nervous system disorders	**Uncommon:** Syncope **Rare:** Somnolence
Eye disorders	**Rare:** Visual disturbance
Ear and labyrinth disorders	**Uncommon:** Vertigo
Cardiac disorders	**Uncommon:** Bradycardia **Rare:** Tachycardia
Vascular disorders	**Uncommon:** Hypotension , orthostatic hypotension
Respiratory, thoracic and mediastinal disorders	**Uncommon:** Dyspnoea, cough **Very rare:** Interstitial lung disease
Gastrointestinal disorders	**Uncommon:** Abdominal pain, diarrhoea, dyspepsia, flatulence, vomiting **Rare**: Dry mouth, stomach discomfort, Dysgeusia
Hepato-biliary disorders	**Rare:** Hepatic function abnormal/liver disorder
Skin and subcutaneous tissue disorders	**Uncommon:** Pruritus, hyperhidrosis, rash **Rare:** Angioedema (also with fatal outcome), eczema, erythema, urticaria, drug eruption, toxic skin eruption
Musculoskeletal and connective tissue disorders	**Uncommon:** Back pain (e.g. sciatica), muscle spasms, myalgia **Rare:** Arthralgia, pain in extremity, tendon pain (tendinitis like symptoms)
Renal and urinary disorders	**Uncommon:** Renal impairment including acute renal failure
General disorders and administration site conditions	**Uncommon:** Chest pain, asthenia (weakness) **Rare:** Influenza-like illness
Investigations	**Uncommon:** Blood creatinine increased **Rare:** Haemoglobin decreased, blood uric acid increased, hepatic enzyme increased, blood creatine phosphokinase increased

OVERDOSE
There is no experience of overdose with Cilnidipine and Telmisartan. Signs and symptoms of overdose are expected to be in line with exaggerated pharmacological effects of individual ingredient.
Telmisartan:
There is limited information available with regard to overdose in humans.
Symptoms: The most prominent manifestations of Telmisartan overdose were hypotension and tachycardia; bradycardia, dizziness, increase in serum creatinine, and acute renal failure have also been reported**.**

Cilnidipine:
Overdose with Cilnidipine may result in excessive peripheral vasodilatation and possibly reflex tachycardia. Marked and probably prolonged systemic hypotension up to and including shock with fatal outcome may occur.

Treatment:
Telmisartan is not removed by haemodialysis. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Management depends on the time since ingestion and the severity of the symptoms. Suggested measures include induction of emesis and / or gastric lavage. Activated charcoal may be useful in the treatment of overdosage. Serum electrolytes and creatinine should be monitored frequently. If hypotension occurs, the patient should be placed in a supine position, with salt and volume replacement given quickly.

PHARMACODYNAMIC AND PHARMACOKINETIC PROPERTIES
Pharmacodynamics
Mechanism of action
Cilnidipine
Cilnidipine is a third generation dihydropyridine calcium antagonist with a slow onset and long duration of action. Calcium antagonists inhibit influx of extracellular calcium ions into the cells, resulting in decreased vascular smooth muscle tone and vasodilation, leading to a reduction in blood pressure.
In vitro and animal studies suggest that Cilnidipine blocks both the L and N type calcium channels. Cilnidipine inhibits the pressor to cold stress by suppressing sympathetic nerve activity in spontaneously hypertensive rats. It does not induce tachycardia caused by hypotensive baroreflexes. In vitro, Cilnidipine inhibits norepinephrine release in electrically stimulated rabbit mesenteric arteries.
In human studies, Cilnidipine had weak inotropic effects and suppressed cardiac sympathetic overactivity. Therefore it may decrease the risk and mortality from long term cardiovascular complications. Once-daily Cilnidipine was associated with less reflex tachycardia and had fewer effect on the autonomic nervous system in hypertensive patients. In contrast to other long acting calcium channel blockers, Cilnidipine and amlodipine did not increase plasma renin activity, thus they may decrease the risk of cardiovascular complications due to metabolic imbalances. Cilnidipine may inhibit norepinephrine and dopamine production, thereby improving insulin resistance in patients with diabetes. It also had beneficial effects on lipid profiles in hypertensive patients by decreasing total cholesterol, triglyceride, and very low density lipoprotein cholesterol level, and increasing high density lipoprotein cholesterol and the ratio of high density lipoprotein cholesterol to total cholesterol.

Telmisartan
Telmisartan is an orally active and specific angiotensin II receptor (type AT_1) antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the AT_1 receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the AT_1 receptor. Telmisartan selectively binds the AT_1 receptor. The binding is long-lasting. Telmisartan does not show affinity for other receptors, including AT_2 and other less characterised AT receptors. The functional role of these receptors is not known, nor is the effect of their possible overstimulation by angiotensin II, whose levels are increased by Telmisartan. Plasma aldosterone levels are decreased by Telmisartan. Telmisartan does not inhibit human plasma renin or block ion channels. Telmisartan does not inhibit angiotensin converting enzyme (kininase II), the enzyme which also degrades bradykinin. Therefore, it is not expected to potentiate bradykinin-mediated adverse effects.
In human, an 80 mg dose of Telmisartan almost completely inhibits the angiotensin II evoked blood pressure increase.
The inhibitory effect is maintained over 24 hours and still measurable up to 48 hours.

Pharmacokinetics
Cilnidipine
Cilnidipine has a slow onset and long duration of action of 24 hours, partly explained by its high lipophilicity.
Cilnidipine has a half-life of 2 – 8 hrs. after administration of 5 – 20 mg.
Telmisartan
Absorption: Absorption of Telmisartan is rapid although the amount absorbed varies. The mean absolute bioavailability for Telmisartan is about 50 %. When Telmisartan is taken with food, the reduction in the area under the plasma concentration-time curve ($AUC_{0-\infty}$) of Telmisartan varies from approximately 6 % (40 mg dose) to approximately 19 % (160 mg dose). By 3 hours after administration, plasma concentrations are similar whether Telmisartan is taken fasting or with food.
Linearity/non-linearity: The small reduction in AUC is not expected to cause a reduction in the therapeutic efficacy. There is no linear relationship between doses and plasma levels. Cmax and to a lesser extent AUC increase disproportionately at doses above 40 mg.
Distribution: Telmisartan is largely bound to plasma protein (>99.5 %), mainly albumin and alpha-1 acid glycoprotein. The mean steady state apparent volume of distribution (V_{ss}) is approximately 500 l.
Biotransformation: Telmisartan is metabolised by conjugation to the glucuronide of the parent compound. No pharmacological activity has been shown for the conjugate.
Elimination: Telmisartan is characterised by biexponential decay pharmacokinetics with a terminal elimination half-life of >20 hours. The maximum plasma concentration (C_{max}) and, to a smaller extent, the area under the plasma concentration-time curve (AUC), increase disproportionately with dose. There is no evidence of clinically relevant accumulation of Telmisartan taken at the recommended dose. Plasma concentrations were higher in females than in males, without relevant influence on efficacy.
After oral (and intravenous) administration Telmisartan is nearly exclusively excreted with the faeces, mainly as unchanged compound. Cumulative urinary excretion is <1 % of dose. Total plasma clearance (Cl_{tot}) is high (approximately 1,000 ml/min) compared with hepatic blood flow (about 1,500 ml/min).

INCOMPATIBILITIES
None known.

PACKAGING INFORMATION
Blister of 7 Tablets & 10 Tablets.

STORAGE AND HANDLING INSTRUCTIONS
Store protected from light & moisture, at a temperature not exceeding 30°C.
Keep out of reach of children.

Marketed by & ® Regd. Trade Mark of:
J. B. Chemicals & Pharmaceuticals Ltd.
Neelam Centre, B Wing, Hind Cycle Road,
Worli, Mumbai 400 030, India.

Manufactured in India by : Pure & Cure Healthcare Pvt. Ltd.
(A Subsidiary of **Akums Drugs & Pharmaceuticals Ltd.**)
Plot No. 26A-30, Sector - 8A, I.I.E., SIDCUL,
Haridwar-249403 (Uttarakhand)

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BACK

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Brand Name Font and Size : Zurich XBlk BT 12 pt.

SAP Code : 128270	Country : Domestic	Mfg. Location : Pure & Cure Healthcare	Product Name : Cilacar T
Packaging Material : Leaflet	Existing / Reference A/W : 127055	Version No.: 1	Date : 06/01/2020
Dimension : (L) 280 x (B) 140 mm ± 1 mm tolerance		Size after Folding : 70 x 35 mm ± 1 mm	Core Dia : NA
Reel Dia : NA	Varnish / Lamination : NA	Folding pattern : 1 Vertical + 3 Horizontal Folds	
Packaging Material Specification (For Supplier only) : ITC Fine print paper		Colours : Black	
Grammage : 40 mm ± 5% gm/m²			
Thickness : NA			
Reason for change : New artwork			J. B. CHEMICALS & PHARMACEUTICALS LTD.
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Artist : Shyam Kawle (JBCPL)	Initiated by	Checked by	Approved by	Approved by
Sign & Date				
Designation	Executive - PDD	Manager - PDD	Regulatory Affairs	V. P. (Supply Chain)