MKPPL

MURLI KRISHNA

PHARMA PVT. LTD.

Murli Krishna Pharma Pvt. Ltd

www.murlikrishnapharma.com

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About Us

Murli Krishna Pharma Private Ltd. is a young and dynamic drug delivery systems (DDS) company in India that provides a range of effective solutions to optimize the delivery of pharmaceutical products.

Murli Krishna Pharma Private Ltd. was established by Ms. Satya Vadlamani & Dr. Vijay K. Shastri in early 2004. Driven by the vision to provide the best possible, range of international quality products at competitive prices through integration, research, innovation, technology & development.

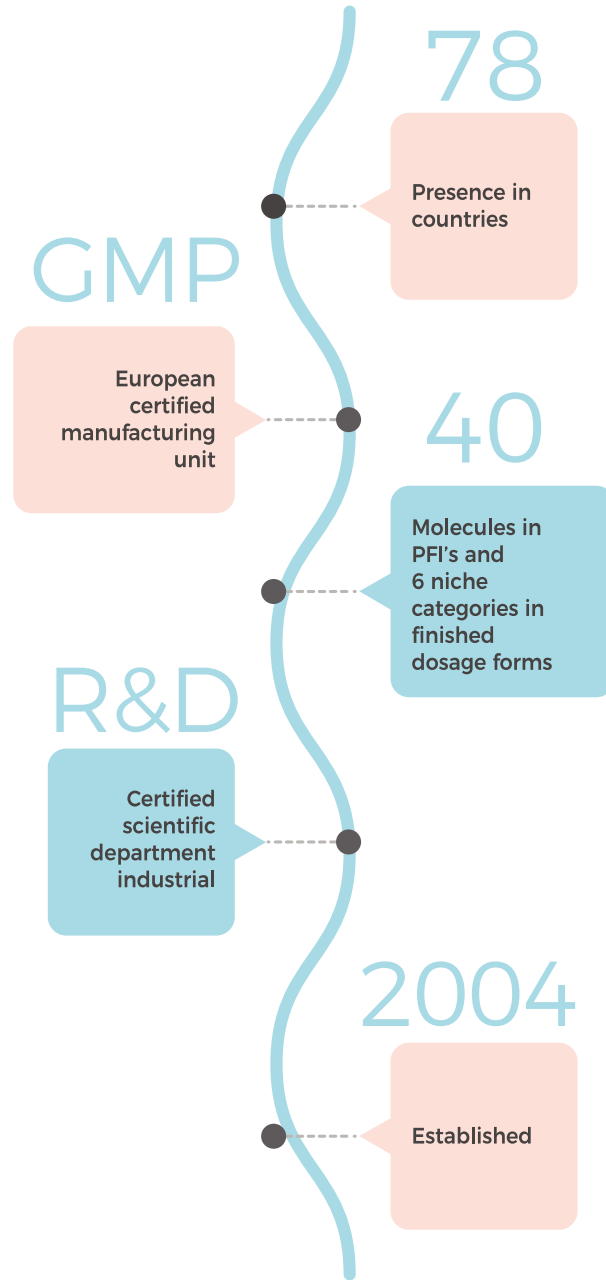
MKPPL plant is approved for manufacturing by European Union & for GMP Compliance by the WHO; Murli Krishna Pharma is equipped to undertake formulation development projects on oral NDDS. And the R&D facility is recently approved by DSIRT.

MKPPL have a world class oral solid dosage form manufacturing facility for Pellets, Micro-Pellets and Granules approved by regulatory authorities of developed countries.

Company want to carve out a niche in the field of Novel Drug Delivery System(NDDS) & would like to be known as one of the Leading Global Research Based, Drug Delivery Companies, with an expertise in novel drug delivery systems, constantly strive towards building and strengthening upon our intellectual property.

Current activities include manufacturing of pre-finished formulations i.e. pellets using Aqueous Based technology and avoiding use of Solvents completely. We have 3 potential IPRs. We develop platform technology implement the same.

GROWTH PATH



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MKPPL - PRODUCT PORTFOLIO (EUGMP Facility)

(Enteric Coated /Delayed /Dual Delayed Released, Immediate/Modified/Sustained Released)
Pellets, Micro-pellets, MUPS, Granules & Nano particle Solutions

SR. NO.	Therapeutic Category / Products	FORM OF PFIs	DOCUMENTATION AVAILABILITY
	Anti-Asthamatic		
1	Budesonide DR Pellets 0.88%	Pellets (for Capsule)	DMF in CTD Format
	Direct Thrombin Inhibitor's (DTIs)		
2	Dabigatran Pellets 35%, 40%	Pellets (for capsules)	DMF under compilation
	Anti-Hypertensives		
3	Nicardipine Pellets 22%	Pellets (for capsules)	DMF under compilation
	Digestant		
4	Pancreatin EC Pellets 70% (Bovine & Porcine)	Pellets/Micro pellets (for capsules)	DMF in CTD Format
	Alpha-Blockers		
5	Tamsulosin HCL SR Pellets (USP43) 0.125%, 0.13%, 0.16%, 0.20%	Pellets/Micro pellets (for capsules)	DMF in CTD format
	Anti-Fungal		
6	Itraconazole IR Pellets 22%, 44% (BP20 & USP43)	Pellets/Micro pellets (for capsules)	DMF in CTD format
	Antiemetic		
7	Aprepitant Pellets 40% (USP43) (Note: offer patent Non-infringing product)	Pellets/Micro pellets (for capsules)	DMF in CTD format
	Anti-Depressant		
8	Duloxetine HCL EC Pellets 17%, 20% (USP43)	Pellets/Micro pellets (for capsules)	DMF in CTD format
9	Venlafaxine SR Pellets 32%, 33% (USP43)	Pellets/Micro pellets (for capsules)	DMF in CTD format
	Anti-Inflammatory		
10	Mesalamine SR Pellets/granules (USP43) 60%,70% & 90% 96.38%	Pellets/Micro pellets (for capsules) Granules (for Tablets)	DMF in CTD format
11	Mebeverine Hcl SR pellets (USP43) 76%, 80%	Pellets/Micro pellets (for capsules)	DMF in CTD format
12	Diclofenac Sodium SR Pellets 30%, 31.25%	Pellets (for capsules)	DMF in CTD format
	Immunosuppressant		
13	Tacrolimus IR Pellets (USP43) 0.5%, 1%, 5%	Pellets/Micro pellets (for capsules)	DMF in CTD format
14	Sirolimus Granules (USP43) 0.3%, 0.6%, 1.2%	Granules (for Tablets)	DMF in CTD format
15	Everolimus Granules (USP43) 2.68% & 5%	Granules (for Tablets)	DMF in CTD format
	Anticoagulants		
16	Dipyridamole ER Pellets 42.5%	Pellets/Micro pellets (for capsules)	DMF under compilation
	Anti-Ulcerant (PPIs)		
17	Lansoprazole EC Pellets/ MUPS 8.5%, 12.5%	Pellets/Micro pellets (for capsules) MUPS (for Tablets)	DMF in CTD format
18	Dexlansoprazole DDR Pellets 17%, 20%, 22.5%, 23%	Pellets/Micro pellets (for capsules)	DMF in CTD format
19	Esomeprazole mg. tri. EC Pellets/ MUPS / Granules (USP43) 8.5%, 22.5%	Pellets/Micro pellets (for capsules) MUPS (for Tablets), Granules (Suspension)	DMF in CTD format
20	Pantoprazole EC Pellets 15% (USP43)	Pellets (for capsules)	DMF in CTD format
21	Omeprazole EC Pellets (USP43) 8.5%, 12.5%, 20%, 22%, 30%	Pellets/Micro pellets (for capsules)	DMF in CTD format
	Anti-Obesity		
22	Orlistat Pellets (In-house & USP 43) 50%, (Note: Offer patent Non-infringing product)	Pellets/Extrudes (for capsules)	DMF in CTD format
	Macrolide Antibiotic		
23	Clarithromycin Taste masked Granules (USP43) 27.5%, 30%, 33%, 42% & 43.75%	Granules (for suspension)	DMF in CTD format

NOTE: Products protected by ongoing Patents are not offered for commercial supplies.

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Oral Solid Dosage Formulations

Sr. No	PRODUCT	BRAND NAME
	Capsule	
1	Dabigatran Etexilate Capsule 110mg, 150mg	CLOGAT
2	Dexlansoprazole DR Capsules 30mg, 60mg	DEXLASO DR
3	Diclofenac Sodium SR Capsule 50mg, 100mg	MKFEN SR
4	Duloxetine HCL DR Capsules 20mg, 30mg, 60mg	DULTOX DR
6	Itraconazole Capsule 100mg, 200mg	KNDID
7	Lansoprazole DR Capsule 15mg, 30mg	MKLANZ DR
8	Mebeverine HCL SR Capsule 135mg, 200mg	KMEVERI SR
9	Nicardipine HCL Capsules 20mg, 30mg, 45mg, 60mg	NIKAPINE
10	Omeprazole Gastro-resistant Capsule 20mg, 40mg	MKOMI
11	Orlistat capsules 60mg, 120mg	MK-STAT
12	Pancreatin Capsule 10000 IU, 25000 IU	MKLIPZ
13	Pantoprazole Gastro-resistant Capsule 20mg, 40mg	KPAM
14	Tacrolimus PR Capsule 0.5mg, 1mg, 5mg	MKLIMUS
15	Tamsulosin HCL Capsules 0.4mg, 0.8mg	MKLOSIN
16	Venlafaxine XR Capsules 37.5mg, 75mg, 150mg	MVENLA XR
17	Vincamine Capsule 30mg	VINKINE
	Tablet	
1	Azithromycin Tablet 250mg, 500mg	BACTZITH
2	Clarithromycin Tablet 250mg, 500mg	CLARIMAY
3	Diclofenac Sodium SR Tablet 50 mg, 100 mg	MKFEN
4	Esomeprazole Tablet 20mg, 40mg,	MEPRAZ
5	Lansoprazole OD Tablet 15mg, 30mg	MKLANZ
6	Mebeverine HCL Tablet 135mg, 200mg	KMEVERI
7	Memantine Tablets 5mg, 10mg	AZMENTA
8	Metformin SR Tablets 500mg, 1000mg	KDIBET
9	Quetiapine Fumarate SR Tablet 25mg, 50mg, 100mg, 200mg	MKQUPI SR
10	Sirolimus Tablet 0.5mg, 1mg, 5mg	MKSIRO
11	Mebeverine HCL Tablet 75mg, 135mg, 200mg	KMEVERI
12	Everolimus Tablets 0.5mg, 0.75mg, 5mg 10mg	EV-CAN
SPECILITY PRODUCTS- (NDDS/NANO)		
1	Transdermal Lotion(Iron, Vitamin D3, Vitamin B12 and Folic Acid)	MK-VITFE LOTION
2	Brinzolamide ophthalmic suspension 1.0% w/v	MK BRINZ DROP
3	Paclitaxel (Protein bound particle) for injectable suspension 100 mg	PACLIONC INJECTION
4	Budesonide Soft Mist Inhaler 0.25mg/ml, 0.5mg/ml	BUDESOFT MIST INHALER

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General Injectables

Sr. No	Product name	Categories
1	Liposomal Amphotericin B Lyophilized Injection 50mg	Antifungal
2	Itraconazole injection 10mg/ml	Antifungal
3	Fluconazole injection 200mg/100ml	Antifungal
4	Ferric Carboxymaltose Injection 50mg/ml ,500mg/10ml	Iorn Suppliment
5	Iron Sucrose Injection USP 20mg/ml	Iron Replacement
6	Iron Dextran Injection USP 50mg,100 mg /ml	Iron Replacement
7	Methylcobalamin 500mcg ,1500 injection 1 ml,2 ml	Multivitamin
8	Vitamin D3 (600000IU) Injection 1 ml	Multivitamin
9	Nicotinamide 200mg+ Folic Acid 15mg+ Vitamin B12 500mcg 10ml injection	Multivitamin
10	Pantoprazole for injection 40mg/vial	Proton Pump Inhibitor
11	Esomeprazole sodium for injection 40mg/vial	Proton Pump Inhibitor
12	Omeprazole sodium for injection 40mg/vial	Proton Pump Inhibitor
13	Lansoprazole sodium for injection 30mg/vial	Proton Pump Inhibitor
14	Phytonadione Injection 10mg/ml	Vitamins K
15	Thiamine Injection 100mg/ml	Vitamins B1
17	Chloroquine Phosphate Injection 40mg/vial	Antimalarial
18	Ascorbic Acid Injection 100mg/ml,250mg/ml,500mg/ml	Antioxidant
19	Diclofenac sodium injection 75mg/ml	NSAID
20	Ketorolac Tromethamine Injection 15mg/ml	NSAID
21	Ondansetron injection 40mg/20ml	Antiemetic
22	Promethazine hydrochloride Injection 25mg	Antiemetic
23	Furosemide injection 40mg/4 ml	Diuretics
24	Noradrenaline injection 1mg	Sympathomimetic Drug

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Oncology Injectables

Sr. No	Product name
1	Paclitaxel Injection IP/USP 30 mg/ 5 ml, 100 mg/17 ml,260 mg/43.4 ml,300 mg/50 ml
2	Paclitaxel (Protein bound particle) for injectable suspension 100 mg
3	Bendamustine Hydrochloride Injection 100 mg/vial
4	Bortezomib Injection IP 2 mg/vial,3.5 mg/vial
5	Carboplatin Injcetion IP/BP 150mg/15 ml,450mg/45 ml
6	Cytarabine Injection BP 100 mg/ml 500 mg/5 ml
7	Dacarbazine Injection USP 200 mg/vial,500 mg/vial
8	Epirubicin Injection 10 mg/vial,50 mg/vial,100 mg/vial
9	Fluorouracil Injection 1000mg/20mL,5000mg/100mL,500mg/10mL,250mg/5mL
10	Gemcitabine for Injection IP/USP 200 mg/vial ,1 gm/vial,1.4 gm/vial
11	Methotrexate Injection IP/USP 500 mg/20 ml,50 mg/2 ml
12	Oxaliplatin Injection 50mg/10 ml
13	Pegaspargase Injection 3750 IU/5 ml
14	Pemetrexed Injection IP/USP 100 mg/vial,500 mg/vial

	Under development
15	Doxorubicin Hydrochloride Injection 10mg/5mL,50mg/25mL
16	Docetaxel Injection IP/USP 20 mg/0.5 ml,80 mg/2 ml
17	Eribulin Mesylate solution for Injection 0.5mg, 0.88 mg/2ml
18	Irinotecan Injection IP/USP 40 mg/ 2 ml,100 mg/ 5 ml , 300 mg/ 5 ml

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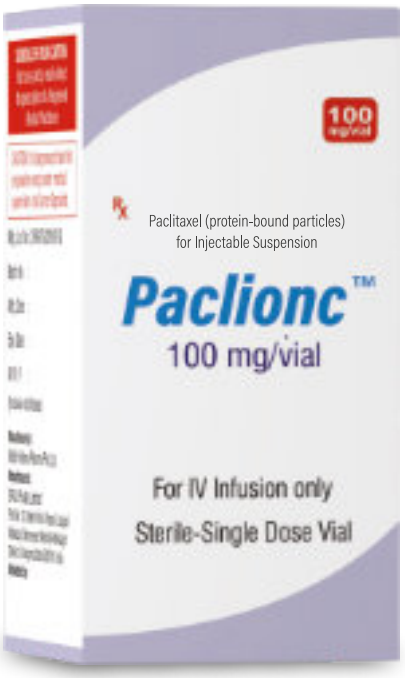
Paclionc™

Cancer Fundamentals:

- Cancer is a complex condition characterized by the uncontrolled growth and division of cells in the body.
- It can manifest in various forms and affect different organs, often arising from genetic mutations or exposure to carcinogens.



Revolutionizing Cancer Care with Nab Paclitaxel Treatment:

- Nab Paclitaxel is a ground-breaking chemotherapy medication.
- It is uniquely formulated as an albumin-bound nanoparticle, which enhances both its efficacy and safety.
- Nab Paclitaxel is utilized in the treatment of breast cancer, pancreatic cancer, and non-small cell lung cancer.
- Administration is typically via intravenous infusion.

The Significance of Encapsulation:

- Encapsulation of paclitaxel is crucial for precise targeting while minimizing side effects.
- Conventional systemic administration affects healthy cells throughout the body.
- Encapsulation guarantees that the drug efficiently reaches the tumor site.

Advantages of Nab Paclitaxel:

- **Enhanced Solubility:** The nanoparticle form of Nab Paclitaxel improves its solubility in water, facilitating easier administration.
- **Targeted Delivery:** Nano-sized particles exhibit a preference for accumulating at tumor sites, boosting the drug's effectiveness.
- **Reduced Side Effects:** Nab Paclitaxel nanoparticles evade recognition by healthy tissues, thereby minimizing adverse effects.
- **Higher Dosing:** This enables the use of higher maximum tolerated doses (MTD).
- **Improved Pharmacokinetics:** Longer half-life and superior tumor accumulation.

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Paclitaxel (protein-bound particles) for Injectable Suspension

Murli Krishna Pharma - Pioneering Nano in Nano Paclionc

As pioneers in the field of Nano in Nano Paclionc, Murli Krishna Pharma (MKPPL) proudly presents a ground-breaking formulation enclosed within nano-sized particles. This innovative technique, protected by our MKPPL patent, is set to revolutionize cancer treatment.

Our commitment to precision begins with our proprietary matrix, carefully crafted using an aqueous system. This matrix is meticulously tailored to target specific tumor characteristics, making it ideally suited for breast cancer, intestinal cancer, and pancreatic cancer. The hallmark of our matrix is its remarkable size precision.

Matrix Development Highlights:

- Our journey to perfection culminated in the finalization of matrix development, verified across five batches, each containing 5 gms of Paclitaxel.
- We achieved an impressive encapsulation efficiency rate of 65%-70%, demonstrating our dedication to quality.

Ensuring Consistency:

- Verification studies have confirmed exceptional repeatability in nanoparticle formation and output, consistently achieving 93% to 94%.

In Vivo Efficacy Assessment:

- In-depth evaluation using the MBT assay on Breast Tumor cell lines yielded remarkable results.
- Our matrix exhibits outstanding tumor cell inhibition activity at a concentration of 2 mg/ml, closely paralleling ABRAXANE (albumin-encapsulated Paclitaxel nanoparticles) at 6 mg/ml.

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Transdermal Liposomal Lotion

product containing API of
Ferrous Bis Glycinate (Elemental Iron),
Vitamin B12, Vitamin D3, Folic acid

1. STUDY SYNOPSIS

Deficiency of micronutrients in infancy can lead to failure of full growth potential. Deficiency of iron and vitamin D is prevalent in India and supplements have been recommended. While oral fortification or supplementation of micronutrients is limited by issues of taste, stability, poor absorption and gastrointestinal disturbances, transdermal delivery using innovative nanotechnology allows easy delivery of micronutrients through skin. MKPPL have developed safe nanoparticles that encapsulate micronutrients and interact with the outermost layer of skin to enhance penetration and can be delivered through a lotion platform. This technology is relatively inexpensive and has a potential for scaling up. This innovative intervention can address the problem of micronutrient deficiency in infants and improve physical and neurodevelopment.

2. BACKGROUND

2.1.Prevalence of iron and vitamin D deficiency in India

Nutritional anemia is due to iron deficiency is one of the commonest deficiencies in Indian infants. Timely correction of iron deficiency is important as it adversely affects cognitive performance, behaviour and physical growth of infants, preschool and school-age children and also the immune status and morbidity from infections of all age groups. The prevalence of anemia in children aged 6- 35 months was estimated to be as high as 78.9% in NFHS-3(2). Subclinical vitamin D deficiency is prevalent in 40-80% Indian infants and toddlers as documented in various studies(3). Timely supplementation of these micronutrients can prevent their deficiencies in future.

2.2.Role of micronutrients in brain growth

Iron deficiency is associated with poor neurodevelopment and iron supplementation has been associated with improved outcomes. Animal studies have shown that maternal deficiency of vitamin D is associated with profound alteration in infant brain. Folate and Vitamin B12 are also crucial for neurological development while calcium is essential for growth of infants. Thus regular supplementation of these micronutrients in infants can potentially improve their nutritional status and have significant impact on neurocognitive development.

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Transdermal Liposomal Lotion

product containing API of
Ferrous Bis Glycinate (Elemental Iron),
Vitamin B12, Vitamin D3, Folic acid

2.3.Transdermal delivery of nanoparticles using fortified lotion

The skin represents a large surface area which is easily accessible and can potentially serve as a very attractive non-invasive route of delivery of drugs. The stratum corneum layer of skin has a "brick and mortar" structure which acts as a defensive wall that needs to be overcome in order to achieve efficient transdermal drug delivery. Nanoparticles can penetrate through the stratum corneum for deeper penetration into the dermis thereby reaching rich capillary network beneath and systemic circulation. Oral delivery of Iron is always a very tedious task as only 15% of the iron is absorbed into the system and there has been signs of gastrointestinal irritation. The iron needs to be available in the Ferrous form in order to be bioavailable in the system.

Why Liposomes?

- A liposome is a spherical vesicle having at least one lipid bilayer. Therefore, it will be helpful to penetrate through the skin brick and mortar model.
- Liposomes are non-toxic, flexible, biocompatible, completely biodegradable, and non- immunogenic for systemic and non-systemic administrations.
- Liposomes can entrap both hydrophobic and hydrophilic molecules, prevent the entrapped combinations from decomposing, and release the entrapped at specific targets.

Benefits of Transdermal Liposomal Lotion:

- Easy for application
- Skin friendly, Non-irritant
- Bypass first pass effect
- Liposomal based formulation possesses advantage over conventional lotion, due to very small particle size they can easily penetrate through the skin uppermost layer.
- Convenient for unconscious patients or patients to have difficulty in oral administration.

Importance of Liposomal lotion formulation?

- Liposomes protect some drugs against chemical and immunological breakdown, as well as protecting them against the effect of enzymes.
- Liposomal formulation is a commercially possible approach to solving the poor solubility as well as poor bioavailability problems of the nutrients.
- This formulation allows such nutrients like iron, vitamin (B12, D3, Folate) which having low absorption ability and susceptible to first pass hepatic metabolism.

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Brinzolamide Eye Drop

(Nano suspension 1% w/v)

PROBLEMS FACED IN FORMULATING Ophthalmic DELIVERY SYSTEMS

The cell structures act as semi permeable paracellular passive diffusion barriers or gates to large and hydrophilic solutes.

Small, lipophilic essential nutrients and toxic metabolites are delivered or removed, respectively, through passive or active site-specific transcellular carrier–mediated influx or efflux transporters.

Several retinal disorders are accompanied by dysfunction or breakdown of this BRB and their associated cell-cell signaling mechanisms.

The static morphologic structure responsible for all these organ-specific barriers is the tight junction (TJ).

Counter intuitively, curative drug therapy to these protected sites requires that drugs circumvent these naturally protective barriers.

"Approach towards Developing Nanoparticles for Ophthalmic Products"

Ophthalmic preparations have an inherent problem of poor bioavailability. The reason is that most ophthalmic preparations are based on an aqueous matrix. Use of an aqueous vehicle with particle has an issue with respect to permeation, as the key absorption site is the cornea, which is hydrophobic while the conjunctiva is hydrophilic. The absorption through the conjunctiva is impaired due to a protective layer known as Ora Serrata.

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Brinzolamide Eye Drop

(Nano suspension 1% w/v)

The Nano emulsion developed by Murlikrishnapharma ensures the following:

- MKPPL developed a Nano particle based matrix, which can deliver hydrophilic as well as hydrophobic drugs using a combination of hydrophilic and hydrophobic excipients as a clear solution. This cogent use of excipients ensures that the drug is absorbed optimally and the Nano particles ensure that the drug penetrates not only through the hydrophobic and hydrophilic channels but also through the OraSerrata, which protects the eye from any foreign body entering the optical cavity.
- The protein binding is minimized due to encapsulation.
- The particle size is to the tune of 100 nm which makes the product easily sterile filterable.
- The formulation is in form of a clear solution and is available in the same concentration as the innovator i.e. 10 mg/ml. The product can be offered as a solution that can be sterile filtered and filled.
- We do offer development services in case of a requirement for different formulation/dosage/strength
- Offer complete technical package for registrations in all regulated/semi regulated markets
- Products protected by ongoing Patents are not offered by MKPPL.

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Budesonide Soft Mist

Key Points of Our Development:

- MKPPL has designed a formulation/ matrix of the drug, lipid and pulmonary surfactants in a complete aqueous base.
- The 100 % potency of this nanosuspension is 0.25 mg/ml and 0.5 mg/ml.
- The size of our nanoparticle based suspension is in between 60 nm to 120 nm with a D90 value of 80 nm and a polydispersity index of 0.103.
- The formulation can be modified to minimize blocking at the delivery nozzle and uniformity in drug distribution.

What are SMI's ?

- Soft Mist Inhalers are typically a novel, multidose, propellant free, liquid inhaler that represents a new category of inhaler devices.

MKPPL 's Vision :

- To work and develop platform technologies for delivery of BCS Class II drugs through SMIs, not only through a propellant free platform but also through an aqueous route.

SMI Device:

Ecomist90
Soft Breezer

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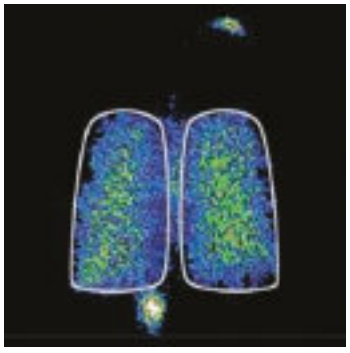
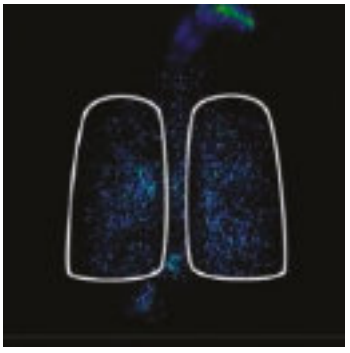
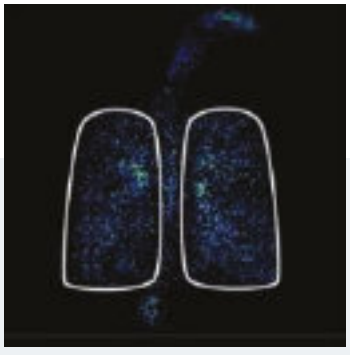
Budesonide Soft Mist



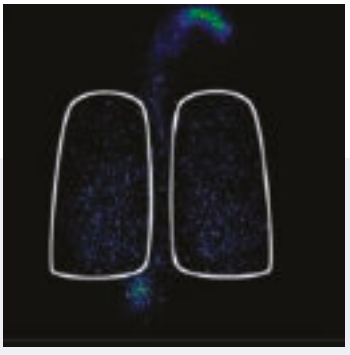
Respimat SMI



Turbohaler DPI - slow



Turbohaler DPI - slow



pMDI

Why SMIS are Considered More Effective?

We are looking at a lung deposition study using different Inhaler platforms through typical scintigraphic images.

Ref : J Aerosol Med, 18:264-72

CLIENTS, CERTIFICATIONS AND AWARDS

Biocon

STADA

Pfizer

SANOFI

MSN

Abbott

European Union GMP

Jordan FDA GMP

WHO GMP

Business Excellence

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