



CORPORATE
BROCHURE
2016



Brooks
LABORATORIES LIMITED
PLM&C, CMP & ISO 9001:2008 CERTIFIED COMPANY

BRIEF COMPANY BACKGROUND

- Brooks Laboratories was incorporated in 2002.
- Company has an experience of more than 13 years in the field of Pharmaceutical Manufacturing.
- Brooks has established itself in the field of Beta Lactam and specializes in formulations of Penicillin.
- Unit I at Baddi – Himachal Pradesh, India, manufactures Injections (Dry and Liquid), Dry Syrup, Tablets & Eye / Ear Drops .
- Last 10 years Brooks has earned a good reputation in terms of quality manufacturing process.
- Brooks does contract manufacturing for Reputed companies like – Cipla, Zydus, Cadila, Alkem, Intas, Alembic, Wockhardt etc.
- Unit I has achieved a good efficiency and runs almost 100% of it's capacity.
- Brooks is ISO 9001:2008 Certified Company.

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BRIEF COMPANY BACKGROUND

- Brooks is now expanding the operations.
- New Manufacturing facility (Unit II) at Baroda,
- Unit II, Baroda plant designed to meet US-FDA, European GMP Standards, MCC South Africa and TGA Australia.
- Special plans to get approval from WHO Geneva.
- Brooks has plans to enter the World market with supplies from its Indian Manufacturing Facilities.

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BROOKS LABORATORIES LTD. – UNIT I BADDI



BROOKS LABORATORIES LTD. – UNIT I BADDI

- Unit I Located at Baddi, which is very close to Chandigarh. 40 kms from Chandigarh Airport.
- Built on a plot of 5200 sq. meters.
- The Unit manufactures –Dry Injections, Liquid Injections, Dry Syrups, Tablets, and Eye/Ear Drops
- Total Built up area 7000 sq. meters built on Ground Plus 2 Floors.
- Ground Floor houses Stores and Administration offices.
- 1st Floor houses Production blocks for various dosage forms.
- 2nd Floor houses Additional Stores, QC Lab, Microbiology Lab and Document Archives.

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BROOKS LABORATORIES LTD. – UNIT I BADDI

- Independent and Uni - Directional Man and Material flow.
- The plant has well established Analytical laboratory including Microbiology sterility test area.
- The plant adheres to the environmental safety norms.
- The plant has around 300 personnel.
- Plant has WHO approval.
- Products manufactured at Baddi – Unit I are supplied to African countries.

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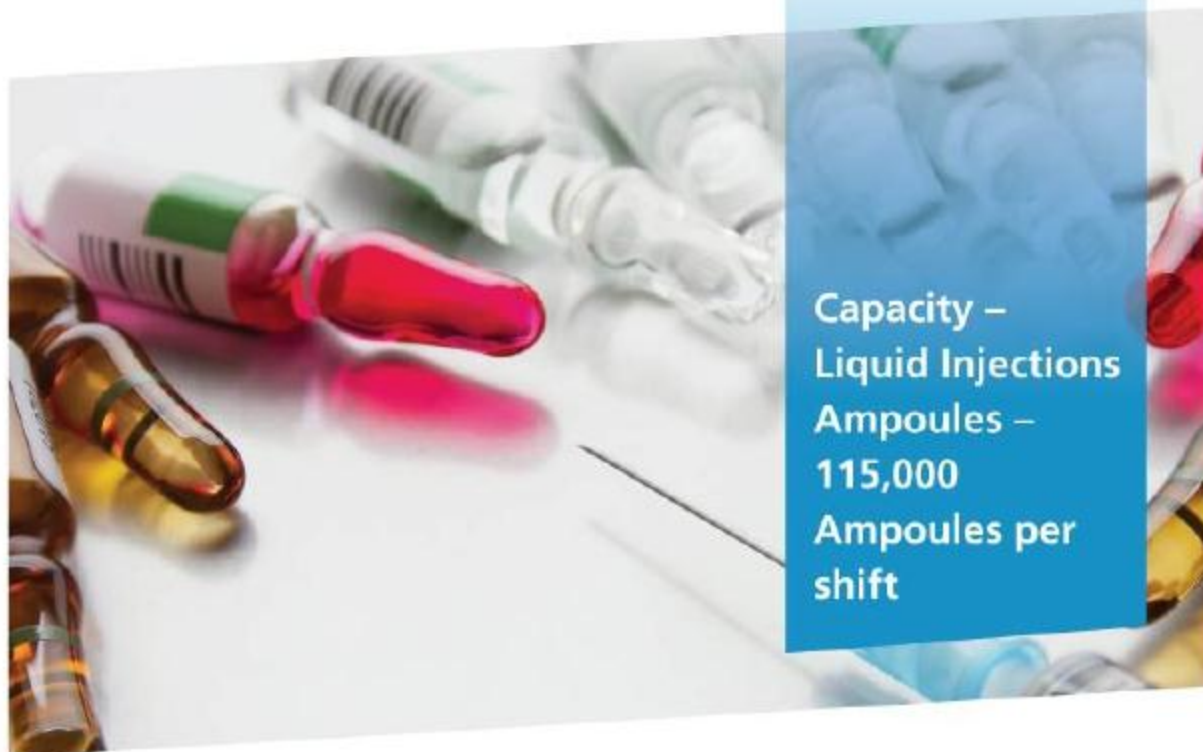
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BROOKS LABORATORIES LTD. – UNIT I BADDI PLANT



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BROOKS LABORATORIES LTD. – UNIT I BADDI PLANT



Capacity –
Liquid Injections
Ampoules –
115,000
Ampoules per
shift

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BROOKS LABORATORIES LTD. – UNIT I BADDI PLANT



Capacity –
Tablets –
3,40000
per shift

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BROOKS LABORATORIES LTD. – UNIT I BADDI PLANT



Capacity –
Eye / Ear Drops –
40000 bottles
per shift



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STABILITY STUDIES

- A Separate and independent highly qualified team is responsible for Stability Studies.
- All 4 Zones Stability Study can be performed as specified by ICH.
- In-house method development for Stability indicative method.

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TESTING FACILITIES

- Independent well equipped Testing Laboratory.
- Adequate well experienced staff having hands-on expertise on Analytical Method Development.
- All major equipment installed viz. HPLC, Osmometer, Liquid Particle counter, Polarimeter, K F Instrument, UV Spectrophotometer etc.
- Separate Air Handling Units for QC and Microbiological Testing Area.

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WATER SYSTEM

- Water System Installed by Metalchem, India.
- The Capacity is 350 Liters / hour

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SITE TRANSFER, CONTRACT MANUFACTURING & TECH. TRANSFER

- Site Transfer, Contract Manufacturing & Tech. Transfer
- Brooks' plant is fully geared in terms of machines and man- power to execute a Site Transfer and long terms supplies of quality products under Supply Agreement.
- The Manufacturing plant can take up contract manufacturing for, Injections – Dry / Liquid, Dry Syrup, Eye/ Ear Drops and Oral Solid Dosage form (Tablets).
- Plant equipped to take on all types of processes and technology.
- Highly qualified team can execute the Site Transfer project with utmost professionalism and achieve desired timelines.

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FORMULATION DEVELOPMENT (R&D)

- Adequate well experienced staff having hands-on expertise in product development.
- Formulation development unit, is the part of R & D center.

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REGULATORY AFFAIRS

- Regulatory department has an expertise to develop Dossiers / ANDAs in CTD / eCTD and ACTD formats for Regulated and Semi Regulated markets.

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BROOKS LABORATORIES LTD. – UNIT II BARODA



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BROOKS LABORATORIES LTD. – UNIT II BARODA PLANT

Highlights of Baroda Plant – Dedicated Beta Lactam Formulation Plant

- Unit II Located at Baroda, which is very close to City and located on Mumbai Ahmedabad Highway.
- The new plant is very well connected to major cities of India by roadways, airways and railways.
- 45 Minutes is the Flying time from Mumbai to Baroda.
- The Plant has abundant supply for Water, Fresh Air and Electricity. Some big and reputed pharma companies like Sun Pharmaceuticals and Alembic have manufacturing units in Baroda.
- Baroda being a Cosmopolitan city has good Educational Institutes hence has got good talent and degree holders for Pharmaceutical Industry. Manpower Selection is easier and good.

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BROOKS LABORATORIES LTD. – UNIT II BARODA PLANT

Highlights of Baroda Plant – Dedicated Beta Lactam Formulation Plant

- The new plant in Baroda is built on a landsread measuring 100000 sq meters.
- The built up Area is 10000 Sq. Meters, built on Ground plus one floor.
- Overall Engineering of plant and Validation consultancy is executed by Specialized Consultant of Designing and Validation
- Independent AHUs with latest technology and HEPA filters (EU14) at supply and return in the entire manufacturing areas. The AHU employs Bag-in / Bag-out system.
- The Plant houses separate areas for Production, Quality Control, Microbiology, Service Area, Utility Area, Water System, Administration Blocks, Laundry Area, Canteen for Factory Staff, Training Centre for Staff and a Separate Formulation Development and Pilot Area.

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Highlights of Baroda Plant – Dedicated Beta Lactam Formulation Plant

- The Plant operations are controlled by BMS (SCADA).
- System has been Designed addressing Data Integrity subject at the highest level in the entire plant operations.
- The plant has been designed for a logical and easy flow of Man and Material.
- The new plant at Baroda has all the features of personnel and environment safety.

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BROOKS LABORATORIES – UNIT II BARODA REGULATORY COMPLIANCE

The Manufacturing facility has been designed and is constructed and built with a view to comply to International cGMP & ICH Guidelines and all machines are 21 CFR compliant. The plant and the quality systems will comply with all international regulations and standards like

- US FDA,
- TGA-Australia,
- UK MHRA,
- EU GMP,
- MCC- South Africa,
- WHO GENEVA and
- Other Regulatory bodies of Latin America like ANVISA-Brazil, INVIMA-Columbia etc.

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TESTING FACILITIES

- Independent well equipped Testing Laboratory.
- Adequate well experienced staff having hands-on expertise on Analytical Method Development.
- All major equipment installed viz. HPLC, GC, Osmometer, Liquid Particle counter, Polarimeter, K F Instrument, UV Spectrophotometer etc.
- Separate Air Handling Units for QC and Microbiological Testing Area.

SITE TRANSFER, CONTRACT MANUFACTURING & TECH. TRANSFER



- Brooks' Baroda plant is fully geared in terms of machines and man-power to execute a Site Transfer and long terms supplies of quality products under Supply Agreement.
- The Manufacturing plant can take up contract manufacturing for, Injections.
- Highly qualified team for Technology Transfer can execute the Site Transfer project with utmost professionalism and achieve desired timelines.

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FORMULATION DEVELOPMENT

- Adequate well experienced staff having hands-on expertise in product development.
- Formulation development is a part of R & D center, which is housed in the new manufacturing facility.
- Separate Analytical Method Validation Cell and Technology Transfer Cell in place.
- Capability to develop Generic equivalence of brands of US & EU markets.

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REGULATORY AFFAIRS

- Regulatory department has an expertise to develop Dossiers / ANDAs in CTD / eCTD and ACTD formats for Regulated and Semi Regulated markets.

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RAW MATERIAL SOURCING

- Identified and Selected API suppliers with established DMF source.
- Company has already signed Long Term Supply Agreements with various suppliers across the globe for Supply of DMF / COS grade API.
- The company is considering only those Vendors which are able to offer Product DMF.

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PRODUCT RANGE

Wide range of products catering to critical care segment.

- Beta Lactam (Penicillin) Tablets and Suspension
- General Injections Dry powder
- General Liquid Injections in Vials and Ampoules.
- Eye & Ear Drops
- Carbapenems

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Sr.No.	Product	Shelf Life	Pack Size
TABLETS			
1	Co-Amoxiclav 625 mg	24Months	7's or 6's ALU-ALU blister/10's Aluminium Strip
2	Co-Amoxiclav 625 LB	24Months	7's or 6's ALU-ALU blister/10's Aluminium Strip
3	Co-Amoxiclav 375 mg	24Months	7's or 6's ALU-ALU blister/10's Aluminium Strip
4	Co-Amoxiclav 375 LB	24Months	7's or 6's ALU-ALU blister/10's Aluminium Strip
5	Co-Amoxiclav 1000 mg	24Months	7's or 6's ALU-ALU blister/10's Aluminium Strip
6	Co-Amoxclav 228.5 DT	24Months	7's or 6's ALU-ALU blister/10's Aluminium Strip
7	Co-Amoxiclav 562.5 mg	24Months	8's ALU-ALU blister
8	Co-Amoxiclav 1125 mg	24Months	8's ALU-ALU blister
ORAL SUSPENSION			
1	Co-Amoxiclav 228.5	24Months	30 ml/60 ml/70 ml/100 ml in a bottle
2	Co-Amoxiclav 156.25	24Months	60 ml/70 ml/ 100 ml in a bottle
3	Co-Amoxiclav 457	24Months	70 ml/100 ml in a bottle
4	Co-Amoxiclav 312.5	24Months	70 ml/100 ml in a bottle
5	Co-Amoxiclav 562.5	24Months	70 ml/100 ml in a bottle
6	Co-Amoxiclav 1125	24Months	70 ml/100 ml in a bottle
7	Amoxicillin+Cloxacillin 250	24Months	70 ml/100 ml in a bottle
8	Amoxicillin 125	24Months	70 ml/100 ml in a bottle
9	Amoxicillin 250	24Months	70 ml/100 ml in a bottle
10	Amoxicillin+Potassium clavulanate drops 1.7 G	24Months	70 ml/100 ml in a bottle
11	Cloxacillin 125	24Months	70 ml/100 ml in a bottle
12	Cloxacillin 250	24Months	70 ml/100 ml in a bottle
13	Flucloxacillin 125	24Months	70 ml/100 ml in a bottle
14	Flucloxacillin 250	24Months	70 ml/100 ml in a bottle

LIQUID INJECTION(GENERAL)

1	Iron sucrose 100mg/5ml	24Months	5 Ampoules with a tray in a monocarton
2	Iron sucrose 50mg/2.5ml	24Months	5 Ampoules with a tray in a monocarton
3	α - β ARTEETHER 150 MG/2 ML	24Months	5 Ampoules with a tray in a monocarton
4	ARTEMETHER INJECTION 80MG	24Months	Ampoule
5	PHENYTOIN SODIUM INJECTION 50MG/ML	24Months	5 Ampoules with a tray in a monocarton
6	DROTAVERINE HYDROCHLORIDE INJECTION 40MG/2ML	24Months	5 Ampoules with a tray in a monocarton
7	TRANEXAMMIC ACID INJECTION 500MG/5ML	24Months	5 Ampoules with a tray in a monocarton
8	INJ.CITICOLINE 500MG/2 ML	24Months	Ampoule
9	INJ.CITICOLINE 4 ML	24Months	Ampoule
10	CLINDAMYCIN INJ 150mg/300mg/600MG	24Months	Ampoule
11	Chloramphenicol Injection 1g	24Months	Ampoule
12	Dobutamine 250mg/5ml	24Months	Ampoule
13	MIDAZOLAM INJECTION 1MG/ML	24Months	5 Ampoules with a tray in a monocarton
14	MIDAZOLAM INJECTION 5MG/ML	24Months	5 Ampoules with a tray in a monocarton
15	NITROGLYCERINE INJECTION 25MG/5ML	24Months	5 Ampoules with a tray in a monocarton
16	NITROGLYCERINE INJECTION 1MG/ML	24Months	5 Ampoules with a tray in a monocarton
17	NITROGLYCERINE INJECTION 50MG/10ML	24Months	5 Ampoules with a tray in a monocarton
18	NORADRENALINE CONCENTRATE 2MG/ML	24Months	Ampoule

19	NETILMICIN SULFATE INJECTION 10 MG/ML	24Months	Ampoule
20	NETILMICIN SULFATE INJECTION 25 MG/ML	24Months	Ampoule
21	NETILMICIN SULFATE INJECTION 50 MG/ML	24Months	Ampoule
22	NETILMICIN SULFATE INJECTION 150 MG/ML	24Months	Ampoule
23	NETILMICIN SULFATE INJECTION 300 MG/ML	24Months	Ampoule
24	NIMODIPINE I.V. INFUSION 10 MG/50ML	24Months	A Vial in a monocarton
25	INJ.N-ACETYLCYSTINE 200MG/ML	24Months	Ampoule
26	INJ.N-ACETYLCYSTINE 1000 MG/5ML	24Months	Ampoule
27	NANDROLONE DECANOATE INJECTION 25 MG/ML	24Months	Ampoule
28	NANDROLONE DECANOATE INJECTION 50 MG/ML	24Months	Ampoule
29	ONDANSETRON HYDROCHLORIDE INJECTION 2MG/ML	24Months	5 or 10 Ampoules with a tray in a monocarton
30	ONDANSETRON HYDROCHLORIDE INJECTION 4MG/ML	24Months	5 or 10 Ampoules with a tray in a monocarton
31	TRAMADOL FOR INJECTION 50MG/ML	24Months	5 Ampoules with a tray in a monocarton
32	TRAMADOL FOR INJECTION 100MG/2ML	24Months	5 Ampoules with a tray in a monocarton
33	DICLOFENAC INJECTION 75MG/3ML	24Months	A Ampoule in a monocarton
34	L-ORNITHINE L- ASAPARTATE INJECTION 5G/10ML	24Months	Ampoule
35	NANDROLONE DECANOATE 25MG/ML	24Months	Ampoule
36	NANDROLONE DECANOATE 50MG/ML	24Months	Ampoule

DRY POWDER INJECTION

1	Artesunate 60 mg with diluent NaCl 0.9% Amp.5ml+1ml Na ₂ CO ₃	24Months	A Vial in a carton with diluent
2	Artesunate 120 mg with diluent 10ml NaCl 0.9% +2ml Na ₂ CO ₃	24Months	A Vial in a carton with diluent
3	Artesunate 30 mg with diluent 10ml NaCl 0.9% +2ml Na ₂ CO ₃	24Months	A Vial in a carton with diluent
4	Artesunate 180 mg with diluent 10ml NaCl 0.9% +2ml Na ₂ CO ₃	24Months	A Vial in a carton with diluent
5	OMEPRAZOLE FOR INJECTION 40 MG	24Months	A Vial in a carton with diluent
6	RABEPRAZOLE FOR INJECTION 20 MG	24Months	A Vial in a carton with diluent
7	PANTOPRAZOLE FOR INJECTION 40 MG	24Months	A Vial in a carton with diluent
8	ACICLOVIR FOR INJECTION 250 MG	24Months	A Vial in a monocarton
9	ACICLOVIR FOR INJECTION 500 MG	24Months	A Vial in a monocarton
10	HYDROCORTISONE SODIUM SUCCINATE INJECTION 100MG	24Months	A Vial in a monocarton
11	METHYLPREDNISOLONE INJECTION 40 MG	24Months	A Vial in a monocarton
12	METHYLPREDNISOLONE FOR INJECTION 125 MG	24Months	A Vial in a monocarton
13	METHYLPREDNISOLONE FOR INJECTION 500 MG	24Months	A Vial in a monocarton
14	METHYLPREDNISOLONE FOR INJECTION 1000 MG	24Months	A Vial in a monocarton
15	VANCOMYCIN 500MG FOR INJECTION	24Months	Vial
16	VANCOMYCIN 1000MG FOR INJECTION	24Months	Vial
17	AZITHROMYCIN 500MG FOR INJECTION	24Months	Vial

EYE/EAR DROPS

1	Gentamicin 0.3%	24Months	5ml in HDPE vial in a monocarton
2	CIPROFLOXACIN EYE DROPS 0.3 % W/V 5 ML	24Months	5ml in HDPE vial in a monocarton
3	CIPROFLOXACIN + DEXAMETHASONE OPHTHALMIC SOLUTION 0.3% W/V + 0.1 % W/V 5ML	24Months	5ml in HDPE vial in a monocarton
4	CIPROFLOXACIN + DEXAMETHASONE EYE /EAR DROPS 0.3% W/V + 0.1 % W/V 10 ML	24Months	5ml in HDPE vial in a monocarton
5	TOBRAMYCIN OPHTHALMIC SOLUTION USP 0.3 % W/V 5 ML	24Months	5ml in HDPE vial in a monocarton
6	TOBRAMYCIN OPHTHALMIC SOLUTION USP 0.3 % W/V 10ML	24Months	5ml in HDPE vial in a monocarton
7	TOBRAMYCIN + DEXAMETHASONE OPHTHALMIC SOLUTION 0.3% W/V + 0.1 % W/V 5ML	24Months	5ml in HDPE vial in a monocarton
8	OFLOXACIN OPHTHALMIC SOLUTION IP 0.3 % W/V 5 ML	24Months	5ml in HDPE vial in a monocarton
9	OFLOXACIN OPHTHALMIC SOLUTION IP 0.3 % W/V 10 ML	24Months	5ml in HDPE vial in a monocarton
10	TROPICAMIDE 0.8% + PHENYLEPHRINE 5 % 10 ML	24Months	5ml in HDPE vial in a monocarton
11	CLOTRIMAZOLE 1 % W/V & LIGNOCAINE HCL 2 % W/V 20 MG/ML	24Months	5ml in HDPE vial in a monocarton
12	BIMATOPROST EYE DROP 0.03% 10 ML	24Months	5ml in HDPE vial in a monocarton
13	HOMATROPINE EYE DROP 2% 10 ML	24Months	5ml in HDPE vial in a monocarton
14	LIDOCAINE 1.73% W/V + OFLOXACIN 0.3% W/V 10 ML	24Months	5ml in HDPE vial in a monocarton
15	PHENYLEPHERINE EYE DROP 5% W/V 5ML	24Months	5ml in HDPE vial in a monocarton
16	SALINE NASAL DROP 0.65% W/V 5ML	24Months	5ml in HDPE vial in a monocarton
17	TIMOLOL EYE DROP 0.5 % 5ML	24Months	5ml in HDPE vial in a monocarton
18	ATROPINE SULPHATE EYE DROP 1 % W/V 10 ML	24Months	5ml in HDPE vial in a monocarton
19	CARBOXYMETHYLCELLULOSE SODIUM (CMC) 0.5 % W/V 5ML	24Months	5ml in HDPE vial in a monocarton
20	GATIFLOXACIN 0.3 % + DEXAMETHASONE 0.1 % 10 ML	24Months	5ml in HDPE vial in a monocarton
21	POLYVINYL POVIDONE 5 % W/V 5ML	24Months	5ml in HDPE vial in a monocarton
22	PREDNISOLONE ACETATE 1 % W/V 10 ML	24Months	5ml in HDPE vial in a monocarton
	PREDNISOLONE ACETATE 0.12 % W/V	24Months	5ml in HDPE vial in a monocarton
23	TROPICAMIDE 0.8 % I P 10 ML	24Months	5ml in HDPE vial in a monocarton
24	CLOTRIMAZOLE 1 % W/V 10ML	24Months	5ml in HDPE vial in a monocarton
25	TIMOLOL MALEATE 0.0025 & 0.005 5ML	24Months	5ml in HDPE vial in a monocarton

26	TROPICAMIDE 0.5% 5ML	24Months	5ml in HDPE vial in a monocarton
27	XYLOMETAZOLINE 0.05% 10ML	24Months	5ml in HDPE vial in a monocarton
28	ATROPINE SULPHATE 0.5% & 1 % 5ML	24Months	5ml in HDPE vial in a monocarton
29	HYDROXYL PROPYL METHYL CELLULOSE 0.3 % 5ML	24Months	5ml in HDPE vial in a monocarton
30	BETAXOLOL HCL 0.5 % 5ML	24Months	5ml in HDPE vial in a monocarton
31	TRAVOPROST 0.004% 3ML	24Months	5ml in HDPE vial in a monocarton
32	BRIMONIDINE TARTRATE 0.15% & TIMOLOL MALEATE 0.5% 5ML	24Months	5ml in HDPE vial in a monocarton
33	BRIMONIDINE 0.2 % 5ML	24Months	5ml in HDPE vial in a monocarton
34	FLUCONAZOLE 0.30 % 5ML	24Months	5ml in HDPE vial in a monocarton
35	FLUOROMETHALONE ACETATE 0.10 % 5ML	24Months	5ml in HDPE vial in a monocarton
36	FLURBIPROFEN 0.03% 5ML	24Months	5ml in HDPE vial in a monocarton
37	NATAMYCIN 5% 5ML	24Months	5ml in HDPE vial in a monocarton
38	CHLORAMPHENICOL 5.0% W/V BECLOMETHASONEDIPROPIONATE 0.025% W/V CLOTRIMAZOLE 1.0% W/V LIGNOCAINE HYDROCHLORIDE 2.0% W/V 10ML	24Months	5ml in HDPE vial in a monocarton
39	ATROPINE SULPHATE 1% W/V CHLOROBUTOL 0.5% W/V	24Months	5ml in HDPE vial in a monocarton
40	CHLORAMPHENICOL 0.5% W/V HYDROXYPROPYLMETHYLCELLULOSE 0.25% W/V PHENYL MERCURIC NITRATE 0.002% W/V 10ML	24Months	5ml in HDPE vial in a monocarton
41	CHLORAMPHENICOL 1.0% W/V DEXAMETHASONE 0.1% W/V PHENYL MERCURIC NITRATE 0.002% W/V 10ML	24Months	5ml in HDPE vial in a monocarton

BETA LACTAM DRY POWDER (PENICILLIN) INJECTIONS

1	AMOXICILLIN + CLAVULANATE POTASSIUM FOR INJECTION 150 / 300 / 600 / 1200 MG	24Months	A Vial in a monocarton
2	PIPERACILLIN + TAZOBACTAM FOR INJECTION 1.125 GM	24Months	A Vial in a monocarton
3	PIPERACILLIN + TAZOBACTAM FOR INJECTION 2.25 GM	24Months	A Vial in a monocarton
4	PIPERACILLIN + TAZOBACTAM FOR INJECTION 4.5 GM	24Months	A Vial in a monocarton
5	AMOXICILLIN FOR INJECTIONS 250 / 500 / 1000 MG	24Months	A Vial in a monocarton
6	AMOXICILLIN + CLOXACILLIN FOR INJECTION 250 / 500 / 1000 MG	24Months	A Vial in a monocarton
7	AMPICILLIN FOR INJECTION 250 / 500 / 1000 MG	24Months	A Vial in a monocarton
8	AMPICILLIN + SULBACTAM 1500 MG	24Months	A Vial in a monocarton
9	AMPICILLIN + CLOXACILLIN FOR INJECTION 250 / 500 / 1000 MG	24Months	A Vial in a monocarton
10	CLOXACILLIN FOR INJECTION 250 / 500 / 1000 MG	24Months	A Vial in a monocarton
11	IMIPENEM + CILASTATIN FOR INJECTION 500 MG	24Months	A Vial in a monocarton
12	IMIPENEM + CILASTATIN FOR INJECTION 1000 MG	24Months	A Vial in a monocarton
13	MEROPENEM FOR INJECTION 125MG	24Months	A Vial in a monocarton
14	MEROPENEM FOR INJECTION 250 MG	24Months	A Vial in a monocarton
15	MEROPENEM FOR INJECTION 500 MG	24Months	A Vial in a monocarton
16	MEROPENEM FOR INJECTION 1000 MG	24Months	A Vial in a monocarton
17	MEROPENEM + SULBACTAM 1500 MG	24Months	A Vial in a monocarton
18	MEROPENEM + TAZOBACTAM 1500 MG	24Months	A Vial in a monocarton
19	DORIPENEM 500 / 1000 MG	24Months	A Vial in a monocarton

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