MEDICINES CONTROL COUNCIL

Licence Number: 0000000236

LICENCE TO MANUFACTURE MEDICINES

In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965

This licence is granted to:

Licence Holder
Pharma-Q (Pty) Ltd
50 Commando Road, Industria West , Johannesburg , 2093

On the following terms and conditions:

The licence holder and the persons described and named in Annexure 1 shall at all times ensure that all medicines manufactured in this facility, irrespective of its registration status, comply with all the provisions of the Medicines and Related Substances Act, 1965, as amended and in particular with sections 14, 18, 18A, 18B, 18C, 19, 20, 22A, 22C, 22G, 33, Regulations 8, 9, 10, 12, 13, 37, 40, 43, 44, 45, 48 and all relevant Medicines Control Council Guidelines.

This facility is authorized to perform the manufacturing activities depicted in Annexure 1 to this licence.

REGISTRAR OF MEDICINES

ISSUE DATE: 23 November 2009

EXPIRY DATE: 23 November 2014

ANNEXURE 1 *0000000236.-.13*

AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES		
1.MANUFACTURING ACTIVITIES	YES	NO
Sterile, Non-Biological Manufacture(includes filling, but not cartoning or labelling)		
Large volume parenteral products	YES	
Small volume parenteral products	YES	
Other sterile dosage forms: Eye Drops, Eye Ointment & Wound Dressing	YES	
Non-Sterile Manufacture		
Tablets	YES	
Capsules	YES	
Liquids	YES	
Semi-solids	YES	
Suppositories	YES	
Other non-sterile dosage forms: -		NO
Biological Manufacture		
Vaccines		NO
Sera and other immunologicals		NO
Blood and other blood products		NO
Other biological products: -		NO
Medical Gas Manufacture		NO
Radioactive Medicines Manufacture		NO
Complementary Medicines Manufacture	YES	
2.PACKAGING ACTIVITIES		
Packaging of bulk product and labelling	YES	
Re-labelling or redressing	YES	
Cartoning or secondary packaging	YES	
3.TESTING ACTIVITIES		
Analytical	YES	
Microbiological	YES	
Sterility	YES	
Stability	YES	
Animal		NO
Other Testing Activities: false		NO
Other Testing Activities Details: -		
4.DISTRIBUTION ACTIVITIES		
Bulk distribution to wholesale pharmacies	YES	
Fine distribution to retail pharmacies and others		NO
5.MATERIALS HANDLED OR STORED AT THIS SITE		
Penicillins		NO
Cephlosporins		NO
Hormones (Finished Packed Products Only)	YES	
Cytostatics/Cytotoxics (Finished Packed Products Only)	YES	
Bulk Pesticides, Herbicides or Rodenticides		NO
Potent Steroids (Finished Packed Products Only)	YES	
Other potent, toxic, sensitising or hazardous materials : -		NO
6. IMPORT		NO
7. EXPORT	YES	
Specific Products Exported: -		

8. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATIONS ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER.

Responsible Pharmacist	Head of Production	Quality Control Person
Dan Breet	Yusuf Patel	Paola Cenizo
BSc Pharm	B.Pharm	NDT Microbiology

9. PARTICULARS OF THE NATURAL PERSON RESPONSIBLE TO THE MEDICINES CONTROL COUNCIL TO ENSURE COMPLIANCE WITH THE MEDICINES AND RELATED SUBSTANCES ACT, 1965.

Responsible Person	DESIGNATION	RESIDENTIAL ADDRESS
Mr D.E. Breet	Managing Director and Responsible Pharmacist	50 Commando Road, Industria West, Johannesburg, 2093
BSc Pharm		

10. LICENCE SPECIFIC CONDITIONS

1. The holder of the licence shall conduct all manufacturing, wholesaling or distribution operations in respect of those medicines for which a registration certificate has been obtained, so as to ensure that the medicine shall conform to the standards of quality, strength and purity applicable to them in accordance with the specification made by the person to whose order they are manufactured, wholesale or distributed or the specifications under which the medicine are sold or supplied.
2. Medicine for export for which a registration certificate has not been obtained from the Medicines Control Council may not be exported without the relevant "Certificate of a Pharmaceutical Product" or alternatively a "Licensing Status of a Pharmaceutical Product" issued by the Council in terms of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce.

11. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)