MEDICINES CONTROL COUNCIL

License number: 0000000511

LICENSE TO MANUFACTURE MEDICINES

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

This license is granted to:

License Holder
Contractum (Pty) Ltd
7 Macintyre Street, North Doorenfontein , Johannesburg , 2023

On the following terms and conditions:

The license 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 license.

H.Z. ZOKUFA

REGISTRAR OF MEDICINES

ISSUE DATE: **05 August 2005**

EXPIRY DATE: **05 August 2010**

ANNEXURE 1 *0000000511.-.3*

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		NO
Small volume parenteral products		NO
Other sterile dosage forms: -		NO
Non-Sterile Manufacture		
Tablets		NO
Capsules		NO
Liquids		NO
Semi-solids		NO
Suppositories		NO
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		**NO**
2.PACKAGING ACTIVITIES		
Packaging of bulk product and labelling	YES	
Re-labelling or redressing	YES	
Cartoning or secondary packaging	YES	
3.TESTING ACTIVITIES		
Analytical		NO
Microbiological		NO
Sterility		NO
Stability		NO
Animal		NO
Other Testing Activities: -		
4.DISTRIBUTION ACTIVITIES		
Bulk distribution to wholesale pharmacies		NO
Fine distribution to retail pharmacies and others		NO
5.MATERIALS HANDLED OR STORED AT THIS SITE		
Penicillins		NO
Cephlosporins		NO
Hormones		NO
Cytostatics/Cytotoxics		NO
Bulk Pesticides, Herbicides or Rodenticides		NO
Potent Steroids		NO
Other potent, toxic, sensitising or hazardous materials : -		NO
6. IMPORT		**NO**
7. EXPORT		**NO**
Specific Products Exported: -		

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

Responsible Pharmacist	Production Pharmacist	Quality Control Person
Merle Rakusin	Anthony Willows	Ivan Skuy
Dip.Pharm	-	Net Technica Diploma

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
Peter Viljoen	Managing Director	7 Macintyre Street, North Doorenfontein, Johannesburg, 2023
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10. LICENSE SPECIFIC CONDITIONS

1. The holder of the license 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 LICENSE SPECIFIC CONDITIONS (IF REQUIRED)

The manufacture should package complementary medicines only.

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