Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 14420 Insp GMP 14420/5065-0005

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : LACSA (PTY) LIMITED

Site address : LACSA (PTY) LIMITED, 72 BALLANTRAE ROAD, MEREBANK, DURBAN, 4052, SOUTH AFRICA
Is an active substance manufacturer that has been inspected in accordance with Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 16/09/2010, it is considered that it complies with:

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

- [2000008519] LACTULOSE SOLUTION

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

LACTULOSE SOLUTION

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

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3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
				Bulk Lactulose only

04/01/2011	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Tel : Confidential

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