Laboratoires MERCK SHARP & DOHME-CHIBRET
SAS au capital de 21.520.000 Euros
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MSD

CERTIFICATE OF ANALYSIS

PRODUCT	Losartan Potassium
DATE OF MANUFACTURE	30 April 2014
RETEST DATE	30 April 2016
BATCH NUMBER	GON-090
BATCH SIZE	849 kg

Test	Specification	Result
Characteristics	White to off-white free flowing crystalline powder.	Conforms
Assay (HPLC, Weight %)	98.5 - 101.0%†	100.0%
Chromatographic Purity (HPLC, Area %):		
Individual Impurities	Max. 0.2%	<0.05%
Total Impurities	Max. 0.5%	<0.05%
Residual Solvents		
Total (cyclohexane + 2-propanol)	Max. 0.3%	0.0%
Water	Max. 0.5%	0.2%
Heavy Metals	Max 10 ppm	Conforms
Identity:		
A. Losartan Potassium (IR)	The sample exhibits maxima only at the same wavelengths as that of an authentic specimen similarly treated.	Conforms
B. Losartan Potassium (UV)	The sample exhibits maxima only at the same wavelengths as that of the standard. The respective absorptivities do not differ by more than 3.0%.	Conforms
C. Potassium (Flame Test)	Violet color observed.	Conforms
Particle Size (Microtrac)	Mean Volume: 19-92 µm d_{10}: 8 - 39 d_{90}: 41 - 146	46 µm 17 µm 84 µm
Bulk Density (loose)	0.33 – 0.52 g/mL	0.41 mg/mL
Color of Solution	Max. 10	1
Clarity of Solution	Max. 5 NTU	0 NTU

† Water and solvent free basis

Prepared by: _____ Date 21st Aug 2014
G. Gourgouillon
QA Manager

Approved by: _____ Date Aug 21st, 2014
J.M. Vignon
QA Engineer

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