

Certificate of Analysis

LEVODOPA

Material no:	10018770	Date of issue:	11-Mar-2009
Batch no:	AX160	Date of Manufacture:	17-Nov-2008
Analysis no:	07406929		
		Batch size:	1950.000 KG
Place of Manufacture / Supplier: DAIICHI SANKYO CHEMICAL INDUSTRIES LTD., JAPAN			

Test	Result
Appearance	crystalline powder
Colour	white
Identity	corresponds
Clarity of a sol. 4 perc. (m/V)	
in HCl 1M (FTU)	0.7 FTU
in HCl 1M	clear
Colour of a sol. 4 perc. (m/V)	
in HCl 1M	B9 Ph. Eur.
pH of a susp. 1 perc. (m/V)	
in H ₂ O	5.8
Spec.op.rot.(dried)589nm,25°,c=2.0,L=1dm	
in HCl 1N / methenamine solution	-163 °
Loss on drying	0.1 %
Sulphated ash	<0.1 %
Heavy metals	<10 ppm
Related substances Liquidchromatography	
D-Dopa	0.11 %
3-(3,4,6-Trihydroxyphenyl)-alanine	<0.05 %
L-Tyrosine	<0.05 %
3-Methoxytyrosine	nd<0.05 %
Veratrylglycine	nd<0.05 %
Impurity	
Other related subs.	each <0.05 %
Sum of other related substances	0.00 %
Sum of all related substances	
(without D-Dopa)	0.00 %

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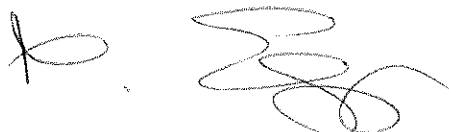
Batch size: 1950.000 KG

Place of Manufacture / Supplier: DAIICHI SANKYO CHEMICAL INDUSTRIES LTD., JAPAN

Test	Result
Assay (dried)	
Titrimetric	99.9 %
Liquid chromatographic	100.0 %

This batch was analysed and released on Feb 27, 2009 by our authorised Quality Control and Assurance Department and was found to meet the specifications.

F. HOFFMANN-LA ROCHE LTD



F. Hoffmann-La Roche Ltd.
Basel, Switzerland
Dr. Notker Egger

Certificate of Analysis

BENSERAZIDE HYDROCHLORIDE

Material no:	10019457	Date of issue:	21-May-2010
Batch no:	SI10048059	Date of Manufacture:	22-Apr-2010
Analysis no:	07464409		
		Batch size:	323.320 KG
Place of Manufacture / Supplier: DSM NUTRITIONAL PRODUCTS, SISSELN, SWITZERLAND			

Test	Result
Appearance	powder with small grains
Colour	almost white
Identity	corresponds
Clarity of a sol. 1 perc. (m/V)	
in H ₂ O	clear
in H ₂ O (FTU)	0.4 FTU
Colour of a sol. 1 perc. (m/V)	
in H ₂ O	BY7 Ph. Eur.
pH of a sol. 1 perc. (m/V)	
in H ₂ O	4.5
Optical rot.	
589 nm , 20°C , c=1.0 (m/V) in H ₂ O	0.00 °
UV-absorption in 0.1N HCl	
Max. wave length	271.7 nm
A (1 perc.,1cm)	32.7
A (1 perc.,1cm) at 291nm	1.74
VIS-absorption in H ₂ O	
A (1 perc.,1cm) at 430nm	0.000
Water	0.7 %
Residual solvent ethanol	1886 ppm
Residual solvent	
methanol	nd<100 ppm
Residual solvent cyclohexane	nd<100 ppm
Sulphated ash	0.01 %
Heavy metals	<20 ppm
Related subs.	



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BENSERAZIDE HYDROCHLORIDE

Material no: 10019457 Date of issue: 21-May-2010
Batch no: SI10048059 Date of Manufacture: 22-Apr-2010
Analysis no: 07464409
Batch size: 323.320 KG
Place of Manufacture / Supplier: DSM NUTRITIONAL PRODUCTS, SISSELN, SWITZERLAND

Test	Result
RO0041419-000	0.11 %
RO0045066-001	nd<0.05 %
RO0081580-001	0.28 %
Not identified impurities	
Unknown Impurities	each<0.05 %
Total all imp without RO0041419-000	0.3 %
Thin layer chromatography	passes test
Assay	
(anhydrous and solvent-free)	99.8 %

This batch was analysed and released on May 20, 2010 by our authorised Quality Control and Assurance Department and was found to meet the specifications.

F. HOFFMANN-LA ROCHE LTD

F. Hoffmann-La Roche Ltd.

Basel, Switzerland
Dr. Markus Boutellier