



PROPARTS S.A.

Office

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R&D Laboratories

Via Carvina 5 - Centro Carvina, CH-6807 Taverne, Switzerland
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CERTIFICATE OF ANALYSIS

Product:

SPA-S-843 - drug substance only for diagnostic use

Batch:

DSD-aa-zz

Analysis n°:

Date: dd.mm.yyyy

Determinations	Specifications	Results
<u>Appearance</u>	Yellow freeze dried powder	satisfactory
<u>Solubility</u>	Soluble in water	conform
<u>Identify test (HPLC)</u>	Conform to standard	satisfactory
<u>pH (1% aqueous solution)</u>	4.6 – 5.6	
<u>Loss on drying (4h vacuum, +60°C)</u>	≤ 4.0%	%
<u>Purity by HPLC</u>		
Partricin A derivate	≥ 90.0%	%
Trans isomer derivate (impurity E)	≤ 5.0%	%
Impurity B	≤ 2.5%	%
<u>Residual solvent</u>		
Methanol	3000 ppm	 ppm
Methylene chloride	300 ppm	 ppm
Acetonitrile	410 ppm	 ppm

Manufacturing date: mm.yyyy

Retest date: 4 years

Notes:

Storage: preserve in well closed container in dark under nitrogen in the freezer.

Conclusion:



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