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CERTIFICATE OF ANALYSIS

Work Order Number:
7011005

Date Reported: 2/1/2017
Date Received: 01/12/2017
Customer #: AS966
Customer P.O.: CC on file

CERTIFICATE OF ANALYSIS

PPAP HCL

(1-Phenyl-2-propyl-aminopentane HCL)

Material Lot#: 20161219 Manufacture Date: 04/06/2016
Country of Origin: China Retesting Date: 04/05/2018

Analysis Claim Result
Assay ≥98% 98%

Test Claim Result
Appearance: White Powder Complies
Solubility: Soluble in glycerol and water. Complies

Impurity Test Claim Result
Impurity A: ≤0.1% Not Detected
H-NMR Analysis: Conforms to Standard Complies
HPLC Assay: ≥98% 98.0%

Supplemental Testing

Sample#: 7011005-01
Description: PPAP HCL / 20161219
Date and Time Sampled: 1/11/2017 0:00
Analysis Performed by: Microbac - HSR

Food Chemistry Analysis	Method	Qualifier	Result	Units	Date	Time	Tech
Residual Solvents	HHGC-MS		See Attached	No Units	2/01/17	0:00	HSR
Analysis Performed by: Microbac Laboratories Inc., Pittsburgh Division							
Food Chemistry Analysis	Method	Qualifier	Result	Units	Date	Time	Tech
Raw Spectrum Data	ESI-MS		See Below	No Units	1/27/17	16:17	MMS
NMR-C13	NMR		See Below	No Units	1/27/17	16:17	MMS
NMR-1H	NMR		See Below	No Units	1/27/17	16:17	MMS

Per Client agreement, NMR-1H, NMR-C13 and ESI-MS analysis subcontracted to UMBC MCAC.

Raw Spectra for NMR-1H, NMR-C13 and ESI-MS attached.

HHGCMS performed at Microbac Hauser Division.

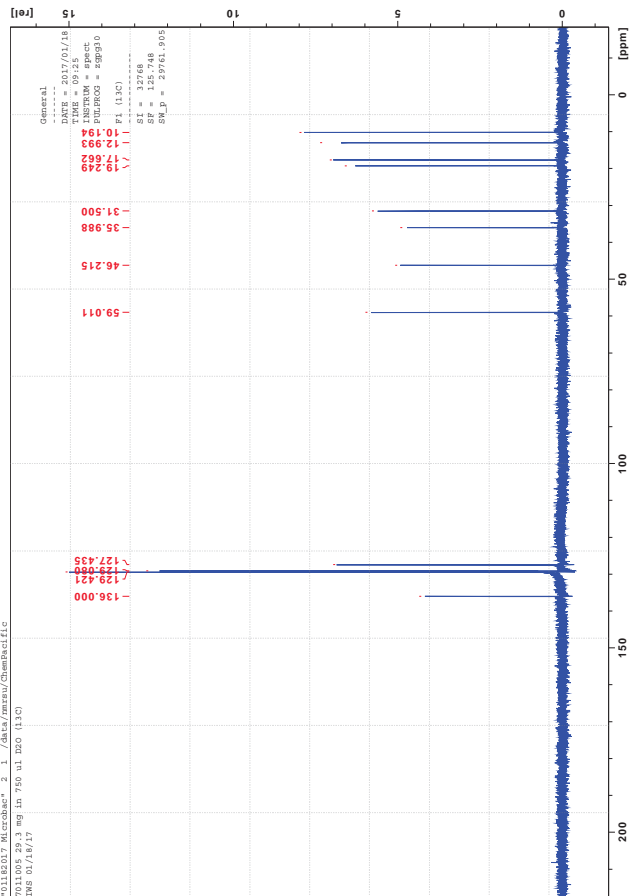
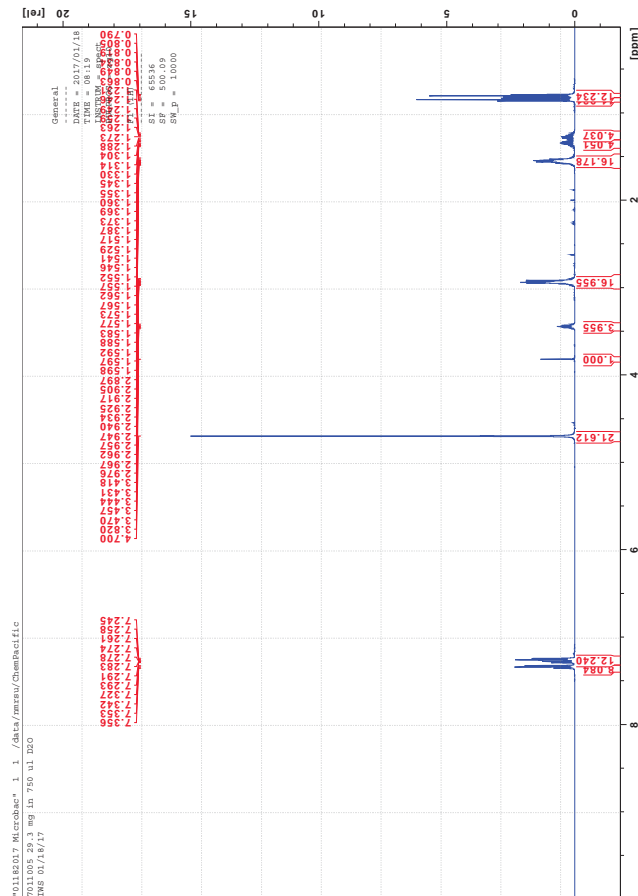
Test report attached.

The data and other information contained in this report, as well as any accompanying documents, represent only the sample(s) analyzed. They are reported upon the condition that they are not to be reproduced wholly or in part for advertising or other purposes without the written approval from the laboratory.

Microbac Laboratories, Inc.

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PPAP HCL should be stored at or below room temperature in a tightly sealed durable container.
PPAP HCL should not be stored in metal or stainless steel containers.
PPAP HCL should be protected from excess heat, direct sunlight, excess humidity and moisture.
PPAP HCL has a stable shelf life of 3 years from the date of manufacture when properly stored.



TEST REPORT

CLIENT: Microbac Pittsburgh
100 Marshall Drive
Warrendale, PA 15086

Attention: Claudia Boerner

SAMPLES: One sample was delivered to Microbac Laboratories, Inc. on January 16, 2017. The sample was labeled "7011005-01."

TESTING: The sample was analyzed by Heated Headspace Gas Chromatography/Mass Spectrometry (HHGCMS). A known weight was diluted in water and transferred to a headspace vial and heated to 80°C for 45min prior to injection into a GCMS instrument with a Restek Rxi-624sil MS (60M, 0.25mmID, 1.4um df), and a Hewlett Packard 5972 Series Mass Selective Detector. Mass spec peaks were identified in SIM mode with comparison to the prepared standards.

RESULTS: See Tables 1 and 2.

Table 1. Class 1 Solvents

Class 1 solvents in pharmaceutical products (solvents that should be avoided)		
Solvent	Concentration limit (ppm)	Concentration in sample
Benzene	2	ND
Carbon Tetrachloride	4	ND
1,2-dichloroethane	5	ND
1,1-dichloroethene	8	ND
1,1,1-trichloroethane	10	ND

REPORT WRITTEN BY:

DATA REVIEWED AND REPORT REVIEWED BY:

Jill Fletcher
Chemistry Department Manager

Russ Willacker
Forensics Department Manager

For any feedback concerning our services, please contact the Managing Director of the Hauser Division or Robert Crookston, COO and President, at robert.crookston@microbac.com and Cabot Earle, CEO, at cabot.earle@microbac.com. This report applies only to the sample(s) tested or analyzed. This report may be copied only in its entirety, unless prior written consent has been granted by an authorized agent of the Hauser Division of Microbac Laboratories, Inc.

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Table 2. Class 2 Solvents – Mix A, B, and C

Class 2 solvents in pharmaceutical products		
Solvent	Concentration limit (ppm)	Concentration in sample
Acetonitrile	410	ND
Chlorobenzene	360	ND
Chloroform	60	ND
Cyclohexane	3880	ND
Cis 1,2-dichloroethene	1870	ND
Dichloromethane	600	ND
1,2-dimethoxyethane	100	ND
N,N-dimethylacetamide	1090	ND
N,N-dimethylformamide	880	ND
1,2-dioxane	380	ND
2-ethoxyethanol	160	ND
Ethylene glycol	620	ND
Formamide	220	ND
Hexane	290	ND
Methanol	3000	ND
2-methoxyethanol	50	ND
Methylbutyl ketone	50	ND
Methylcyclohexane	1180	ND
N-methylpyrrolidone	4840	ND
Nitromethane	50	ND
Pyridine	200	ND
Suffolane	160	ND
Tetralin	100	ND
Toluene	890	ND
1,1,2-trichloroethene	80	ND
Xylene	2170	ND
Methylene Chloride	600	<500
Chloroform	60	ND
Benzene	2	ND
Trichloroethylene	80	ND
1,4-dioxane	380	ND

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