PROCOS S.p.A. Via Matteotti n. 249 - 28062 CAMERI - NOVARA - ITALY
Phone: ++39-0321-642211 - Fax: ++39-0321-642219

E-mail: procos@procos.it
www.procos.it

lote: C080713

Sample Nr.	210031616	Manufacturing Date	13/05/2013	Retest Date	13/05/2018

Code	Lot/Batch	Description	Product Class
09MM	0000194547	PHENELZINE SULFATE USP	FERT CLASSE A

Tests	Results	Units	Specification
CHARACTERS			
APPEARANCE	Complies to specification	-	White to off-white crystalline powder
SOLUBILITY			
SOLUBILITY	Complies to specification	-	Complies to Note A
C-USP<197> - C-EP 2.2.24.			
IR IDENTIFICATION	Complies to specification	-	Complies with Ref.STD
IDENTIFICATION B 09 C-USP			
COLOUR TEST	Complies to specification	-	Complies with c-USP
C-USP<191> - C-EP 2.3.1. METHOD A (SUL)			
SULFATES IDENTIFICATION	Complies to specification	-	Complies to c-USP - c-EP
C-USP<741>			
MELTING RANGE	Complies to specification	-	Between 164°C and 168°C
MELTING POINT	167	°C	About 166°C
C-USP<791> - C-EP 2.2.3.			
pH	1.7	pH	Between 1.4 and 1.9
HPLC 09 C-USP			
Hydrazine	Not Detected	%	NMT 0.1%
TLC 09 C-USP			
Ordinary impurities	Complies to specification	-	Complies with c-USP
RELATED SUBSTANCES HPLC 09-II			
2-Phenylethanol	0.01	%	NMT 0.1%
Phenylethylamine	0.02	%	NMT 0.1%
Any impurity	Not Detected	%	NMT 0.10%
Total impurities	0.03	%	NMT 0.5%
HPLC 09T C-USP			
ASSAY (dried basis)	100.0	%	Between 98.0% and 102.0%
RESIDUAL SOLVENTS GC 09SR			
CHLOROFORM	0	ppm	NMT 60 ppm
ETHANOL	5	ppm	NMT 5000 ppm

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09MM	0000194547	PHENELZINE SULFATE USP	FERT CLASSE A

Tests	Results	Units	Specification
METHANOL	7	ppm	NMT 3000 ppm
C-USP<231>METHOD II - C-EP 2.4.8.			
HEAVY METALS	Complies to specification	-	NMT 20 ppm
C-USP<281> - C-EP 2.4.14.			
RESIDUE ON IGNITION/SULPHATED ASH	0.01	%	NMT 0.1%
LOD			
LOSS ON DRYING	0.14	%	NMT 1.0%

Notes

FERT	Pharmaceutical Active Ingredient
USP/PROCOS CLASS	PRODUCT COMPLIES WITH cUSP, PROCOS SPECIFICATIONS
A: SOLUBILITY (PHENELZINE SULFATE)	Freely soluble in water, practically insoluble in alcohol, in chloroform and in ether.

Lot Released : Complies with all specifications of the testing instruction and with GMP standard.

Cameri, June 24, 2013

Procos Spa
Quality Control

Authorized Person
X ROBERTO SALGHETTI DRIOLI

Metapharmaceutical

25/06/13