



Certificate of Analysis

Product name **PIPAMPERONE DIHYDROCHLORIDE**

Product Code C4850
Batch Number 2150003347
Batch Size 337,000 KG

Manufacturing date 26/11/2021
Re-test date 18/11/2026
Certificate Nr. 040000046723

<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
DESCRIPTION: white or almost white crystalline powder	complies		complies
IDENTIFICATION (IR)	complies		complies
IDENTIFICATION (UV)	complies		complies
IDENTIFICATION (chlorides)	complies		complies
APPEARANCE OF SOLUTION: a 12.0% w/v solution in water is clear	complies		complies
WATER	$\leq 2,0$	%	0,14
SULPHATED ASH	$\leq 0,1$	%	0,00
Palladium	≤ 5	ppm	< LOQ (0,7)
Impurity 1 (rel.sub. HPLC)	$\leq 0,15$	%	0,06
Impurity 2 (rel.sub. HPLC)	$\leq 0,15$	%	< Disregard limit (0,02)
Impurity 3 (rel.sub. HPLC)	$\leq 0,15$	%	< Disregard limit (0,02)
Any other Impurity (rel.sub. HPLC)	$\leq 0,10$	%	< Disregard limit (0,02)
Sum of all Impurities (rel.sub. HPLC)	$\leq 0,50$	%	0,06
RESIDUAL SOLVENTS:	-		-
-Acetone (GC)	≤ 1000	ppm	343
-Methylisobutylketone (GC)	≤ 1000	ppm	< LOQ (50)
ASSAY : with reference to the anhydrous and solvent-free substance (pot.)	99,0 - 101,0	%	100,4
4-chloro-4'-fluoro-butyrophenone (rel.sub.HPLC) $\leq 2,5$ ppm	$\leq 2,5$ ppm		$\leq 2,5$ ppm
4-chloro-butyrophenone (rel.sub.HPLC) $\leq 2,5$ ppm	$\leq 2,5$ ppm		$\leq 2,5$ ppm
4-chloro-2'-fluoro-butyrophenone (rel.sub.HPLC) $\leq 2,5$ ppm	$\leq 2,5$ ppm		$\leq 2,5$ ppm

Solubility: freely soluble in water; soluble in methanol; sparingly soluble in chloroform.

Andrea Rebora QC Manager Approved December 09, 2021	Agnese Messina Qualified Person Released December 09, 2021
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Specification

M.U.

Result

Complies with: in-house specs

This material has been prepared following the current Good Manufacturing Practice (cGMP).

Andrea Rebora

QC Manager

Approved December 09, 2021

Agnese Messina

Qualified Person

Released December 09, 2021

Capitale Sociale € 40.000.000 i.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100157 - R.E.A. Milano n. 1201640

Società Capogruppo P. & R. Principi Attivi S.p.A

Società con Socio unico - Strada Rivoltana km. 6/7 - 20053 Rodano (MI) ITALY - Capitale sociale € 1.200.000 i.v.- C.F. e P.IVA 11155530964

Modello: C4850-STD / 1

December 09, 2021

This CoA is electronically dated and signed by authorized personnel of the Quality Unit December 09, 2021

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