



Inspiring Science™

SAFC®

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www.safglobal.com**CERTIFICATE OF ANALYSIS**
CLOMIPRAMINE HYDROCHLORIDE**BP 2014/EP 8th Edition**

Lot No.:

B-CLHFD 129-423

Weight:

1.0kg

Date:

17th Jul 14

SPECIFICATION	RESULT
1. CHARACTERISTICS: A white or slightly yellow, crystalline powder; slightly hygroscopic. Very soluble in water, freely soluble in dichloromethane. Soluble in Ethanol (96%).	A white crystalline powder; slightly hygroscopic. Very soluble in water freely soluble in dichloromethane. Soluble in Ethanol (96%).
2. IDENTIFICATION: B. Infra Red Spectrum. E. Chloride Test.	Conforms. Conforms.
3. pH: Limit: 3.5 to 5.0	4.3
4. APPEARANCE OF SOLUTION: Limit: Solution is clear and not more intensely coloured than Reference Solution Y5.	Clear and not more intensely coloured than reference solution Y5.
5. HEAVY METALS: Limit: Not More than 20 ppm.	Not more than 20 ppm.
6. RELATED SUBSTANCES (HPLC): Limit: Imipramine Hydrochloride 1.0% Dehydroclomiprimine HCl 0.2% 3,7-Dichloroimprimine HCl 0.2% Total other impurities 0.2% 3-Chloroiminodibenzyl 0.1% Other Impurities Individually 0.10% Total Impurities 1.0%	LT LOQ 0.01% 0.02% 0.1% Not Detected 0.03% 0.2%
7. LOSS ON DRYING: Limit: 0.5%.	0.1%
8. SULPHATED ASH: Limit: 0.1%.	0.1%
9. ASSAY: Limit: 99.0% - 101.0%.	100.0%
10. RESIDUAL SOLVENTS: Not more than 2000ppm Isopropanol Not more than 890ppm Toluene Not more than 5ppm 2 Chloropropane	538.2 ppm 1.8 ppm Not Detected
11. MELTING POINT: Limit: 191°-195°C.	193.3°C
12. DSC: Limit: One peak in the range 191°-195°C.	193.7°C
13. RELATED SUBSTANCES (TLC): Limit: Imipramine Hydrochloride NMT 1.0% Other Impurities NMT 0.2%.	NMT 1.0% NMT 0.2%

Approved by:

Mairéad McCabe
QC Supervisor

Date of Manufacture:

June 2014

Date of Approval:

July 2014

Expiry Date:

June 2018

Date: 17 July 14FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

14G25-B01

Director Técnico

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