



Inspiring Science™

SAFC®

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**CERTIFICATE OF ANALYSIS**  
**CLOMIPRAMINE HYDROCHLORIDE**  
**BP 2014/EP 8th Edition**

Lot No.:

B-CLHFD 129-423

Weight:

1.0kg

Date:

17<sup>th</sup> Jul 14

| SPECIFICATION                                                                                                                                                                                                                                                                | RESULT                                                                                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| 1. <b>CHARACTERISTICS:</b><br>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. <b>IDENTIFICATION:</b><br>B. Infra Red Spectrum.<br>E. Chloride Test.                                                                                                                                                                                                     | Conforms.<br>Conforms.                                                                                                               |
| 3. <b>pH:</b><br>Limit: 3.5 to 5.0                                                                                                                                                                                                                                           | 4.3                                                                                                                                  |
| 4. <b>APPEARANCE OF SOLUTION:</b><br>Limit: Solution is clear and not more intensely coloured than Reference Solution Y5.                                                                                                                                                    | Clear and not more intensely coloured than reference solution Y5.                                                                    |
| 5. <b>HEAVY METALS:</b><br>Limit: Not More than 20 ppm.                                                                                                                                                                                                                      | Not more than 20 ppm.                                                                                                                |
| 6. <b>RELATED SUBSTANCES (HPLC):</b><br>Limit: Imipramine Hydrochloride 1.0%<br>Dehydroclomipramine HCl 0.2%<br>3,7-Dichloroimipramine HCl 0.2%<br>Total other impurities 0.2%<br>3-Chloroiminodibenzyl 0.1%<br>Other Impurities Individually 0.10%<br>Total Impurities 1.0% | LT LOQ<br>0.01%<br>0.02%<br>0.1%<br>Not Detected<br>0.03%<br>0.2%                                                                    |
| 7. <b>LOSS ON DRYING:</b><br>Limit: 0.5%.                                                                                                                                                                                                                                    | 0.1%                                                                                                                                 |
| 8. <b>SULPHATED ASH:</b><br>Limit: 0.1%.                                                                                                                                                                                                                                     | 0.1%                                                                                                                                 |
| 9. <b>ASSAY:</b><br>Limit: 99.0% - 101.0%.                                                                                                                                                                                                                                   | 100.0%                                                                                                                               |
| 10. <b>RESIDUAL SOLVENTS:</b><br>Not more than 2000ppm Isopropanol<br>Not more than 890ppm Toluene<br>Not more than 5ppm 2 Chloropropane                                                                                                                                     | 538.2 ppm<br>1.8 ppm<br>Not Detected                                                                                                 |
| 11. <b>MELTING POINT:</b><br>Limit: 191°-195°C.                                                                                                                                                                                                                              | 193.3°C                                                                                                                              |
| 12. <b>DSC:</b><br>Limit: One peak in the range 191°-195°C.                                                                                                                                                                                                                  | 193.7°C                                                                                                                              |
| 13. <b>RELATED SUBSTANCES (TLC):</b><br>Limit: Imipramine Hydrochloride NMT 1.0%<br>Other Impurities NMT 0.2%.                                                                                                                                                               | NMT 1.0%<br>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 14

FAGRON IBÉRICA, S.A.U  
Corresponde al lote de Fagron:

14G 25-B01

Director Técnico

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