

## CERTIFICATE OF ANALYSIS

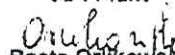
Product: **CARBAMAZEPINE**  
 Code: **QCBF-0000-000** Batch number: **119101610** Batch size: **165 kg**  
 Manufacturing date: **13.10.2016** Analysis date: **14.11.2016** Retest date: **10.2019**  
 Manufacturer: **Pharmaceutical Works POLPHARMA S.A., POLAND**  
 Delivered to: **NL, FAGRON SERVICES B.V.**

| TEST                                                                                                                                                      | TEST METHOD           | SPECIFICATION                                                                                                     | RESULTS                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Appearance                                                                                                                                                | visual                | white or almost white, crystalline powder                                                                         | white, crystalline powder                                |
| Solubility                                                                                                                                                | Ph. Eur.              | very slightly soluble in water, freely soluble in methylene chloride, sparingly soluble in acetone and in alcohol | conforms                                                 |
| Identification<br>A. Melting point<br>B. IR spectrum                                                                                                      | Ph. Eur.              | 189 °C to 193 °C<br>comparison with reference substance spectrum                                                  | 191.4 °C<br>conforms                                     |
| Acidity or alkalinity                                                                                                                                     | Ph. Eur.              | according to Ph. Eur.                                                                                             | conforms                                                 |
| Related substances (HPLC)<br>- 10,11-dihydrocarbamazepine (impurity A)<br>- iminodibenzyl (impurity E)<br>- unspecified impurities<br>- sum of impurities | Ph. Eur.              | not more than 0.15 %<br>not more than 0.15 %<br>not more than 0.10 %<br>not more than 0.5 %                       | 0.07 %<br>less than 0.05 %<br>less than 0.05 %<br>0.07 % |
| Chlorides                                                                                                                                                 | Ph. Eur.              | not more than 140 ppm                                                                                             | less than 140 ppm                                        |
| Heavy metals                                                                                                                                              | Ph. Eur.              | not more than 20 ppm                                                                                              | less than 20 ppm                                         |
| Loss on drying                                                                                                                                            | Ph. Eur.              | not more than 0.5%                                                                                                | 0.19 %                                                   |
| Sulfated ash                                                                                                                                              | Ph. Eur.              | not more than 0.1 %                                                                                               | 0.02 %                                                   |
| Assay calculated on dried substance                                                                                                                       | Ph. Eur.              | 98.0 % to 102.0 %                                                                                                 | 100.0 %                                                  |
| Residual solvents<br>methanol<br>toluene                                                                                                                  | POLPHARMA<br>S/6-0065 | not more than 1000 ppm<br>not more than 500 ppm                                                                   | 16 ppm < 33 ppm (QL)<br>31 ppm                           |

**CONCLUSION:** This material complies with the requirements of the **Ph. Eur., S/2-0002.13 ed. 02.**

Starogard Gdański, 14.11.2016

Certification Team Coordinator  
API Plant

  
 Beata Orlikowska  
 14.11.2016

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

L18060007

  
 Director Técnico