

**ATABAY**

KİMYA SANAYİ VE TİCARET A.Ş.

Date : 13.05.2015

**PRODUCT INFORMATION****PARACETAMOL PH EUR/USP CRYSTALS-CAPSULE GRADE  
(CODE APC 162)**

Batch No : 21504332  
Quantity : 2000 KG  
Name of Customer : FAGRON SERVICES B.V.  
MOLENWERF 13-1911 DB  
UITGEEST P.O. BOX 120-1910 AC  
THE-NETHERLANDS  
Manufacturing Date : 04/2015  
Expiry Date : 04/2020

| TESTS                                 | SPECIFICATIONS                                                           | RESULTS  | METHODS                                  |
|---------------------------------------|--------------------------------------------------------------------------|----------|------------------------------------------|
| Characteristics                       | White or almost white, crystals.                                         | Conforms | PH EUR Current Edition                   |
| Identification                        | Conforms to PH EUR Current Edition (A,C)                                 | Conforms | PH EUR Current Edition                   |
| Solubility                            | Conforms to PH EUR Current Edition                                       | Conforms | PH EUR Current Edition                   |
| Heavy Metals, ppm                     | Maximum 20                                                               | <20      | PH EUR Current Edition ( Method B )      |
| Related Substances                    | p-Aminophenol : Max. 50 ppm                                              | <50      | PH EUR Current Edition                   |
|                                       | p-Nitrophenol : Max. 0.05 %                                              | <0.05    |                                          |
|                                       | Any other Impurity : Max. 0.05 %                                         | <0.05    |                                          |
|                                       | Total of other Impurities : Max. 0.1 %                                   | <0.1     |                                          |
|                                       | p-Chloroacetanilide : Max. 10 ppm                                        | ND       |                                          |
| Loss on Drying, %                     | Maximum 0.5                                                              | 0.14     | PH EUR Current Edition                   |
| Sulphated Ash, %                      | Maximum 0.1                                                              | 0.01     | PH EUR Current Edition                   |
| Assay, %                              | 99.0 - 101.0 C <sub>8</sub> H <sub>9</sub> NO <sub>2</sub> (Dried Basis) | 99.24    | In-House (HPLC)                          |
| Sieve Test<br>(Cumulative % Retained) | 20 Mesh ( 850 µm ) : Maximum 5                                           | 0        | PH EUR Current Edition (Air Jet Sieving) |
|                                       | 80 Mesh ( 180 µm ) : Minimum 65                                          | 88       |                                          |
|                                       | 200 Mesh ( 75 µm ) : Minimum 85                                          | 97       |                                          |
| Bulk Density, g/mL                    | 0.70 - 0.80                                                              | 0.72     | PH EUR Current Edition ( Method I )      |
| Tapped Density, g/mL                  | 0.85 - 1.00                                                              | 0.88     | PH EUR Current Edition ( Method I )      |

Residual Solvent Statement

Residual solvent test in PH EUR current edition is not routinely performed since solvents included in Table 1 (Class 1) and Table 2 (Class 2) under General Chapter "5.4 Residual Solvents" are not used in the synthesis of Paracetamol PH EUR/USP. Acetic acid (Class 3 solvent) is produced as a side product during the acetylation of para-aminophenol with acetic anhydride. Acetic acid content in Paracetamol is analysed by using Loss on Drying test method with max limit of 0.5 %.

This product conforms to the current requirements of PH EUR/USP  
This batch has been manufactured, packaged, tested and released in accordance with EU GMP.

ORDER NO : BI150588

QUALITY CONTROL  
E. Deniz KAPLANQUALITY ASSURANCE  
Banu YAVUZTÜRKFAGRON IBÉRICA, S.A.U  
Corresponde al lote de Fagron:

15F 11-B01

Director Técnico

ADDRESS : Acıbadem Köftüncü Sokak No.1 Kadıköy 34718 İstanbul - TURKEY  
TEL : +90 216 326 69 65 - +90 216 326 65 33  
FAX : +90 216 340 13 77  
E-mail : info@atabay.com