



**ATABAY**  
KİMYA SANAYİ VE TİCARET A.Ş.

Date : 18.05.2012

**CERTIFICATE OF ANALYSIS**  
**4000 KG PARACETAMOL CRYSTALS**  
**INVOICE 044P/2011 REF 280/11**  
**FSNL ORDER BI111151**

Batch No  
Quantity  
Name of Customer

: 21205368  
: 2000 KG  
: FAGRON SERVICES B.V.  
: MOLENAARWEG 43-1911 DB  
: UITGEEST P.O. BOX 120-1910 AC  
: THE NETHERLANDS  
: 05/2012  
: 05/2017

Manufacturing Date  
Expiry Date

**TESTS**

Characteristics  
Identification  
Solubility  
Melting Point, °C  
Heavy Metals, ppm  
4-Aminophenol, %  
Related Substances

**SPECIFICATIONS**

: White, odorless, crystals.  
: Conforms to PH EUR, USP Current Editions  
: Conforms to PH EUR, USP Current Editions  
: 168.0 - 172.0  
: 10 maximum  
: 0.005 maximum  
: 4-aminophenol : max 50 ppm  
: 4-nitrophenol : max 0.05 %  
: any other impurity : max 0.05 %  
: total of other impurities : max 0.1 %  
: p-chloroacetanilide : max 10 ppm

**RESULTS**

Conforms  
Conforms  
Conforms  
169.4  
<10  
0.0013  
<50  
<0.05  
<0.05  
<0.1  
ND  
0.25  
0.24  
0.00  
100.31  
2  
90  
96  
<0.014  
<0.02  
Conforms  
Conforms  
Conforms  
5.57  
0.72  
0.87

**METHODS**

PH EUR, USP Current Editions  
PH EUR, USP Current Editions  
PH EUR, USP Current Editions  
PH EUR, USP Current Editions  
PH EUR Current Edition  
USP Current Edition  
PH EUR Current Edition  
PH EUR Current Edition  
PH EUR Current Edition  
PH EUR Current Edition  
PH EUR Current Edition  
USP Current Edition  
PH EUR Current Edition  
USP Current Edition  
PH EUR, USP Current Editions (Dry Sieving Method)  
PH EUR, USP Current Editions (Dry Sieving Method)  
PH EUR, USP Current Editions (Dry Sieving Method)  
USP Current Edition  
USP Current Edition  
USP Current Edition  
USP Current Edition  
USP 21  
PH EUR Current Edition  
PH EUR Current Edition

Loss on Drying, %

Water, % (K.F)

Sulphated Ash, %

Assay, %

Sieve Test

(Cumulative % Retained)

Chloride, %

Sulfate, %

Sulfide

Readily Carbonizable Substances

pH

Apparent Density, g/ml

OVI Statement

p-Chloroacetanilide Statement

: Organic Volatile Impurities test in the USP is not routinely tested since solvents included in the OVI table under "Organic Volatile Impurities" (467) method V-USP Current Edition are not used in the synthesis of Paracetamol PH EUR/USP.  
: Limit of p-chloroacetanilide test in the USP is not routinely tested since it cannot be present in our product due to the method of synthesis.

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.

: BI120703

QUALITY CONTROL  
E.Deniz KAPLAN

QUALITY ASSURANCE  
Banu YAVUZTURK

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