

**ATABAY**

KİMYA SANAYİ VE TİCARET A.Ş.

Date : 14.04.2014

**CERTIFICATE OF ANALYSIS
PARACETAMOL PH EUR/USP CRYSTALS
CRYSTALS-CAPSULE GRADE
(CODE APC 162)**

Batch No : 21404242
Quantity : 2000 KG
Name of Customer : FAGRON SERVICES B.V.
MOLLENWERF 13-1911 DB
UITGEEST P.O. BOX 120-1910 AC
THE NETHERLANDS
Manufacturing Date : 04/2014
Expiry Date : 04/2019

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
168.4
<10
0.00027
<50
<0.05
<0.05
<0.1
ND
0.17
0.16
0.00
100.20
0
83
95
<0.014
<0.02
Conforms
Conforms
5.72
0.70
0.89

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 21
PH EUR Current Edition
PH EUR Current Edition

Loss on Drying, % : 0.5 maximum
Water, % (K.F) : 0.5 maximum
Sulphated Ash, % : 0.1 maximum
Assay, % : 99.0 - 101.0 C₈H₉NO₂ (Dried Basis)
Sieve Test : BS # 18 Mesh - 5 maximum
(Cumulative % Retained) : BS # 85 Mesh - 65 minimum
: BS # 200 Mesh - 85 minimum
Chloride, % : 0.014 maximum
Sulfate, % : 0.02 maximum
Sulfide : Conforms to USP Current Edition
Readily Carbonizable Substances : Conforms to USP Current Edition
pH : 5.1 - 6.5
Apparent Density, g/ml : Poured density : 0.70 - 0.80
: Tapped density : 0.85 - 1.00

OVI 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.
p-Chloroacetanilide Statement : 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. : BI140585

QUALITY CONTROL
E. Deniz KAPLAN

QUALITY ASSURANCE
Banu YAVUZTÜRK

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Director Técnico