

**ATABAY**

KİMYA SANAYİ VE TİCARET A.Ş.

Date : 30.12.2013

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

Batch No : 21312858
 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 : 12/2013
 Expiry Date : 12/2018

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
 : 0.5 maximum
 : 0.5 maximum
 : 0.1 maximum
 : 99.0 - 101.0 C₈H₉NO₂ (Dried Basis)
 : BS # 18 Mesh - 5 maximum
 : BS # 85 Mesh - 65 minimum
 : BS # 200 Mesh - 85 minimum
 : 0.014 maximum
 : 0.02 maximum
 : Conforms to USP Current Edition
 : Conforms to USP Current Edition
 : 5.1 - 6.5
 : Poured density : 0.70 - 0.80
 : Tapped density : 0.85 - 1.00

RESULTS

Conforms
 Conforms
 Conforms
 169.6
 <10
 0.00024
 <50
 <0.05
 <0.05
 <0.1
 ND
 0.15
 0.14
 0.00
 100.06
 0
 91
 96
 <0.014
 <0.02
 Conforms
 Conforms
 5.70
 0.71
 0.86

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, 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

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. : B1131849

QUALITY CONTROL
 Gözde ARAS

QUALITY ASSURANCE
 Banu YAVUZTURK

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Director Técnico