

**ATABAY**

KİMYA SANAYİ VE TİCARET A.Ş.

Date : 04.04.2017

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

Batch No : 21703253
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 : 03/2017
Retest Date : 03/2022

TESTS	SPECIFICATIONS	RESULTS	METHODS
Characteristics	White or almost white, crystals.	Conforms	PH EUR Current Edition
Identification (A) -Melting Point, °C	168-172	170	PH EUR Current Edition
Identification (C)	Conforms to PH EUR Current Edition	Conforms	PH EUR Current Edition
Solubility	Sparingly soluble in water, freely soluble in alcohol, very slightly soluble in methylene chloride.	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	0.10	PH EUR Current Edition
Sulphated Ash, %	Maximum 0.1	0.00	PH EUR Current Edition
Assay, %	99.0 - 101.0 C ₉ H ₉ NO ₂ (Dried Basis)	100.1	In-House (HPLC)
Sieve Test (Cumulative % Retained)	20 Mesh (850 µm) : Maximum 6	0	PH EUR Current Edition (DrySieving Method)
	80 Mesh (180 µm) : Minimum 66	89	
	200 Mesh (75 µm) : Minimum 86	95	
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 %.
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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 : BI170426

QUALITY CONTROL
E.Deniz KAPLANQUALITY ASSURANCE
Fulya SEVER

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