



KİMYA SANAYİ VE TİCARET A.Ş.

ATABAY

Date : 31.07.2017

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

Batch No : 21707530
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 : 07/2017
Re-test Date : 07/2022

TESTS	SPECIFICATIONS	RESULTS	METHODS
Characteristics	White or almost white, crystals.	Conforms	PH EUR Current Edition
Identification (A)-Melting Point, °C	158-172	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 p-Nitrophenol : Max. 0.05 % Any other impurity : Max. 0.05 % Total of other impurities : Max. 0.1 % p-Chloroacetanilide : Max. 10 ppm	<50 <0.05 <0.05 <0.1 ND	PH EUR Current Edition
Loss on Drying, %	Maximum 0.5	0.09	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)	100.8	In-House (HPLC)
Sieve Test (Cumulative % Retained)	20 Mesh (850 µm) : Maximum 6 80 Mesh (180 µm) : Minimum 65 200 Mesh (75 µm) : Minimum 85	0 88 95	PH EUR Current Edition (Dry Sieving Method)
Bulk Density, g/mL	0.70 - 0.80	0.76	PH EUR Current Edition (Method I)
Tapped Density, g/mL	0.85 - 1.00	0.89	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 "6.4 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 : B1171039

QUALITY CONTROL
Özlem ÖZMEN

QUALITY ASSURANCE
Fulya SEVER

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