



ATABAY
KİMYA SANAYİ VE TİCARET A.Ş.

Date : 13.05.2015

PRODUCT INFORMATION
PARACETAMOL PH EUR/USP CRYSTALS-CAPSULE GRADE
(CODE APC 162)

Batch No : 21504332
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 : 04/2015
Expiry Date : 04/2020

TESTS	SPECIFICATIONS	RESULTS	METHODS
Characteristics	White or almost white, crystals.	Conforms	PH EUR Current Edition
Identification	Conforms to PH EUR Current Edition (A,C)	Conforms	PH EUR Current Edition
Solubility	Conforms to PH EUR Current Edition	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	0.14	PH EUR Current Edition
Sulphated Ash, %	Maximum 0.1	0.01	PH EUR Current Edition
Assay, %	99.0 - 101.0 C ₈ H ₉ NO ₂ (Dried Basis)	99.24	In-House (HPLC)
Sieve Test (Cumulative % Retained)	20 Mesh (850 µm) : Maximum 5	0	PH EUR Current Edition (Air Jet Sieving)
	80 Mesh (180 µm) : Minimum 65	88	
	200 Mesh (75 µm) : Minimum 85	97	
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 : B1150588

QUALITY CONTROL
E. Deniz KAPLAN

QUALITY ASSURANCE
Banu YAVUZTÜRK

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