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CERTIFICATE OF ANALYSIS

Batch-number	: 453973 (H1983)	Container	: PE-bags in fiber drum
Product	: PHENYTOIN	CAS Nr.	: 57-41-0
Manuf.date	: December 20, 2019	Re-test date	: December 18, 2024

	Specification	Analysis result
Description	White fine powder, odorless	complies
Identification	Infrared spectrum:pos.; Colorreaction:pos.; HPLC: pos.	complies
Particle size X90	max. 50 µm	13 µm
Solution in sodium hydroxide	Clear and colorless, NMT st.BY6	complies
Melting point	292 - 299 °C	293.5 °C
Loss on drying	max. 0.50 %	< 0.01 %
Residue on ignition	max. 0.10 %	< 0.01 %
Acid/base (0.01M)	max. 0.50 ml	0.05 ml
Benzilic acid HPLC	max. 0.10 %	<0.03 %
Diureine	max. 0.1 %	0.03 %
Benzofenon HPLC	max. 0.10 %	<0.03 %
Benzil	max. 0.10 %	<0.03 %
Diphenylglycine	max. 0.1 %	0.01 %
Carbamoyldiphenylglycine	max. 0.1 %	<0.02 %
Each unknown impurity (highest value)	max. 0.10 %	<0.01 %
Total organic impurities	max. 0.50 %	0.04 %
Foreign particles	max. 10 ppm	complies
Methanol	max. 200 ppm	<12 ppm
Chloride	max. 100 ppm	< 100 ppm
Heavy metals	max. 10 ppm	< 10 ppm
Arsenic	max. 2 ppm	< 2 ppm
Assay titration, dry substance	99.0 - 100.5 %	100.4 %
Assay HPLC, dry substance	98.0 - 102.0 %	98.6 %

Residual solvents: In the production process no solvents are used as mentioned in the USP and EP class 1

We have tested the material and confirm that the product we shipped meets the requirements of the current valid edition USP/Ph.Eur/JP

Release date : January 27, 2020

Katwijk Chemie by
 Quality Unit

