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ARBOCEL® P290

Powdered Cellulose Ph. Eur., NF, JP, E460 (ii), FCC

CERTIFICATE OF ANALYSIS

Batch No.:
Re-evaluation date: 05/2023 Manufacturing Site: Weissenborn, Germany
Manufacturing date: 05/2020

Description

Appearance White or almost white, fine or granular powder
Solubility Practically insoluble in water, slightly soluble in a 50 g/ L solution of sodium hydroxide, practically insoluble in acetone, in anhydrous ethanol, in toluene, in dilute acids and in most organic solvents.

Characteristics	Acceptance Criteria	Batch result	Reference
Identification A, (1): zinc chloride-test	Passes	Passes*	Ph. Eur., NF, JP
Identification (2): dispersion test	Passes	Passes*	JP
Degree of polymerization (Ident. B, (3))	More than 440	Passes*	Ph. Eur., NF, JP
Ether soluble substances	Max. 0.15 %	0.01 %	Ph. Eur., NF, JP
Heavy metals	Max. 10 ppm	< 10 ppm*	JRS Method
Loss on drying	Max. 6.5 %	4.5 %	Ph. Eur., NF, JP
pH	5.0 - 7.5	6.1	Ph. Eur., NF, JP
Solubility (Cu-am solution)	Passes	Passes*	Ph. Eur.
Sulphated ash / Residue on ignition	Max. 0.3 %	< 0.3 %*	Ph. Eur., USP, JP
Water soluble substances	Max. 1.5 %	0.2 %	Ph. Eur., NF, JP
Total aerobic microbial count (TAMC)	10^3 cfu/ g	Passes*	Ph. Eur., USP, JP
Total molds and yeasts count (TYMC)	10^2 cfu/ g	Passes*	Ph. Eur., USP, JP
E. coli, Staph. aureus, Pseudomonas aerugin.	Absent in 1 g	Absent*	Ph. Eur., USP, JP
Salmonella spec.	Absent in 10 g	Absent*	Ph. Eur., USP, JP
Bulk density	270 – 330 g/ L	304 g/ L	JRS Method
Particle size (retained on air jet sieve)			
> 32 µm (450 mesh)	Min. 50 %	69 %	JRS Method
> 75 µm (200 mesh)	Max. 30 %	18 %	
> 250 µm (60 mesh)	Max. 1 %	0 %	

* Results reported are expected results based on periodic testing. z74817p06_pe.docx

The batch described by this certificate meets the requirements of Ph. Eur., NF and JP monographs for "Powdered Cellulose" current edition, it complies with E 460 (ii) monograph (231/2012), FCC and all relevant EU Food Regulations. It is released on the basis of the results ascertained.
ARBOCEL is manufactured under GMP for excipients according to IPEC and USP <1078>.
The raw materials, manufacturing process, and product do not contain any of the solvents listed in Residual Solvents (Ph. Eur.<5.4>, USP<467>).
Elements listed in ICH Q3D Guideline for elemental impurities are not used in manufacturing and not analyzed per batch; detailed information is available on request.

Storage recommendation: **Protect from excessive heat and moisture. Keep containers closed.**

June 04, 2020
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QC MICROCELLULOSE WEISSENBORN

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