# Kalchem International

## Chemicals & Compounding Supplies

**Avicel® Microcrystalline Cellulose, NF, Ph. Eur,JP,**

***Type : PH-105***
***Lot No : 51338C***
Manufacturing Date: 19-Sep-2013
Reevaluation Date: 18-Sep-2017

Customer Purchase Order : EMAIL KALYN 04.11
Delivery Number : 80594404

| Standard | Specification | Lot Analysis |
|---|---|---|
| Loss on Drying, % | NMT 5.0 | 2.0 |
| Loose Bulk Density, g/cc | 0.20 - 0.30 | 0.26 |
| DP ,units (ID B USP,EP)(ID 3 JP) | NMT 350 | 208 |
| P.S.D.,Malvern LD, μm ,d10 (FRC, Ph.eur) | - | 7 |
| P.S.D.,Malvern LD, μm ,d50 (FRC, Ph.eur) | - | 18 |
| P.S.D.,Malvern LD, μm ,d90 (FRC, Ph.eur) | - | 39 |
| Identification A(USP,EP, JP 1) | PASS | Pass |
| Identification 2 (JP) | PASS | Pass |
| pH | 5.5 - 7.0 | 6.3 |
| Conductivity,μS/cm | NMT 75 | 36 |
| Residue on Ignition, % | NMT 0.050 | 0.030 |
| Water Soluble Substances, mg/5g | NMT 12.5 | 7.5 |
| Water soluble substances, % | NMT 0.25 | 0.15 |
| Heavy Metals, % | NMT 0.001 | Pass |
| Sol.in Cu Tetramine Hydroxide | Soluble | Pass |
| Ether Soluble Substances,mg/10g | NMT 5.0 | 0.3 |
| Air Jet Particle Size, wt. % +60Mesh | NMT 0.1 | 0.0 |
| Air Jet Particle Size, wt. % +400Mesh | NMT 1.0 | 0.7 |
| Total Aerobic Microbial Count, cfu/gram | NMT 100 | Pass |
| Total Yeast and Mold Count, cfu/gram | NMT 20 | Pass |
| Salmonella Species | Absent in a 10g sample | Pass |
| Escherichia coli | Absent in a 10g sample | Pass |
| Staphylococcus aureus | Absent in a 10g sample | Pass |
| Pseudomonas aeruginosa | Absent in a 10g sample | Pass |
| Coliform species | Absent in a 10g sample | Pass |

***Storage Conditions:*** Store at ambient conditions, keep containers sealed, material is hygroscopic.

We certify that as of the date of shipment the product conforms with the current USP / NF, Ph.Eur & JP specifications on the date of manufacture. This product is manufactured in accordance to GMP as detailed in IPEC GMP guide for Bulk Excipients. FMC test methods are used when the test is not listed in the Pharmacopeia.
The Product meets the requirement for Residual Solvents USP < 467 > and ICH Guide Q3C.
***ISO 9001:2008 Certified Quality System.*** Refer to package label for Kosher status.
***FRC's (Ph.Eur)*** Hausner Ratio Typical values: For all Avicel PH grades: 1.18 - 1.45.
Degree of Crystallinity Typical Values: For all Avicel PH grades, approximately 80% by Intensity and 66% by Area.
Typical Degree of Polymerization range for Avicel PH Microcrystalline Cellulose is 100 to 300.
***Expiry date***: None, but FMC recommend retesting for Loss on Drying after re-evaluation date listed above.

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