

Specification

Product: HME Cleaner Plus (GMP)			
Date: 13.03.2017			
Composition			
Excipient:	Quality:	Colour Ind.	
Hydroxypropylmethylcellulose	EP / USP / JP		
Methylcellulose	EP / USP / JP		
Propylenglycol	EP / USP / JP		
Colloidal Silica	EP / USP-NF / JP		
Control	Specification		Method
Appearance	white powder		1005
Odour	moderate own smell		1005
Taste	moderate own taste		1005
Loss on drying	< 36 %		1050
pH	5.5 - 9.5		1030
Ash	3.0 - 10.0 %		1006
Identification (IR spectrum ATR, 500 - 3700 cm ⁻¹)	must comply with the standard		1315

Retest-Period 1 year, if stored in original, tightly sealed containers below 30 °C

Dioxin / Aflatoxin The product is corresponding to the requirements of EC 1881/2006:

Aflatoxine	B1	<2 ppb
Aflatoxines	B1+B2+G1+G2	<4 ppb

Radiation The product or the containing raw materials were not exposed to radiation.

GMO / GVO The product is corresponding to the requirements of EC 1829/2003 and 1830/2003. In the sense of this regulation, duty for particular labelling is not required.

Residual Solvents The product corresponds to the requirements of CPMP/ICH/283/95.

Microbial purity (audit basis) Acceptance criteria according to Ph. Eur. 5.1.4. / USP <1111>
Total aerobic microbial count (TAMC): max. 10³ CFU/g.
Total combined yeasts and moulds count (TYMC): max. 10² CFU/g.

Heavy metals max. 20 ppm

BSE/TSE No animal based materials are used in the manufacture of this product.



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Head of Quality Unit