

Description SSB 55 PHARMA FP

Art.No.: 0341 0002

SSB® 55 PHARMA FP is a dewaxed, physically decolorized and powdered SSB® PHARMA Flake Shellac with a particle size $\leq 300\mu\text{m}$. Solutions in aqueous and also in organic solvents are light coloured and transparent. This high quality product with excellent binding and film forming properties meets the requirements of international pharmacopoeias (Ph.Eur. / USP / JP – latest edition). SSB® 55 Pharma FP is an EC-wide legalized food additive (E 904) according to the Supplement II of the EU Food Additive Regulation 1333/2008 and complies with the specific purity criteria according to the directive VO (EU) 231/2012 required for shellac as a food additive.

Specification according:	USP Latest Edition	Ph. Eur. Latest Edition	JP Latest Edition
Appearance	not applicable	according	according
Solubility	not applicable	according	according
Identification A, TLC	not applicable	according	not applicable
Identification B, TLC	not applicable	according	not applicable
USP Identification A, IR	according	not applicable	not applicable
USP Identification B, TLC	according	not applicable	not applicable
USP Monogr. Shellac	according	not applicable	not applicable
JP Monogr. Purified Shellac:	not applicable	not applicable	according
Ph.Eur. Monogr. Shellac	not applicable	according	not applicable
Purity, Colophony, TLC	according	according	according
Wax	$\leq 0,2\%$	not applicable	$\leq 0,2\%$
Acid value	68 - 79mg KOH/g	65 - 95 mg KOH/g	60 - 80 mgKOH/g
Arsenic	not applicable	$\leq 3,0$ ppm	$\leq 5,0$ ppm
Heavy Metal	not applicable	not applicable	≤ 10 ppm
Loss of drying	$\leq 2,0\%$	$\leq 2,0\%$	$\leq 2,0\%$
Ethanol-insoluble substances	$\leq 2,0\%$	not applicable	$\leq 2,0\%$
Ash	$\leq 1,0\%$	not applicable	$\leq 1,0\%$
Chloride	$\leq 0,14\%$	not applicable	not applicable
Microbiological parameters Ph.Eur. 5.1.4 pharmaceutical preparations, latest edition			
Total aerobic microbial count TAMC/g		≤ 1000	
Enterobacteriaceae/g		≤ 100	
E.coli/g		negative	
Staphylococcus aureus/g		negative	
Salmonellen/10g		negative	
Total yeast and mould count TYMC/g		≤ 100	
Ph.Eur. Cat. 3B		according	
Miscellaneous			
Colour index	Lovibond PRS-Scala	(20% shellac in ethanol)	1 – 1,75
Particle Size			$\leq 300 \mu\text{m}$

Packaging

Solids: Fibre drums with inner PE bag, 25 kgs net

Storage / Transport

The shelf life of this product will be 2 years if stored / transported at temperatures $<20^{\circ}\text{C}$. Higher temperatures will speed up aging of the solid material and raise the risk of "blocking" especially under the influence of humidity. Because of reasons mentioned above we recommend refrigerated transport during the warm summer months.

Note

The specifications mentioned in this technical data sheet do only serve as product description. They have been ascertained immediately after production. A legally binding guarantee of certain properties or of the suitability for a concrete application cannot be deduced from these data. Improper transport and / or improper storage can cause changes. The specifications in this data sheet do not release the customer from his own examinations of the characteristics of the product and the suitability for the intended use.