



Dronabinol  
Release Specification  
(Germany)

Version 02  
(January 2020)

API: Dronabinol ( $\Delta^9$ -THC, pure substance)  
Type of Specification: Release Specification  
Market: Germany  
Quality: DAC (Monograph No. D-100)  
Storage conditions: Tightly closed, protected against light, at room temperature

Test Parameter	Test Method	Specification
Properties	Organoleptic	Almost colourless to light yellow, oily fluid or resin-like mass, sometimes slightly purple at the surface
<u>Identity Test</u>		
A. IR Spectrum	Ph.Eur. 2.2.24 acc. to DAC D-100, Identity Test A	Substance spectrum complies to reference spectrum
B. TLC	Thin-layer chromatography (TLC) acc. to DAC D-100, Identity Test B	Substance chromatogram complies to reference chromatogram
C. Colour test	Colouration test acc. to DAC D-100, Identity Test C	Brownish-red colourisation appears
<u>Purity Test</u>		
Related Substances	Ph.Eur. 2.2.29 acc. to DAC D-100	Comply with DAC D-100
- Impurity D (CBN)		max. 1.0 %
- Impurity E ( $\Delta^8$ -THC)		max. 2.0 %
- Each other impurity		max. 1.0 %
- Sum of all impurities (except Impurity E)		max. 3.0 %
Microbiological Quality	Ph.Eur. 2.6.12, Ph.Eur. 2.6.13	Comply with Ph.Eur. 5.1.4, table 5.1.4-2
- TAMC		max. $10^3$ cfu/g
- TYMC		max. $10^2$ cfu/g
Residual Solvents	Ph.Eur. 2.4.24	Comply with Ph.Eur. 5.4
- Heptane		max. 5000 ppm
- Acetone		max. 5000 ppm
- Methanol		max. 3000 ppm
<u>Assay Test</u>		
- $\Delta^9$ -THC	Ph.Eur. 2.2.29 acc. to DAC D-100	95.0 – 100.0 %

Approved by	Date	Signature
Head of Quality Control Constanze Pelzer	31. JAN. 2020	