



## Spezifikation

Produktbezug:	
Produktnummer	61256TPEUJ
Handelsname / Bezeichnung	Papaverin HCl, EP, USP, JP
CAS Nummer	61-25-6
Andere Bezeichnungen / Synonyme	+1-(3,4-dimethoxyphenyl)methyl]-6,7-dimethoxyisoquinoline; +Papaverinhydrochlorid; +papaverine hydrochloride;
EG Nummer	200-502-1
Zolltarifnummer / CN-Code	29391900
Molekulargewicht [g/mol]	339,38504
Formel	C <sub>20</sub> H <sub>21</sub> NO <sub>4</sub>

Parameter	Methode	Spezifikation	Einheit
<b>Sensorische Prüfung</b>			
Aussehen der Lösung	Wasserlösung	klar	
Aussehen		Weißes geruchloses kristallines Pulver	
Farbe	Wasserlösung	<<= 6th level EP	
<b>Physikalische Parameter</b>			
Trocknungsverlust		≤ 0,50	%
pH-Wert		(2% in H <sub>2</sub> O) 3,0 – 4,0	
Schüttdichte		Gewindet 0,70 – 0,90	g/ml
Schüttdichte		Lose 0,60 – 0,80	g/ml
<b>Identifikation</b>			
Gehalt	USP	98,5 – 100,5	%
Gehalt	Eur.Ph	99,0 – 101,0	%
Infrarot Spektroskopie		entspricht den Vorgaben	
UV-Spektroskopie		Entspricht USP	
<b>Verunreinigungen</b>			
Leicht carbonisierbare Substanzen	USP/JP	entspricht der Referenz	
Sulphatasche		≤ 0,10	%
Verunreinigung	HPLC	≤ 0,50	%
Verunreinigung	HPLC	A: (NOSCAPINE): Nicht auf unseren Prozess anwendbar	%
Verunreinigung	HPLC	B: (PAPAVERINOL) ≤ 0,10	%
Verunreinigung	HPLC	C: (DIHYDROPAPAV) ≤ 10,0	%
Verunreinigung	HPLC	D: (PAPAVERALD) ≤ 10,0	%
Verunreinigung	HPLC	E: (TETRAHYDROPAP) ≤ 10,0	%
Verunreinigung	HPLC	F: ≤ 10,0	%
Verunreinigung	HPLC	Gegenseitig ≤ 10,0	%
<b>Restlösemittel</b>			
2-Chloropropane	Vollständigkeit der Chloroformlösung	Komplett	
Chloroform	Vollständigkeit der Chloroformlösung	Komplett	
DimethylSulfOxide (DMSO)		Org.res.solv. ≤ 50	ppm
Methanol		Org.res.solv. ≤ 100	ppm
<b>Elementare Verunreinigungen</b>			
Chloride (Cl)		positiv	
<b>Partikelgrößenverteilung</b>			
Partikel		D (10%) 10 – 50	µm
Partikel		D (50%) 20 – 100	µm
Partikel		D (90%) 100 – 400	µm

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 11. Sep. 2020

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