



## Specification

Concerning Product:	
Article number	612561PEUJ
Trade name / designation / denomination	Papaverin HCl, EP, USP, JP
CAS number	61-25-6
Other names / synonyms	+1-(3,4-dimethoxyphenyl)methyl]-6,7-dimethoxyisoquinoline, -papaverine hydrochloride;
EC number	200-502-1
Customs tariff number / CN code / TARIC	29391900
Molecular weight [g / mol]	339.38504
Formula	C <sub>20</sub> H <sub>21</sub> NO <sub>4</sub>

Parameter	Test Method	Specification	Unit
<b>Organoleptic test</b>			
Appearance of solution	of Water Solution	Clear	
Appearance		White odorless crystalline powder	
Colour	of Water Solution	<<= 6th level EP	
<b>Physical parameter</b>			
Loss on drying		≤ 0,50	%
pH value		(2% in H <sub>2</sub> O) 3,0 – 4,0	
Bulk density		Loose 0,60 – 0,80	g/ml
Bulk density		Tapped 0,70 – 0,90	g/ml
<b>Identity</b>			
Assay	Eur.Ph	99,0 – 101,0	%
Assay	USP	98,5 – 100,5	%
Infrared absorption spectrometry		conform to the reference	
UV spectroscopy		Complies USP	
<b>Impurities</b>			
Readily carbonizable substances	USP/JP	complies with the reference	
Sulphated ash		≤ 0,10	%
Impurity	HPLC	≤ 0,50	%
Impurity	HPLC	A: (NOSCAPINE): Not applicable to our process	%
Impurity	HPLC	B: (PAPAVERINOL) ≤ 0,10	%
Impurity	HPLC	C: (DIHYDROPAPAV) ≤ 10,0	%
Impurity	HPLC	D: (PAPAVERALD) ≤ 10,0	%
Impurity	HPLC	E: (TETRAHYDROPAP) ≤ 10,0	%
Impurity	HPLC	Each other ≤ 10,0	%
Impurity	HPLC	F: ≤ 10,0	%
<b>Residual Solvents</b>			
Chloroform	Completeness of chloroform solution	Complete	
2-Chloropropane	Completeness of chloroform solution	Complete	
DimethylSulfOxide (DMSO)		Org.res.solv. ≤ 50	ppm
Methanol		Org.res.solv. ≤ 100	ppm
<b>Elemental Impurities</b>			
Chlorides (Cl)		positiv	
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<b>Particle size distribution</b>			
Particles		D (10%) 10 – 50	µm
Particles		D (50%) 20 – 100	µm
Particles		D (90%) 100 – 400	µm

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 11. Sep. 2020

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