



Specification

Concerning Product:	
Article number	1115704PPEBU
Trade name / designation / denomination	Metformin HCl EP/BP/USP
CAS number	1115-70-4
Other names / synonyms	•1,1-DIMETHYLBIGUANIDE; •1,1-DIMETHYLBIGUANIDE HYDROCHLORIDE; •1,1-Dimethylbiguanide Hydrochloride; •1,1-Dimethylbiguanide hydrochloride; •1,1-Dimethylbiguanide, Hydrochloride; •1-carbamimidamido-N,N-dimethylmethanimidamide hydrochloride; •3-(diaminomethylidene)-1,1-dimethylguanidine hydrochloride; •METFORMIN; •METFORMIN HCL; •Metformin HCl;
EC number	214-230-6
Customs tariff number / CN code / TARIC	29252900
Molecular weight [g / mol]	165.62458
Formula	C ₄ H ₁₂ ClN ₅

Parameter	Specification	Unit
Organoleptic test		
Appearance of solution	clear and colourless	
Appearance	white crystalline powder	
Physical parameter		
Loss on drying	(105° C/5h): ≤ 0,5	% [w/w]
Solubility	in Water: freely soluble in Alcohol: slightly soluble in Acetone and Methylene Chloride: insoluble	
Identity		
Assay	98,5 – 101,0	% [w/w]
Identification	B. (IR): IR Spectrum complies	
Identification	E. Chloride: complies	

Impurities		
Heavy Metals (as Pb)	≤ 10	ppm
Sulphated ash	≤ 0,1	% [w/w]
Impurity	F.: ≤ 0,05	% [w/w]
Related substances	Impurity A: ≤ 0,02	% [w/w]
Related substances	Impurity B: ≤ 0,05	% [w/w]
Related substances	total impurities: ≤ 0,2	% [w/w]
Related substances	unspecified impurity: ≤ 0,05	% [w/w]
Particle size distribution		
Particles	< 100 μm ≥ 90	%
Particles	< 180 μm ≤ 100	%

Regulatory information:

BSE/TSE statement: Product does not contain ingredients or is produced by raw materials of animal origin.

Registration status: CEP

Residual solvents: Methanol: ≤ 1000 ppm

Xylene: ≤ 500 ppm

Supplemental information:

Shelf life: 5 years

Derivation: synthetic

Complies with monographie: PhEur-9.0, BP-2018, USP-40

Regional origin: IND

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 24. Jul. 2019

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