



Spezifikation

Produktbezug:	
Produktnummer	1115704PPEBU
Handelsname / Bezeichnung	Metformin HCl EP/BP/USP
CAS Nummer	1115-70-4
Andere Bezeichnungen / Synonyme	•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;
EG Nummer	214-230-6
Zolltarifnummer / CN-Code	29252900
Molekulargewicht [g/mol]	165.62458
Formel	C ₄ H ₁₂ ClN ₅

Parameter	Spezifikation	Einheit
Sensorische Prüfung		
Aussehen der Lösung	klar und farblos	
Aussehen	weißes, kristallines Pulver	
Physikalische Parameter		
Trocknungsverlust	(105° C/5h): ≤ 0,5	% [w/w]
Löslichkeit	in Wasser: löslich in Alkohol: kaum löslich in Aceton und Methylen Chlorid: unlöslich	
Identifikation		
Gehalt	98,5 – 101,0	% [w/w]
Identifizierung	B. (IR): IR Spektrum entspricht	
Identifizierung	E. Chloride: entspricht	

Verunreinigungen		
Schwermetalle (als Pb)	≤ 10	ppm
Sulphatasche	≤ 0,1	% [w/w]
Verunreinigung	F.: ≤ 0,05	% [w/w]
Verwandte Substanzen	Impurity A: ≤ 0,02	% [w/w]
Verwandte Substanzen	Impurity B: ≤ 0,05	% [w/w]
Verwandte Substanzen	unbestimmte Verunreinigung: ≤ 0,05	% [w/w]
Verwandte Substanzen	Verunreinigungen gesamt: ≤ 0,2	% [w/w]
Partikelgrößenverteilung		
Partikel	< 100 µm ≥ 90	%
Partikel	< 180 µm ≤ 100	%

Regulatorische Informationen:

BSE/TSE Hinweis: Das Produkt enthält keine tierischen Inhaltsstoffe oder wird aus Rohstoffen tierischen Ursprungs hergestellt.

Registrationsstatus: CEP

Restlösemittel: Methanol: ≤ 1000 ppm

Xylene: ≤ 500 ppm

Zusätzliche Angaben:

Mindesthaltbarkeit: 5 Jahre

Herleitung: synthetisch

Entspricht der Monographie: PhEur-9.0, BP-2018, USP-40

regionaler Ursprung: IND

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 24. Jul. 2019

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