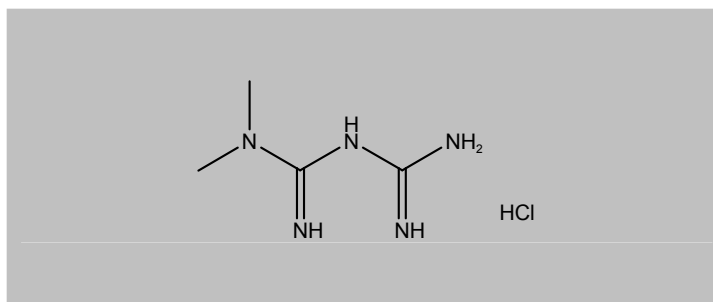


Certificate Of Analysis
Quality Control Testing and Research ApplicationCOA Preparation Date: 25/09/2013
COA Revision Date: 25/09/2016

Product: Metformin hydrochloride
Cat. No.: BG0401
Batch No.: 0401BG/02
Chemical Name: 1,1-Dimethyl-biguanide hydrochloride

1. PHYSICAL AND CHEMICAL PROPERTIES

Batch Molecular Formula: C₄H₁₁N₅ .HCl
Batch Molecular Weight: 165.62
CAS No.: [1115-70-4]
Physical Appearance: White crystalline powder
Melting Point: 223 - 226° C
Solubility: Soluble in water
Storage: RT
Batch Molecular Structure:

**Product Description:**

A Biguanide hypoglycemic agent used in the treatment of non-insulin-dependent diabetes mellitus not responding to dietary modification. It improves glycemic control by improving insulin sensitivity and decreasing intestinal absorption of glucose. Recently it was shown that it is a potent inhibitor of cell proliferation in endometrial cancer cell lines. This effect is partially mediated through AMPK activation and subsequent inhibition of the mTOR pathway. It acts on τ phosphorylation via mTOR/protein phosphatase 2A (PP2A) signaling, suggesting a potential beneficial role of Metformin in the prophylaxis and / or therapy of AD.

References:

1. Hess and Sullivan (2004) Ann Pharmacother 38:1283; 2. Cantrell et al. (2010) Gynecol Oncol 116:92; 3. Brown et al. (2010) Breast Cancer Res Treat 123:591; 4. Kickstein et al. (2010) Proc Natl Acad Sci USA 107:21830; 5. Kato et al. (2012) Mol Cancer Ther 11:549

- CAUTION - Not fully tested. For Research use only. Not for human use. -

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BG0401 Metformin hydrochloride

2. ANALYTICAL DATA

HPLC: corresponds to the reference

MS: corresponds to the reference

Tests: Loss on drying: 0.09% (complies); Sulphated ash: 0.06% (complies); Heavy Metals: < 10 ppm (complies); HPLC Assay: 99.4% (complies). Conforms to BP2002.

Test Item	Specifications	Results
Appearance	White or almost white crystalline powder	White crystalline powder
Identification	A Melting point 222°C-226°C	A. 223.5°C
	B. Infrared absorption spectrophotometry	B. Compliance
	C. Thin-Layer chromatography	C. Compliance
	D. A pink color develops	D. Compliance
	E. It gives reaction of chlorides	E. Compliance
Loss on drying	≤0.5%	0.09%
Appearance of solution	Solution S is clear and colourless	Compliance
Related substances	Cyanoguanidine ≤0.02%	0.008%
	Other large single impurity ≤0.01%	0.007%
Sulphated ash	≤0.1%	0.06%
Heavy metals	≤10PPM	Compliance
Assay	98.5%~101.0%	99.4%
Conclusion: Conforms to the BP2002 standard		

Expiry Date: May 2014

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