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MERCK SANTE

CENTRE DE PRODUCTION DE MEYZIEU

10 Av. DE LATTRE DE TASSIGNY 69330 MEYZIEU ZI / FRANCE

ORIGINAL

M₁₉₋₁₀
MERCK

CERTIFICATE OF ANALYSIS

PRIMARY STANDARD



PRODUCT NAME : **METFORMIN HCl**

ORIGIN : MERCK SANTE MEYZIEU

BATCH N° : METF-02

MANUFACTURING DATE: 20 Jan 2016

ANALYSIS DATE : 25 Jan 2016

RETEST DATE: 20 Jan 2018

EXPIRY DATE : 20 Jan 2026

INTENDED USE: Identification and assay

SOP REF : 20068550

TESTS	SPECIFICATIONS	RESULTS
Appearance	White or almost white crystals	White crystals
IR Identification	Conforms to reference spectrum	Conforms
Identification of chlorides	Positive	Positive
Appearance of aqueous solution	Clear colourless	Clear colourless
Related Substances (HPLC w/w %)		
Impurity A (cyanoguanidine)	≤ 0.020%	0.001%
Impurity B (guanylmelamine)	≤ 0.050%	0.000%
Impurity C (dimethylmelamine)	≤ 0.050%	0.000%
Major impurity	≤ 0.050%	0.000%
Total related substances	≤ 0.200%	0.001%
Impurity F (dimethylamine) w/w %	≤ 0.050	0.001%
Heavy Metals- Method A	≤ 10ppm	< 10ppm
Loss On Drying	≤ 0.50%	0.01%
Sulphated ashes	≤ 0.10%	0.01%
Titrimetric assay on dry product- Metformin HCl titration	98.5 % - 101.0 %	99.9%