泰华医药化工(杭州)有限公司
Teva Pharmaceutical & Chemical (Hangzhou) Co., Ltd.

1708000387

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

Product Name: Methyldopa
Control No.: 701100817
Order No.: 1U70003601
Client Packing Order: 222330
Customer Name: LABORATORIO CHILE S.A.
Quantity: 165.300 KG
Quality Market: LAT
Manufacturing Site: TPC-CHINA
Original Analysis Date: 08-July-2017
Manufacturing Date: July 2017
Re Test date: June 2022
Packaging and storage: Store at Up to 25°C. Do not freeze. Keep in a well closed container. Protect from light.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
USP TESTS		
Description	White to yellowish-white, odorless, fine powder, which may contain friable lumps	Conforms
Solubility	Sparingly soluble in water; very soluble in 3 N hydrochloric acid; slightly soluble in alcohol; practically insoluble in ether	Conforms
Identification		
By UV	Absorptivities at 280 nm, calculated on the anhydrous basis, do not differ by more than 3.0%.	-2.3%
By IR	Spectra similar to that of corresponding preparation of the methyldopa USP referance standard.	Conforms
Color reaction	Should conforms	Conforms
Specific Rotation	Between -25° and -28°	-26.3°
Acidity	Not more than 0.50 ml (0.1 N NaOH)/g	0.10ml/g
Water	Between 10.0% and 13.0%	11.9%
Residue on ignition	Not more than 0.1%	0.03%
Heavy metals	Not more than 0.001%	Less than 0.001%
Limit of 3-O-methylmethyldopa (By TLC)	Not greater than 0.5%	Less than 0.5%
Assay	98.0% to 101.0 % (On the anhydrous basis)	100.8%
IN HOUSE TESTS		

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
IN HOUSE TESTS		
Assay	98.5% to 101.0 % (On anhydrous basis)	100.8%
Residual Solvents TESTS		
Residual solvents (By GC)		
Acetone	Not more than 500 ppm	52ppm
Methylene chloride	Not more than 100 ppm	Less than 10ppm
IN HOUSE for PHY TESTS		
Particle size (with sieves) *(Method ref:001-PHY)*		
100 micron	Min 80%	88.4%
100 - 400 micron	Max 20%	11.6%

Remarks:
1. Conforms to the requirements of the USP and IN HOUSE and Residual Solvents and IN HOUSE for PHY Specifications.
2. The product meets the requirements for residual solvents USP <467> and ICH guide Q3C. The non-ICH solvents are supported by suitable qualification information.
3. Corresponds to Current USP Pharmacopeia.

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Released by Quality Control Manager:	Signature**: Jiyuan Sun 12 July 2017 06:42:13
Jiyuan Sun	Print Date: 12 July 2017

(*) Upon completion of the 'Results' column this document becomes a certificate of analysis **End of C.O.A.**

(**) This document was signed electronically and this is the manifestation of the electronic signature.