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

2005000138

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

Product Name: Methyldopa
Control No.: 701100120
Order No.: 1U90003801
Client Packing Order: 241849
Customer Name: LABORATORIO CHILE S.A.
Quantity: 475.000 KG
Quality Market: LAT
Manufacturing Site: TPC-CHINA
Original Analysis Date: 27-March-2020
Manufacturing Date: January 2020
Re Test date: December 2024
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 IR) By IR	Spectra is similar to that of corresponding preparation of the methyldopa USP reference standard	Conforms
Identification (By UV) By UV	Absorptivities at 280 nm, calculated on the anhydrous basis,do not differ by more than 3.0%	0.2%
Identification (Color reaction) Color reaction	Should conforms	Conforms
Acidity	Not more than 0.50 ml (0.1 N NaOH)/g	0.09ml/g
Specific Rotation	Between -25° and -28°	-25.9°
Residue on ignition	Not more than 0.1%	0.03%
Water	Between 10.0% and 13.0%	11.5%
Assay	98.0% to 101.0 % (On the anhydrous basis)	100.0%
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%

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TEL. 86-571-82171201 FAX. 86-571-82172333

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
IN HOUSE TESTS		
Assay	98.5% to 101.0 % (On anhydrous basis)	100.0%
Residual Solvents TESTS		
Residual solvents (By GC)		
Acetone	Not more than 500 ppm	Less than 50ppm
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%	84.1%
100 - 400 micron	Max 20%	15.9%

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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Quality Control Manager:	Signature**: Jianhua Ye 13 April 2020 05:40:26
Jianhua Ye	Print Date: 13 April 2020

(*) 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.

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