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TEVA API Division

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

Product Name: Levodopa
Control No.: 03004503616

Order No.: SU60329002
Client Packing Order: PO 220741

Customer Name: LABORATORIO CHILE S.A.
Quantity: 315.000 KG

Quality Market: EUR
Manufacturing Site: Bulciago

Original Analysis Date: 22-July-2016

Manufacturing Date: July 2016

Re Test date: July 2021

Packaging and storage: Preserve in tight, light -resistant containers, store in a dry place, and prevent exposure to excessive heat, excursions permitted up to 30 °C.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
	Ph.Eur TESTS	
Description	white or almost white crystalline powder	Conforms
Solubility	sligthly soluble in water, pratically insoluble in ethanol (96 per cent). It is freely soluble in 1 M hydrochloric acid and sparingly soluble in 0.1 M hydrochloric acid	Conforms
Identification (by IR)	the infrared absorption spectrum of the preparation of the test specimen exhibits maxima only at the same wavelengths as that of a similar preparation of the corresponding reference standard.	Conforms
Appearance of Solution	not more coloured than BY6	less than BY6
pH	4.5 to 7.0	5.0
Related Substances (by HPLC) EP impurity A impurity B impurity C unspecified impurity total impurities	 not more than 0.1% not more than 0.5% not more than 0.2% not more than 0.05% not more than 1.0%	 Less than 0.03% 0.15% Less than 0.03% Less than 0.03% 0.15%
Enantiomeric purity	not more than 0.5%	Less than 0.05%
Heavy Metals	not more than 10 ppm	Less than 10ppm
Loss on Drying	not more than 1.0%	0.26%

Sicor Societa' Italiana Corticosteroidi S.r.l
Via Messina 38, 20154 Milan Italy

Manufacturing site : Via Briantea km 36 n. 83, 23892, Bulciago (LC) Italy TEL. 031872.1 FAX. 031872351

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TESTS AND METHODS	SPECIFICATIONS	RESULTS*
Ph.Eur TESTS		
Sulphated Ash	not more than 0.1%	0.03%
Assay (on the dried basis)	99.0 to 101.0 %	99.5%
Residual Solvents In House TESTS		
Residual Solvents Acetone	not more than 300 ppm	39ppm
Physical TESTS		
Bulk Density In-House	between 0.4 and 0.6 g/ml	0.6g/ml
Tapped bulk density In-House	between 0.7 and 1.0 g/ml	1.0g/ml
Particle size (Alpine air jet) In-House passed through 63µ sieve passed through 125µ sieve	 between 30 and 94% between 57 and 100%	 50% 90%

Remarks:
1. Conforms to the requirements of the Ph.Eur and Residual Solvents In House and Physical Specifications.
2. Product according to current EU Pharmacopeia
3. None of Class 1 solvent are used to manufacture the product

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Released by Quality Control Manager:	Signature**: Pierangelo Colombo 3 February 2017 18.13.02
Pierangelo Colombo	Print Date: 3 February 2017
	QA Approval: Sergio Fracchia

(*) 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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