沈阳新地药业有限公司

SHENYANG SYNDY PHARMACEUTICAL CO., LTD.

ADD: 2,MIAOPULI.ZHONGGONG ST.SHENYANG,P.R.CHINA

CERTIFICATE OF ANALYSIS

Prode: Dexchlorpheniramine Maleate

Batch: DCPM201017HT Quantity: 320Kg

Date of manufacture: Oct.17,2020

Date of analysis: Oct.20,2020

Retest Data: Oct.16,2023

Standard: USP43

Analysis test	Limits		Results
IDENTIFICATION			
A (IR)	Confirms to RS.		Complies
B(HPLC)	RTs of maleic acid and dexchlorpheniramine in		Complies
ASSAY	HPLC. (dried basis)	98.0%-102.0%	101.0%
IMPURITIES			
Residue on ignition		NMT0.2%	0.05%
Organic impurities			
	Pheniramine.	NMT0.4%	NMT0.2%
	Any other unspecified impurity.	NMT0.10%	NMT0.10%
	Total impurities.	NMT1%	NMT0.5%
ENANTIOMETRIC PURITY	R-enantiomer in the portion of dexchlorpheniramine	NMT2%	Complies
SPECIFIC TESTS			
Optical rotation	50mg/mL in dimethylformamide.	+39.5°-+43.0°	+41.1°
Loss on drying	Dry a sample at 65°for4h.	NMT0.5%	0.07%
PH	10mg/ml	4.0-5.0	4.67

Conclusion: In compliance with USP43

Linda Cao

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Quality control

This document is valid with a signature.