

# 沈阳新地药业有限公司

SHENYANG SYNDY PHARMACEUTICAL CO., LTD.

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

**Conclusion:** In compliance with USP43

Linda Cao  
Quality Control

This document is valid with a signature.