

# 河北华晨药业集团有限公司检验报告书

Hebei Huachen Pharmaceutical Group Co.,Ltd Certificate of Analysis

|                   |                                |              |             |
|-------------------|--------------------------------|--------------|-------------|
| 产品名称              | 氯化镁                            | 批号           | 检验编号        |
| Product:          | Magnesium Chloride hexahydrate | Batch No.:   | 220201      |
| 包装规格              | 25kg/ Bag                      | 数量           | 5000Kg      |
| Packing:          | 25kg/ Bag                      | Quantity:    | 5000Kg      |
| 生产日期              | FEB.08.2022                    | 报告日期         | FEB.16.2022 |
| Manufacture Date: | FEB.08.2022                    | Report Date: | FEB.16.2022 |
|                   |                                | 依据           | 英国药典 2015 版 |
|                   |                                | Standard:    | BP2015      |
|                   |                                | 有效期至         | FEB.07.2024 |
|                   |                                | Expiry Date: | FEB.07.2024 |

| 检验项目<br>Items                  | 标准<br>Limit   | 结果<br>Result     |
|--------------------------------|---|------------------|
| 【性状】<br>Characteristics        | 白色结晶性粉末，易溶于水，乙醇。<br>Colourless crystals, hygroscopic, very soluble in water, freely soluble in alcohol. | 符合规定<br>Conform  |
| 【鉴别】<br>Identification         | 应呈正反应<br>Positive   | 呈正反应<br>Positive |
| 【检查】<br>Acidity or alkalinity  | 4.5-7.0   | 6.5              |
| 溶液外观<br>Appearance of Solution | 符合规定<br>Conform   | 符合规定<br>Conform  |
| 溴化物<br>Bromides                | 不得过 0.05%<br>Not more than 0.05%  | 符合规定<br>Conform  |
| 铝盐<br>Aluminium                | 不得过 0.0001%<br>Not more than 0.0001%  | 符合规定<br>Conform  |
| 铁盐<br>Iron                     | 不得过 0.001%<br>Not more than 0.001%  | 符合规定<br>Conform  |
| 硫酸盐<br>Sulphate                | 不得过 0.01%<br>Not more than 0.01%  | 符合规定<br>Conform  |
| 重金属<br>Heavy Metals            | 不得过 0.001%<br>Not more than 0.001%  | 符合规定<br>Conform  |
| 砷盐<br>Arsenic                  | 不得过 0.0002%<br>Not more than 0.0002%  | 符合规定<br>Conform  |
| 钙盐<br>Calcium                  | 不得过 0.1%<br>Not more than 0.1%  | 符合规定<br>Conform  |
| 钾盐<br>Potassium                | 不得过 0.05%<br>Not more than 0.05%  | 符合规定<br>Conform  |
| 水分<br>Water                    | 51.0%~55.0%   | 53.7%            |
| 细菌内毒素<br>Bacterial endotoxins  | 不得过 0.25EU/ml<br>Not more than 0.25EU/ml  | 符合规定<br>Conform  |
| 微生物限度<br>Microbial limit       | 总菌数不得过 500cfu/g<br>Not more than 500cfu/g   | 符合规定<br>Conform  |
| 【含量】 Assay                     | 98.0%~101.0%  | 98.8%            |

结论  
Decision

检验人 Inspector: 刘尚尚

符合英国药典 2015 版规定  
Complies With the BP2015

复核人 Checker: 吴林

