

**HUNAN YUXIN PHARMACEUTICAL CO., LTD.**

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**CERTIFICATE OF ANALYSIS**

|  |   |                                 |                |                    |               |
|--|---|---------------------------------|----------------|--------------------|---------------|
| <b>Product name</b>  | Betamethasone valerate  |                                 |                |                    |               |
| <b>Batch No.</b>   | BTW-210301  | <b>Quantity</b>                 | 105.0kg        |                    |               |
| <b>Mfg. Date</b>   | Mar., 10, 2021  | <b>Expiry date</b>              | Mar., 09, 2024 |                    |               |
| <b>Specification</b>   | EP9   |                                 |                |                    |               |
| <b>Items</b>   | <b>Standard</b>   | <b>Results</b>                  |                |                    |               |
| <b>Appearance</b>  | White or almost white crystalline powder  | almost white crystalline powder |                |                    |               |
| <b>Solubility</b>  | practically insoluble in water ,freely soluble in acetone and in methylene chloride ,soluble in ethanol | Complies                        |                |                    |               |
| <b>Melting point</b>   | About 192 °C(188~196 °C)  | 190.0~192.0 °C                  |                |                    |               |
| <b>Identification (A,B)</b>  | Complies with the Standard  | Complies                        |                |                    |               |
| <b>Specific optical Rotation</b>   | +77° ~+83°  | +79.0°                          |                |                    |               |
| <b>Related Substances</b>  |   |                                 |                |                    |               |
| - impurity A   | Not more than 0.7%  | 0.10%                           |                |                    |               |
| - impurity D   | Not more than 0.1%  | 0.02%                           |                |                    |               |
| - impurity E   | Not more than 0.3%  | 0.20%                           |                |                    |               |
| - impurity G   | Not more than 0.3%  | 0.01%                           |                |                    |               |
| - impurity C   | Not more than 0.15%   | n.d                             |                |                    |               |
| - impurity H   | Not more than 0.15%   | 0.02%                           |                |                    |               |
| - impurity I   | Not more than 0.15%   | n.d                             |                |                    |               |
| -unspecified impurities  | Not more than 0.10%   | 0.03%                           |                |                    |               |
| -total impurities  | Not more than 1.5%  | 0.43%                           |                |                    |               |
| <b>Loss on drying</b>  | Not more than 0.5%  | 0.04%                           |                |                    |               |
| <b>Assay(UV, basis on drying)</b>  | 97.0%~103.0%  | 100.5%                          |                |                    |               |
| <b>Particle size</b>   | 100%≤30um   | complies                        |                |                    |               |
| <b>Residual solvents</b>   |   |                                 |                |                    |               |
| <b>THF</b>   | not more than 720ppm  | n.d                             |                |                    |               |
| <b>Methanol</b>  | not more than 3000ppm   | n.d                             |                |                    |               |
| <b>Acetone</b>   | not more than 5000ppm   | 1046ppm                         |                |                    |               |
| <b>Pyridine</b>  | not more than 200ppm  | n.d                             |                |                    |               |
| <b>Packaging and storage:</b> Preserve in tight, light-resistant containers. |   |                                 |                |                    |               |
| <b>Conclusion:</b> The test product complies with the requirements of EP9.   |   |                                 |                |                    |               |
| <b>Analyst</b>   | panyong   | <b>Checker</b>                  | panwang        | <b>Approved by</b> | yangmingcheng |