

## 摘要

本次设计为年产 1.5 亿氨氯地平的车间工艺设计。氨氯地平，钙通道阻滞剂，又称钙拮抗剂，由于能有效地降低总外周血管阻力，20 世纪 80 年代起即已成为广泛应用的降压药物。二氢吡啶类 CCB 降压作用起效迅速，降压疗效较强，一般能降低血压 10%,15%，剂量与疗效呈正相关关系，疗效的个体差异较小。CCB 较少有禁忌证，对血脂、血糖等代谢无明显影响，长期控制血压的能力和服药依从性较好。此外，CCB 还具有以下优势:对老年患者降压疗效较好;高钠摄入不影响降压疗效;非类固醇类抗炎药不干扰降压作用;对嗜酒患者也有显著的降压作用;可用于合并糖尿病、冠心病或外周血管病患者;长期治疗时具有抗动脉粥样硬化作用。由于在降压治疗上的这些特点，CCB 是两岸三地高血压患者最常用的降压药物，在国外具有较好的应用价值。

设计内容包括:氨氯地平合成路线选择、工艺流程设计、工艺计算、车间布置设计、非工艺设计等内容。

本设计采用的工艺设计为:以  $\beta$ -胸苷为起始原料，通过在糖基上不同的保护基进行叠氮化反应，制备氨氯地平。其收率为 43.6%，HPLC 含量为 99.5%。该工艺流程具有直线式合成、原料经济相对易得、反应条件较温和、对环境友好、总收率相对高等特点。设计生产班次为每周生产批，年产量 1.5t。

本设计中车间设计包括:生产区、辅助生活区、洁净区三方面设计。考虑到经济性及实用性，整个车间为长方形一层结构，车间设计考虑生产工艺、生产规模、设备摆放等要求。

**关键词:** 氨氯地平; 车间布置; 工艺流程; GMP

# Workshop Process Design for Annual Production of 150 Million Amlodipine

## Abstract

The design is a workshop process design with an annual output of 150 million amlodipine. Amlodipine, a calcium channel blocker, also known as calcium antagonist, has become a widely used antihypertensive drug since the 1980s because it can effectively reduce the total peripheral vascular resistance. Dihydropyridine CCB can reduce blood pressure by 10% and 15%. The dose is positively correlated with the therapeutic effect, and the individual difference of the therapeutic effect is small. CCB has fewer contraindications, and has no significant effect on blood lipid and blood sugar metabolism. The ability of long-term blood pressure control and medication compliance are better. In addition, CCB has the following advantages: good antihypertensive effect for elderly patients; high sodium intake does not affect antihypertensive effect; non-steroidal anti-inflammatory drugs do not interfere with antihypertensive effect; significant antihypertensive effect for alcoholic patients; can be used for patients with diabetes, coronary heart disease or peripheral vascular disease; long-term treatment has anti-atherosclerosis effect. Because of these characteristics in antihypertensive therapy, CCB is the most commonly used antihypertensive drug for hypertensive patients across the Straits and in three places, and has good application value abroad.

The design contents include: the selection of synthetic route of amlodipine, process flow design, process calculation, workshop layout design, non-process design and so on.

The process design adopted in this design is to prepare zidovudine from beta-thymidine by azide reaction with different protective groups on the glycosyl group. The yield was 43.6% and the content of HPLC was 99.5%. The process is characterized by linear synthesis, relatively easy availability of raw materials, mild reaction conditions, environmental friendliness and relatively high overall yield. The designed production schedule is weekly production batch with annual output of 1.5T.

The design of the plant design includes three production areas: assisted living area, clean area design, taking into account the economy and practicability, the whole plant is rectangular layer structure. Design Considerations workshop production technology, production scale, equipment placement requirements.

**Key Words: amlodipine; process design; plant layout; GMP**

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