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[56] Title of the Invention

Low-concentration atropine ophthalmic preparation that inhibits myopic progression and method for the production thereof

[57] Abstract

The invention relates to a low-concentration atropine ophthalmic preparation that inhibits myopic progression and a method for its production; although all of the high-concentration

atropine preparations currently in medical use (0.5% or 1%) inhibit myopic progression, the complication of photophobia is highly problematic, resulting in unfavorable compliance and a high rate of patients failing to come in for return visits, which causes poor efficacy; the low-concentration atropine ($< 0.1\%$) used in the invention as a preparation for the treatment of myopia shows relatively low rates of photophobia and systemic adverse reactions with quite favorable compliance, and it reduces possible damage to the eyes resulting from ultraviolet radiation and blue light such as cataracts and macular disease.

1. A low-concentration atropine ophthalmic preparation that inhibits myopic progression, characterized in that the atropine content of said ophthalmic preparation is effectively controlled to a concentration of 0.1% by weight or less.

2. The low-concentration atropine ophthalmic preparation that inhibits myopic progression of Claim 1, characterized in that the atropine content of said ophthalmic preparation is 0.05% by weight.

3. A method for producing a low-concentration atropine ophthalmic preparation that inhibits myopic progression, characterized chiefly in that atropine is contained in a solution that is harmless to the human body, diluted to an atropine concentration of less than 0.1% by weight.

4. The method for producing a low-concentration atropine ophthalmic preparation that inhibits myopic progression of Claim 3, characterized in that said diluent solution is distilled water.

5. The method for producing a low-concentration atropine ophthalmic preparation that inhibits myopic progression of Claim 3, characterized in that said diluent solution is physiological saline.

Low-concentration atropine ophthalmic preparation that inhibits myopic progression and method for the production thereof

Technical field

The invention relates to a low-concentration atropine ophthalmic preparation that inhibits myopic progression and a method for the production thereof and that constitutes a drug for treating aggravation of myopia in humans, thus relating primarily to the field of human pharmacology.

Prior art

Myopia is an important ophthalmologic disease, particularly high myopia (myopia exceeding 600 degrees), and it can lead to numerous complications such as juvenile cataracts, a propensity to develop glaucoma, retinal detachment, macular hemorrhage, retinal degeneration, and even blindness. In Taiwan, as myopia is already the second-leading cause of blindness in the elderly, the prevention of high myopia is extremely important; this prevention of high myopia must start in children, with average annual increases of approximately 75-100 degrees in children in Asia and approximately 50 degrees in children in the West; once a child develops myopia, the condition will continuously increase in severity until the end of puberty, with a high probability of a subsequent progression to high myopia on maturity, and the matter of how to effectively inhibit the progression of this disease is an important issue.

Treatment of myopic progression in schoolchildren and prevention of high myopia are important issues, and a review of past research and recent studies clearly shows that atropine is the only drug capable of effectively inhibiting myopic progression.

A study published in 1999 by YF Shih et al. of National Taiwan University (Shih YF, Chen CH, Chou AC, et al., Effects of different concentrations of atropine on controlling myopia in myopic children. J Ocul Pharmacol Ther 1999; 15: 85-90.) showed that 0.5% atropine was most effective, and although the high-efficacy dose of 1% atropine currently used in many countries and the dose of 0.5% used in Taiwan are both effective, these doses are quite difficult to use in the clinical setting, primarily because of the all-day photophobia occurring after instillation, which causes primary school children to miss physical education, in turn resulting in poor compliance and a high rate of discontinuation of treatment.

Description of the invention

The technical problem to be solved by the present invention is as follows: although the high concentrations of atropine currently used in many countries to treat myopia (concentrations of 0.5% by weight and above) are effective, all-day photophobia occurs after clinical instillation, causing primary school children to miss physical education, in turn resulting in poor compliance and a high rate of discontinuation of treatment.

The invention solves the above technical problem by providing a low-concentration atropine ophthalmic preparation that inhibits myopic progression, characterized in that the atropine content of the ophthalmic preparation is effectively controlled to 0.1% by weight or less.

The atropine concentration of the ophthalmic preparation is advantageously 0.05% by weight.

Moreover, the method for producing a low-concentration atropine ophthalmic preparation that inhibits myopic progression according to the invention is characterized chiefly in that atropine is contained in a solution that is harmless to the human body, diluted to an atropine concentration of less than 0.1% by weight;

wherein the diluent solution is distilled water;

wherein the diluent solution is physiological saline.

The invention chiefly discloses a low-concentration atropine ophthalmic preparation that inhibits myopic progression; with respect to the atropine content of the ophthalmic preparation, in the study published by Dr. YF Shih, the most effective dose was the already largely established concentration of 0.5%, and one could not imagine that a concentration of less than 0.1% atropine would still be effective.

The invention therefore provides a low-concentration atropine ophthalmic preparation that inhibits myopic progression, characterized in that the atropine content of the ophthalmic preparation provided by the invention is effectively controlled to 0.1% by weight or less; moreover, further experimental data established that the concentration of 0.05% was even more effective than 0.1% and 0.25%, and compliance was improved, making the preparation suitable for the broad-range mass treatment of progressive myopia.

First, the response of our clinical subjects showed that 0.1% atropine still causes the complication of photophobia, accompanied by poor compliance, but the concentration of 0.05% atropine, compared with 0.1%, clearly alleviated pupil dilation and the complication of photophobia, and its effect of inhibiting myopic progression was not inferior to that of the concentrations of 0.1% and 0.25%, compare Tables 1 and 2 below:

Table 1. 1999 study of Dr. Shih

	Study group and control group			
Atropine concentration	0.5%	0.25%	0.1%	Control group (0%)
Aggravation of myopia	4 (degrees/yr)	45 (degrees/yr)	47 (degrees/yr)	106 (degrees/year)

Table 2. Our study of 2006

	Study group and control group	
Atropine concentration	0.05%	Control group (0%)
Aggravation of myopia	28 (degrees/yr)	75 (degrees/year)

It can be seen from the experimental data shown in Table 1 and Table 2 above that the action of 0.05% atropine in inhibiting the progression of myopia did not differ from that of 0.1% and 0.25% atropine, with the effect being quite favorable in some cases.

Furthermore, Table 3 below shows data by year on the status of myopia in patients given 0.05% atropine:

Table 3. Data by year on use of 0.05% atropine to treat progressive myopia

	First year	Second year	Third year	Total
Annual aggravation in degrees	34 (degrees/yr)	32 (degrees/yr)	14 (degrees/yr)	29 (degrees/year)

It can be seen from the data by year in Table 3 on the status of myopia in patients given 0.05% atropine that the long-term effect of the preparation was also quite favorable.


Furthermore, myopic progression is often associated with close work, which in turn is associated with chronic excessive accommodation, and if this accommodation can be inhibited, this tends to prevent aggravation of myopia, as shown in Table 4 below:

**Table 4. Effect of various concentrations of atropine
on accommodation in human subjects**

	Study group and control group		
Atropine concentration	0.05%	Control group (0%)	0.1%
Accommodation	27 degrees	75 degrees	21 degrees
P value	$P=0.001$		
		$P=0.001$	

It can be seen from the experimental data shown in Table 4 above that there is no clear difference between the accommodation-inhibiting action of the atropine concentration of 0.05% by weight and that of 0.1% by weight, with both the 0.1% group and the 0.05% group showing *P* values of 0.001 ($P<0.05$) compared with the control group (0%), a statistically significant difference, indicating a clear action of inhibiting accommodation and thus demonstrating that an atropine concentration of 0.05% has a favorable effect of inhibiting accommodation. Table 5 shows a further example.

Table 5. Mydriatic effect of various concentrations of atropine in human subjects

	Study group and control group		
Atropine concentration	0.05%	Control group (0%)	0.1%
Pupil diameter	5.52 mm (millimeters)	2.93 mm (millimeters)	6.10 mm (millimeters)
P value	$P<0.0001$		
		$P<0.0001$	
	$P=0.0364$		

It can be seen from the experimental data shown in Table 5 that the mydriatic effect of 0.05% atropine was less than that of 0.1% atropine, with the difference being statistically significant ($P<0.05$).

As shown by the data in Table 6 below, the patients administered 0.05% atropine showed a much lower incidence of photophobia than those administered 0.1% atropine, indicating that the former concentration is indeed less likely to induce photophobia.

Table 6. Incidence of photophobia after treatment of patients with atropine

Atropine concentration	0.05%	0.1%
Incidence of photophobia	66.67%	85.71%

It can therefore be seen from the above clinical statistics that the 0.1% atropine ophthalmic preparation caused photophobia in patients, and compliance was also poor. In contrast, the 0.05% atropine of the present invention showed a clear effect of alleviating mydriasis and photophobia compared with 0.1% atropine (compare Table 5 and Table 6 above), and its effect of inhibiting myopic progression showed no major difference compared with 0.1% atropine and 0.25% atropine (compare Table 1 and Table 2 above), with patients not having to be concerned about ophthalmological or systemic adverse reactions, thus increasing patient compliance and decreasing resistance to treatment.

It can be seen from the test results in the table below that the duration of mydriasis for the 1% atropine preparation was approximately 7-14 days; cyclopentolate hydrochloride showed a duration of approximately 2 days; tropicamide showed a duration of approximately 6 hours; and in trial use of the above three drugs for the treatment of myopia, only atropine was effective. As shown in the table below, however, the duration of mydriasis in using the 0.05% atropine preparation of the invention was approximately 12-18 hours, thus demonstrating that its mydriatic action was clearly less than that of 1% and 0.5% atropine.

Generic name	Brand name	Concentration (%)	Duration of action	Duration of mydriasis
Atropine sulfate	Atropisol Atropine-Care Isopto Atropine Available generically	Soln, 0.5%-2% Soln, 1% Soln, 0.5%-3% Soln, 1% Ointment, 0.5%-1%	45-120 min.	7-14 days
Cyclopentolate hydrochloride	AK-Pentolate Cycogyl Available generically	Soln, 1% Soln, 0.5%-3% Soln, 1%	30-60 min.	2 days
Tropicamide	Mydriacyl Tropicacyl Available generically	Soln, 0.5%, 1% Soln, 0.5%, 1% Soln, 0.5%, 1%	20-40 min.	4-6 hr.
Atropine sulfate		Soln, 0.05%	45-120 min.	12-18 hr.

Finally, the preparation of the invention may be produced by diluting atropine in distilled water or physiological saline to form an atropine solution with a concentration of less than 0.1% by weight.

In summary, the content of atropine in the preparation of the invention is decreased from the currently-used concentrations of 1%, 0.5%, 0.25%, or 0.1% to less than 0.1% (preferably 0.05%), and this adjustment in concentration makes it possible to alleviate the adverse reactions of mydriasis and photophobia after instillation, strengthen patient compliance, and improve the rate of return visits, allowing the treatment to be continued until it is effective, thus making the invention suitable for broad-range and universal mass treatment of progressive myopia.

The preparation of the invention has the following effects:

1. It decreases mydriasis, prevents photophobia, increases compliance, and reduces dropout rates.
2. The low concentration of atropine makes it possible to effectively inhibit accommodation and the progression of myopia.

3. The low concentration of atropine makes it possible to prevent systemic adverse reactions.

4. Reducing the high concentration of atropine alleviates its unwanted action of causing an increase in the rate of myopic progression after stopping the drug.

5. It provides the treating physician with flexibility and allows the treatment to be adapted to individual patient differences.

Description of preferred embodiments

The above explanations serve only to provide an overview of the invention in order to allow the person skilled in the art to understand it by reading this description and implement the invention based thereon; the following explanations by no means limit the scope of the invention, and any relevant modifications or amendments made in accordance with the spirit of the invention are therefore included in the scope of protection thereof.

Embodiment 1

The preparation of the invention may be produced by dissolving atropine in distilled water to a concentration of less than 0.1% by weight.

Embodiment 2

The preparation of the invention may be produced by dissolving atropine in physiological saline to a concentration of less than 0.1% by weight.

Embodiment 3

The preparation of the invention may be produced by dissolving atropine in distilled water to a concentration of less than 0.05% by weight.


Embodiment 4

The preparation of the invention may be produced by dissolving atropine in physiological saline to a concentration of less than 0.05% by weight.

I, Matthew J. McGaughey, declare as follows:

1. I am a native speaker of English.
2. I am fluent in Chinese.
3. I have 34 years of experience translating from Chinese to English.
4. I translated the document "CN101049287A.pdf" from Chinese to English.
5. I certify that the translation of the document "CN101049287A.pdf" is, to the best of my knowledge, a true and accurate translation from Chinese to English.
6. In signing this declaration, I understand that the declaration may be filed as evidence in a contested case. I acknowledge that I may be subject to cross-examination in this case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.
7. I declare under penalty of perjury that all statements made herein of my own knowledge are true and that all statements made herein on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

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Matthew J. McGaughey

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[54] 发明名称

抑制近视度数增加的低浓度阿托平眼药剂及其制造方法

[57] 摘要

本发明关于一种抑制近视度数增加的低浓度阿托平眼药剂及其制造方法，目前医学上皆使用的高浓度的阿托平(0.5%或1%)来抑制近视度数增加，但怕光的问题相当困扰病患，使得顺从性不好且不回诊率高，反而效果不好，本发明利用一种低浓度的阿托平(<0.1%)来作为治疗近视的药剂，具有较不怕光，较不怕全身性副作用，且顺从性较好，并可减少紫外线及有害蓝光对眼睛的可能伤害，如白内障，视网膜黄斑病变等。

1、一种抑制近视度数增加的低浓度阿托平眼药剂，其中该眼药剂的阿托平含量，有效控制在0.1%重量百分比浓度以下。

2、如权利要求1所述抑制近视度数增加的低浓度阿托平眼药剂，其中该眼药剂的阿托平含量为0.05%重量百分比浓度。

3、一种抑制近视度数增加的低浓度阿托平眼药剂制造方法，主要将阿托平药物以对人体无害的液体，稀释成为小于0.1%重量百分比浓度阿托平药剂。

4、如权利要求3所述抑制近视度数增加的低浓度阿托平眼药剂制造方法，其中该稀释的液体为蒸馏水。

5、如权利要求3所述抑制近视度数增加的低浓度阿托平眼药剂制造方法，其中该稀释的液体为生理食盐水。

抑制近视度数增加的 低浓度阿托平眼药剂及其制造方法

技术领域

本发明涉及一种抑制近视度数增加的低浓度阿托平眼药剂及其制造方法，主要涉及人体医药领域中，一种用来治疗人体眼睛近视恶化的药物发明。

背景技术

近视是一个重要的眼疾，特别是高度近视(近视度数超过六百度)，会导致许多并发症，如年轻型白内障、青光眼较易发生、视网膜剥离、黄斑出血及视网膜退化，甚至失明。在台湾，近视已经成为老年人失明主因的第二位，所以预防高度近视是很重要的，预防高度近视必须从儿童着手，在亚洲儿童约每年会增加 75~100 度，西方儿童约每年增加 50 度，儿童一旦近视，度数会一直增加到青春期结束才会停止，儿童罹患近视，以后成年变成高度近视的机会相当高，如何有效抑制近视增加是一个重要的课题。

对于学童治疗近视度数增加及避免高度近视是一个重要的课题，在之前的研究及最近的论文回顾都显示阿托平(atropine)是唯一有效抑制近视度数增加的药物。

1999 年台大施永丰医师等人发表的研究(Shih YF, Chen CH, Chou AC, et al. Effects of different concentrations of atropine on controlling myopia in myopic children. J Ocul Pharmacol Ther 1999;15:85 - 90.)，显示 0.5% 阿托平(atropine)最有效，目前有许多国家使用较强效的 1% 阿托平(atropine)或台湾使用的 0.5% 阿托平(atropine)虽然有效，但是在临床上使用却有相当的困难，主要是因为点药后会整天畏光，小学学童无法上体育课，故顺应性差及放弃治疗的比率很高。

发明内容

本发明欲解决的技术问题点：目前许多国家使用高浓度(0.5%重量百分比浓度以上)的阿托平(atropine)来治疗近视虽有效，但是在临床上点药后，却会出现整天畏光，小学学童无法上体育课的现象，故顺应性差及放弃治疗的比率很高。

本发明解决问题的技术特点：提出一种抑制近视度数增加的低浓度阿托平眼药剂，其中该眼药剂的阿托平(atropine)含量，有效控制在 0.1%重量百分比浓度

以下。

有利的是，该眼药剂的阿托平（atropine）含量为 0.05%重量百分比浓度。

另外，本发明抑制近视度数增加的低浓度阿托平眼药剂的制造方法，主要将阿托平（atropine）药物以对人体无害的液体，稀释成为小于 0.1%重量百分比浓度阿托平（atropine）药剂。

其中，该稀释的液体系为蒸馏剂。

其中，该稀释的液体系为生理食盐剂。

本发明主要揭示一种抑制近视度数增加的低浓度阿托平眼药剂，有关阿托平眼药剂的阿托平（atropine）含量，在施永丰医师发表的研究后，几乎已被定论为 0.5% 的含量最有效，不会想到小于 0.1% atropine 居然还会有效。

因此本发明提出一种抑制近视度数增加的低浓度阿托平眼药剂，其中本发明提出的眼药剂的阿托平（atropine）含量，系有效控制在 0.1%重量百分比浓度以下；并且本发明以下更要以实验数据证明，0.05%甚至比 0.1%及 0.25%有效，并有顺从性更好，使得广泛的对于大众治疗近视恶化变成可能。

首先在我们临床的病人反应上发现，0.1%阿托平（atropine）仍然会造成病患畏光的症状，顺应性也不好，但 0.05%阿托平（atropine）比 0.1%，则会显著的改善瞳孔的放大及病患的畏光症状，并且其抑制近视度数增加的效果也不会比 0.1%和 0.25%差，请配合参看以下表 1 及表 2 所示：

表 1、1999 年施医师的研究

	实验组与控制组			
阿托平浓度	0.5%	0.25%	0.1%	控制组(0%)
近视的增加	4(度/年)	45(度/年)	47(度/年)	106(度/年)

表 2、2006 年我们的研究

	实验组与控制组	
阿托平浓度	0.05%	控制组(0%)
近视的增加	28(度/年)	75(度/年)

而由上述表 1、表 2 的实验数据可知，0.05%阿托平（atropine）对于近视抑制的效果，与 0.1%和 0.25%阿托平（atropine）没有差异，有些病患效果很好。

另外，以下的表 3 系以分年来显示，施用 0.05% 阿托平（atropine）的病患，逐年近视的状态：

表 3、施用 0.05% 阿托平治疗近视的逐年恶化数据表

	第一年	第二年	第三年	全部
每年增加度	34(度/年)	32(度/年)	14(度/年)	29(度/年)

由表 3 的数据可知，表 3 以分年来显示施用 0.05% 阿托平 (atropine) 的病患，逐年近视的状态，显示长期的效果也很好。

另外，近视度数恶化与近距离工作多有关，而近距离工作多又与过度持续使用高的调节力，所以调节力若能被抑制，则近视度数便不易恶化，如以下表 4 所示，其中：

表 4、表示施用不同浓度的阿托平对于人体调节力的影响

	实验组与控制组		
阿托平浓度	0.05%	控制组 (0%)	0.1%
调节力	27 度	75 度	21 度
P 值	P=0.001		
		P=0.001	

而由上述表 4 的实验数据可知，重量百分比浓度 0.05% 的阿托平 (atropine) 药剂对于调节力的抑制，相较于重量百分比浓度 0.1% 阿托平 (atropine) 药剂，在相较上没有十分明显的差异，但相较于控制组，则无论是阿托平重量百分比浓度 0.1% 或 0.05% 的实验组比较于控制组 (0%)，皆呈现 $P=0.001$ (P 值小于 0.05)，在统计学上的意义，即表示有显著抑制调节力的作用，故可证明 0.05% 的阿托平 (atropine) 药剂即具有良好抑制调节力的功效。又如表 5。

表 5、表示施用不同浓度的阿托平对于人体散瞳的效力

	实验组与控制组		
阿托平浓度	0.05%	控制组 (0%)	0.1%
瞳孔直径	5.52mm(毫米)	2.93mm(毫米)	6.10mm(毫米)
P 值	P<0.0001		
		P<0.0001	
	P=0.0364		

其中由表 5 的实验数据可知，0.05% 阿托平 (atropine) 对于散瞳的效力，显然较 0.1% 阿托平 (atropine) 在统计学上有显著较小的效果 ($P<0.05$)。

由下表 6 数据可证明,施用 0.05%阿托平(atropine)的病患,显然较施用 0.1%阿托平(atropine)的病患,在畏光比例上低很多,确实较不易使施用者产生畏光的现象。

表 6 病患使用阿托平治疗后的畏光比率

阿托平浓度	0.05%	0.1%
畏光人数比率	66.67%	85.71%

故由前述我们的临床统计可知,0.1%阿托平(atropine)眼药剂,会造成病患畏光的症状,顺应性也不好。但反观本发明的 0.05%阿托平(atropine),则比 0.1%阿托平(atropine)显著的改善瞳孔的放大及病患的畏光症状(如上表 5、表 6 所示),并且其抑制近视度数增加的效果,相较于 0.1%阿托平(atropine)和 0.25%阿托平(atropine),并无太大的差异(如表 1、表 2 所示),病患较不担心眼睛及全身性副作用,故药物顺从性也提升,减少治疗的阻力。

在下列的表格中,则可看到其试验的结果数据,1%重量百分比浓度的阿托平(atropine)散瞳的期间约需七至十四天;Cyclopentolate Hydrochloride(盐酸环喷托酯)约两天;而 Tropicamide(托吡卡胺)则约为六个小时,而以上三种药物都被尝试用来作为治疗近视的药剂,只有阿托平(atropine)有效。而如下表所示,本发明以 0.05%重量百分比浓度的阿托平(atropine),其散瞳期间约 12~18 小时,可得证对于散瞳的效力,显然较 1%及 0.5%阿托平(atropine)有显著较小的效果。

通用名称	注册名称	浓度(%)	发生作用时间	散瞳期间
Atropine sulfate (阿托平)	Atropisol Atropine-Care Isopto Atropine Available generically	Soln, 0.5%-2% Soln, 1% Soln, 0.5%-3% Soln, 1% Ointment, 0.5%-1%	45-120 分钟	7-14 天
Cyclopentolate Hydrochloride (盐酸环喷托酯)	AK-Pentolate Cycogyl Available generically	Soln, 1% Soln, 0.5%-2% Soln, 1%	30-60 分钟	2 天

Tropicamide (托吡卡胺)	Mydriacyl Tropicacyl Available generically	Soln, 0.5%, 1% Soln, 0.5%, 1% Soln, 0.5%, 1%	20-40 分钟	4-6 小时
Atropine sulfate (阿托平)		Soln, 0.05%	45-120 分钟	12-18 小时

最后，本发明药剂的制造，可将阿托平（atropine）药物以蒸馏剂或生理食盐剂，稀释成为小于 0.1%重量百分比浓度阿托平（atropine）的药剂。

综上所述，本发明利用将阿托平（atropine）于药剂中的含量，由目前 1%、0.5%、0.25%或 0.1%，降为小于 0.1%阿托平（atropine）含量（较佳为 0.05%），如此调整下，可改善用药后病患瞳孔放大及畏光等副作用，进而强化患者的顺从性及回诊率，使治疗能持续而达到效果，使得广泛且普及的对于大众近视恶化的治疗变成可能。

本发明的药剂可达成以下的功效：

- 1、减少瞳孔放大，避免怕光症状，提高医嘱遵从性，减少落跑率。
- 2、低浓度的阿托平（atropine）就可有效抑制调节力，有效抑制近视度数的增加。
- 3、低浓度的阿托平（atropine）可避免全身性副作用。
- 4、降低高浓度阿托平（atropine）所造成停药后反而近视度数增加更快的作用。
- 5、提供医师治疗的选择并可依照病患个体差异调整药物。

具体实施方式

惟上述的说明仅为本发明的概述，为使阅读本说明书的专业人士能了解本发明，并可依本说明书内容据以实施，故配合图标说明如下，惟并非对本发明做任何形式上的限制，是以，凡在相同的发明精神下所作有关的任何修饰或变更，皆应包括在本发明保护范围的內。

实施例 1

本发明药剂的制造，系可将阿托平（atropine）药物以蒸馏剂，稀释成为小于 0.1%重量百分比浓度阿托平（atropine）的药剂。

实施例 2

本发明药剂的制造，系可将阿托平（atropine）药物以生理食盐剂，稀释成为于 0.1%重量百分比浓度阿托平（atropine）的药剂。

实施例 3

本发明药剂的制造，系可将阿托平（atropine）药物以蒸馏剂，稀释成为 0.05%重量百分比浓度阿托平（atropine）的药剂。

实施例 4

本发明药剂的制造，系可将阿托平（atropine）药物以生理食盐剂，稀释成为 0.05%重量百分比浓度阿托平（atropine）的药剂。