

A STUDY OF ROSE WATER OINTMENT.*

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Bulletin 26 (1), of the Sub-Committee on Cerates, Ointments and Miscellaneous Galenicals, is a report on ointments. In it Chairman L. A. Seltzer has the following to say about official Ointment of Rose Water:

The U. S. P. X ointment is so definitely subject to rancidity as to make the improvement of that formula imperative. I have had occasion to discard considerable quantities of the ointment for that reason. The use of liquid petrolatum should be considered.

We believe it is no exaggeration to say that every dispensing pharmacist has had, at some time, the experience of throwing away rancid ointment of rose water.

This preparation has remained basically the same through every issue of the Pharmacopœia. According to Moore (2), the questionable idea of incorporating rose water is an offspring of our own Pharmacopœia. He further states that the Pharmacopœia of 1830, New York Revision, had the wisdom to leave out the rose water in this formula.

Galen, according to Piesse (3), is given the credit for having invented "that peculiar unguent, a mixture of grease and water, which is now distinguished as cold cream in perfumery, and as Ceratum Galeni in Pharmacy." The modern formula for cold cream is, however, quite a different thing to that given in the works of Galen in point of odor and quality, although substantially the same—"grease and water." If, as is suggested, Galen's Cold Cream was a mixture of grease and water, it takes no stretch of the imagination to believe that it has always been a troublesome preparation and our Pharmacopœia simply inherited a bad formula. If, as Moore (2) implies, the incorporation of rose water is an American idea, then we may admit that the pharmaceutical sins of our forefathers have been visited upon us for several pharmacopœial generations and perhaps it is about time to "clean house."

We are all sure of one thing about Ointment of Rose Water. That is, it is not a satisfactory ointment from the standpoint of keeping qualities and, we, as pharmacists, are looking for a better formula. The present formula has remained practically unchanged for the past four revisions of the Pharmacopœia. This fact should be evidence that it is a thoroughly satisfactory preparation, but it is not. That this preparation is problematical is borne out in a recent vote of Sub-Committee 13 upon several proposed formulas for it. In reporting the vote, Seltzer (4) said:

With reference to Ointment of Rose Water, the majority favor Formula A, yet since, in Bibbins' opinion, none are satisfactory, and others think some other vegetable oil might be found more satisfactory, the matter will be kept open for further study.

We are presenting, in this paper, a brief study of this preparation. A number of formulas have been prepared. They differ mostly as to the oils or fats used. Vegetable oils were used in about half of the formulas studied. Liquid petrolatum was used to replace the vegetable oils in a number of other formulas. A small number were made with white petrolatum and a mixed base instead of

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a liquid fat. Many lesser variations in the formulas will be seen in the various tables of formulas that follow.

The procedure for making these preparations is essentially the same for all. It is as follows:

Melt the wax and cetaceum over a water-bath and then add the oil and allow the mixture to reach a temperature of about 65°. Put this fused warm mixture into a mixing bowl. Dissolve the borax in the water and warm the solution to about the same temperature as that of the oil mixture. Pour the aqueous solution into the oil. Emulsify the liquids by means of an egg beater, stirring at medium speed for about 30 seconds. When cool, perfume to suit.

Continued beating or high speed is unnecessary for good emulsification in cold cream formulas of this kind. Some advocate pouring the warm soft ointment into containers, but to us a better plan is to allow the mass to cool first. It has been stated that official cold cream keeps well in tin tubes. We have tubed parts of several batches for later observation.

Table I following shows the original formulas of the official Rose Water Ointment. It will be observed that these have remained essentially unchanged through the eleven issues of the Pharmacopœia.

TABLE I.

| | 1820. | 1830. | 1840. | 1850. | 1860. | 1870. | 1880. | 1890. | 1900. | 1910. | 1920. |
|---------------------|---------|--------------------|---------|---------|------------------------|------------------------|---------|---------|---------|---------|---------|
| Oil of almonds | 2 oz. | 2 oz. ¹ | 2 oz. | 2 oz. | 3 1/2 oz. ² | 3 1/2 oz. ² | 50 pts. | 600 cc. | 580 Gm. | 560 Gm. | 560 Gm. |
| Spermaceti | 1/2 oz. | 1/2 oz. | 1/2 oz. | 1/2 oz. | 1 oz. ² | 1 oz. ² | 10 pts. | 125 Gm. | 125 Gm. | 125 Gm. | 125 Gm. |
| White wax | 1 dr. | 1 dr. | 1 dr. | 1 dr. | 2 dr. | 2 dr. | 10 pts. | 120 Gm. | 120 Gm. | 120 Gm. | 120 Gm. |
| Rose water | 2 oz. | 2 oz. | 1 oz. | 1 oz. | 2 oz. | 2 oz. | 30 pts. | | | | |
| Stronger rose water | .. | .. | .. | .. | .. | .. | .. | 190 cc. | 190 Gm. | 190 Gm. | 190 Gm. |
| Sodium borate | .. | .. | .. | .. | .. | .. | .. | 5 Gm. | 5 Gm. | 5 Gm. | 5 Gm. |

¹ U. S. P. 1st Revision, Washington Convention.

² Troy ounce.

An analysis of the formulas in Table I shows that the important constituents have remained substantially the same in all of them. The variations in proportions of oil, wax and water are about as outlined below.

| Pharmacopœia. | Ratio of Oil-Wax-Water. | | | Pharmacopœia. | Ratio of Oil-Wax-Water. | | |
|----------------|-------------------------|------|------|---------------|-------------------------|------|------|
| 1820 and 1830* | 1.00 | 0.31 | 1.00 | 1880 | 1.65 | 0.67 | 1.00 |
| 1840 and 1850 | 2.00 | 0.67 | 1.00 | 1890 and 1900 | 3.20 | 1.30 | 1.00 |
| 1860 and 1870 | 1.75 | 0.62 | 1.00 | 1910 and 1920 | 3.00 | 1.30 | 1.00 |

* 1st Revision, New York Convention not included.

Beginning with the Pharmacopœia of 1890 the ratio of oil and wax to that of water was increased to about twice that of the previous issues. At this time borax was introduced and considerable objection has been made to its use from time to time. In 1900 the amount of oil was reduced to 40 cc. or 6 2/3%. There was objection to this reduction.

VEGETABLE OILS IN OINTMENT OF ROSE WATER.

There is a strong feeling that vegetable oils are preferable to mineral oils in this preparation. For purposes of comparison we made a number of cold cream formulas using both vegetable and mineral fats. These are shown in Tables II, III and IV. Comments accompany each table.

Table II is a record of 10 vegetable oil formulas. Numbers 1, 2 and 3 are those recently suggested by Sub-Committee 13 for study. Number 1 is the official formula with very minor changes in composition. Numbers 2, 7 and 8 are too soft. Number 3 is cerate-like. Number 4 is the official ointment. Of the vegetable oils, other than almond oil, we feel that sesame oil makes the best formula. It is odorless and of good texture. Upon standing the cottonseed oil ointment became rancid and sticky. Olive oil imparted an undesirable color and the peanut oil developed a rancid odor to the ointments in which they were used.

TABLE II.

| | 1. ¹ Gm. | 2. ² Gm. | 3. ³ Gm. | 4. Gm. | 5. Gm. | 6. Gm. | 7. Gm. | 8. Gm. | 9. Gm. | 10. Gm. |
|------------------------|------------------------|------------------------|------------------------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| Spermaceti | 125 | 80 | 165 | 125 | 80 | 80 | 125 | 125 | 125 | 125 |
| White wax | 120 | 70 | 85 | 120 | 70 | 70 | 120 | 120 | 120 | 120 |
| Sodium borate | 5 | ... | ... | 5 | ... | 5 | 5 | 5 | 5 | 5 |
| Water | 190 | 250 | ... | ... | 250 | 250 | ... | ... | ... | ... |
| Oil of rose | 0.5 | 0.5 | ... | ... | 0.5 | 0.5 | ... | ... | ... | ... |
| Stronger rose water | ... | ... | ... | 190 | ... | ... | 190 | 190 | 190 | 190 |
| Glycerin | ... | ... | 110 | ... | ... | ... | ... | ... | ... | ... |
| Oil of almonds | 560 | 600 | 640 | 560 | 600 | 600 | ... | ... | ... | ... |
| Cottonseed oil | ... | ... | ... | ... | ... | ... | 560 | ... | ... | ... |
| Olive oil | ... | ... | ... | ... | ... | ... | ... | 560 | ... | ... |
| Peanut oil | ... | ... | ... | ... | ... | ... | ... | ... | 560 | ... |
| Sesame oil | ... | ... | ... | ... | ... | ... | ... | ... | ... | 560 |
| Castile soap | ... | ... | ... | ... | 0.5 | ... | ... | ... | ... | ... |

¹ Formula A, Sub-Com. 13, Bull. 26 (1932), 51.

² Formula B, Sub-Com. 13, Bull. 26 (1932), 52.

³ Formula C, Sub-Com. 13, Bull. 26 (1932), 52.

LIQUID PETROLATUM IN OINTMENT OF ROSE WATER.

While a number favor the use of a vegetable oil for this formula, about an equal number favor the use of liquid petrolatum. There are arguments in favor of the use of either oil which we will not present here except to say that there seems to be abundant evidence that liquid petrolatum cold creams are in very wide use. They are favored by manufacturers because of their marked keeping properties; dermatologists are about evenly divided on the use of mineral oil and vegetable oil cold creams; and the laity does not stop to ask the difference. Ointment of Rose Water made with liquid petrolatum has long been favored by many pharmacists, and an ointment of this type was considered in the last revision. It is up again for study.

In Table III are thirteen formulas of Ointment of Rose Water made with liquid petrolatum. Variations in the proportions of the basic constituents are not great. The formulas all made up nicely and have stood up well. For appearance, spreading property and texture, we feel that formula Number 6 is most nearly like that of the present official formula. Formulas 1, 2 and 4 also made very nice looking preparations. Numbers 11 and 12 are those proposed by Fueller and Molyneaux. The latter formula seems to have had wide publicity through the drug journals. It is a good cold cream. Number 7 makes a stiff ointment and Number 8 makes one that is too soft. Numbers 9 and 10 are too much like vanishing creams.

TABLE III.

| | 1. ¹ Gm. | 2. ² Gm. | 3. Gm. | 4. Gm. | 5. Gm. | 6. Gm. | 7. Gm. | 8. Gm. | 9. Gm. | 10. Gm. | 11. ³ Gm. | 12. ⁴ Gm. | 13. Gm. |
|---------------------|------------------------|------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|-------------------------|-------------------------|------------|
| White wax | 146 | 250 | 146 | 300 | 200 | 150 | 400 | 200 | 200 | 250 | 100 | 130 | 80 |
| Spermaceti | ... | ... | ... | ... | 100 | 150 | ... | ... | ... | ... | ... | ... | ... |
| Sodium borate | 10 | 5 | ... | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | ... |
| Water | 281 | ... | 281 | 210 | 210 | 210 | 153 | 253 | ... | ... | 200 | 190 | ... |
| Oil of rose | 0.5 | ... | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| Stronger rose water | ... | 250 | ... | ... | ... | ... | ... | ... | 210 | 210 | ... | ... | ... |
| Liquid petrolatum | 563 | 495 | 563 | 480 | 480 | 480 | 435 | 535 | 480 | 480 | 540 | 485 | 540 |
| Soap | ... | ... | 10 | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| Stearic acid | ... | ... | ... | ... | ... | ... | ... | ... | 10 | 5 | ... | ... | ... |
| Paraffin | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | 100 | 125 | 160 |
| Cacao butter | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | 4 | ... | ... |

¹ Formula D, Sub-Com. 13, Bull. 26 (1932), 52.

² Formula D, Sub-Com. 13, Bull. 31 (1932), 65.

³ Proposed by Fueller, *Bull. Pharm.*, 21 (1907), 36.

⁴ Proposed by Molyneaux, *Ibid.*, 21 (1907), 336.

WHITE PETROLATUM AND A MIXED BASE IN OINTMENT OF ROSE WATER.

A number of writers have proposed the use of white petrolatum as a substitute for the liquid fats commonly used in making Ointment of Rose Water. A number of formulas of this kind are shown in Table IV. Of these Number 3 is the most acceptable. The others are too stiff. The presence of stearic acid in Formulas 4, 5 and 6 seems to improve the texture of the finished product.

Formulas 7, 8 and 9 have a very low wax content and are, therefore, quite soft. Otherwise, they are nice appearing ointments.

TABLE IV.

| | 1. Gm. | 2. Gm. | 3. Gm. | 4. Gm. | 5. Gm. | 6. Gm. | 7. Gm. | 8. Gm. | 9. Gm. |
|-------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Spermaceti | ... | 100 | 150 | ... | ... | ... | ... | ... | ... |
| White wax | 300 | 200 | 150 | 200 | 250 | 250 | ... | ... | ... |
| Sodium borate | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Water | 210 | 210 | ... | ... | ... | ... | 290 | 240 | 190 |
| Oil of rose | 0.5 | 0.5 | ... | ... | ... | ... | 0.5 | 0.5 | 0.5 |
| Stronger rose water | ... | ... | 210 | 210 | 210 | 260 | ... | ... | ... |
| White petrolatum | 480 | 480 | 480 | 480 | 480 | 430 | ... | ... | ... |
| Stearic acid | ... | ... | ... | 100 | 50 | 50 | ... | ... | ... |
| Mixed base ¹ | ... | ... | ... | ... | ... | ... | 700 | 750 | 800 |

¹ Mixed base formula: Anhydrous lanolin, 5 Gm. White wax, 5 Gm. White petrolatum, 90 Gm.

Many attempts have been made to stabilize the official formula for Ointment of Rose Water.

Doliber (5) added four drachms of tincture of benzoin to a pound of the cold cream and found that it remained sweet for some time but finally granulated upon the surface. Fairthorne (6) said, "One of the objections to the rose water ointment of the Pharmacopoeia is its unstable character." For this reason, he maintained, druggists make their own substitute for it. In 1883 salicylic acid was suggested as a preservative for cold cream. Parisen (7) proposed a formula containing glycerin but no water. Williams (8) claimed that much of the trouble with the preparation was due to the fact that the water and the oils were mixed while too hot.

The efforts of many workers to stabilize the ointment by adding preservatives or making minor changes in the formula or technique of manufacture did not accomplish the desired results. A radical change in the formula was proposed when liquid petrolatum was suggested as a substitute for the oil of almonds in the official formula. Many pharmacists accepted the suggestion favorably, others did not.

Concerning this, Dawson (9) said, "Petrolatum and mineral oils are unsuitable for use in cold cream on account of their unabsorbability." On the other hand, Cooban (10) says, "A cold cream that will not become rancid is made from paraffin oil." In speaking of liquid petrolatum creams, St. James (11) said, "It seems to me that more interest should be paid to creams of this class, for they are truly elegant preparations, and in practice give splendid results." Fueller (12) had the following to say about a liquid cold cream which he used: "It does not become rancid, fall down or change color and is not excessively greasy like some I have seen, nor does it get granular, but remains perfectly smooth."

In summarizing the statements of men concerning revision problems:

Cook (13) quotes Hilton as follows: "Use liquid petrolatum instead of oil of almonds. Liquid petrolatum makes a far superior product, does not become rancid on standing, is more acceptable generally and as usually employed seems to be a better product as it is not as readily absorbed." Further testimony in favor of a liquid petrolatum cold cream is taken from a report of Sub-Committee 2, U. S. P. X (14). The majority report of the committee of three on Therapeutics was as follows: "If it is practical to make provisions that will effectively prevent the dispensing of any rancid specimen, the old formula would be preferable. If this is not practical, it would be better to change to the petrolatum formula."

This is a running cross section of the controversy that has taken place over the official cold cream. Much more could be said about it.

In giving consideration to the problems which this preparation presents we would do well to remember two things: In the first place, pharmacists, "in the good old days," made it in amounts to suit their immediate needs and as an extemporaneous ointment it is quite satisfactory. In our own time the preparation is left to the manufacturer to make. This necessitates long periods of storage under all sorts of climatic conditions. The pharmacist in turn buys in amounts in excess of his needs and soon finds a deteriorated product on his hands. In the second place, the official cold cream is an emulsion and it is perhaps too much to expect it to remain unchanged over long periods of time.

Finally, as pharmacists, it is not within our province to make decisions upon matters of therapeutics and use of medicinal products, but we should certainly be alert to the challenge of elegance, stability and usefulness of well-known galenicals.

REFERENCES.

- (1) U. S. P. XI Bulletins, Sub-Committee 13, Bull. 26 (1932), 51.
- (2) J. B. Moore, *Am. J. Pharm.*, 42 (1870), 63.
- (3) S. Piesse, *Ibid.*, 28 (1856), 83.
- (4) U. S. P. XI Bulletins, Sub-Committee 13, Bull. 31 (1932), 82.
- (5) T. Doliber, *Proc. A. Ph. A.*, 15 (1867), 385.
- (6) R. J. Fairthorne, *Am. J. Pharm.*, 53 (1881), 565.
- (7) G. W. Parisen, *Drug. Circ.*, 34 (1890), 175.
- (8) J. P. Williams, *Bull. Pharm.*, 14 (1900), 474.
- (9) W. A. Dawson, *Ibid.*, 15 (1901), 35.
- (10) B. S. Cooban, *Ibid.*, 19 (1905), 42.

- (11) J. C. A. St. James, *Bull. Pharm.*, 19 (1905), 342.
 (12) H. C. Fueller, *Ibid.*, 21 (1907), 36.
 (13) E. F. Cook, *Jour. A. Ph. A.*, 9 (1920), 417.
 (14) U. S. P. X Circ. Gen. Com., Vol. 5, Circ. 491, page 2454.

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UNGUENTUM AQUÆ ROSÆ.*

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The chairman of Sub-Committee on Cerates and Ointments (of which I am a member) has designated me to prepare a report on Cold Cream, known officially in U. S. P. X as *Unguentum Aquæ Rosæ*.

My own observations on *Unguentum Aquæ Rosæ* are, that a change in the present formula is desirable, because of its tendency to rancidity and the tendency of borax in the present formula to interact with many substances with which the ointment is combined.

U. S. P. VIII devotes a paragraph to the latter; it reads: "When this Ointment is to be used as a vehicle for metallic salts, the Sodium Borate should be omitted."

Before entering into a discussion as to the merits or faults of the present formula, let us trace the history of this preparation. I find in "LaWall's 4000 Years of Pharmacy" the following:

"The most famous preparation handed down to us by Galen, and referred to in the medieval pharmacopœias as unguentum or ceratum refrigerans, Galeni, is the well-known Cold Cream or rose water ointment."

In "Quincy's Dispensatory," published in 1746, on page 300, I find a formula for *Unguentum Album* as follows:

"Take of oil of roses, 9 ounces; of ceruse, carefully washed in rose water and powdered, 3 ounces; of white wax, 2 ounces; when the wax is melted in the oil, sift in the ceruse, after it hath been well dried from its washing, first in common and then in rose water, so that together they may be made into an ointment, *s. a.*"

In U. S. P. I, published in 1820, on page 247, I find the following formula:

| | |
|-------------------------|----------------|
| "Take of Oil of almonds | 2 fluidounces |
| Spermaceti | ½ ounce |
| White wax | 1 drachm |
| Rose water | 2 fluidounces" |

and direction for preparation.

The same formula occurs in U. S. P. II and U. S. P. III. In U. S. P. IV there is a revision to the extent of proportions of the same ingredients.

In U. S. P. VIII, we have for the first time the introduction of Sodium Borate in the formula, with the alleged object of promoting saponification of the oils and waxes. The same reference is made in U. S. P. IX and in U. S. P. X.

* Section on Practical Pharmacy and Dispensing, A. Ph. A., Toronto meeting, 1932.