

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-282

STATISTICAL REVIEW(S)

**STATISTICAL REVIEW AND EVALUATION
CLINICAL STUDIES
(STABILITY)**

| | |
|----------------------|---|
| Date | |
| NDA # | 21-282 |
| Applicant | Adams |
| Name of Drug | Mucinex |
| Indication | |
| Document Reviewed | Sponsor's cover letter dated 1/11/02 Vol. 1 (in response to FDA approvable letter of 12/21/01) Section: Exhibits, K and L (1/11/02) Sponsor's cover letter dated 5/8/02 Vol. 1 (in response to FDA teleconference of 3/8/02) Section: Exhibits, K and L (5/8/02) Data sets reviewed: Section Exhibits, K and L (1/11/02, 5/8/02), manually entered into Excel workbook by this reviewer for analysis purpose Reviewer's analysis data set can be viewed at: http://ereview/scripts/broker.exe? service=default& program=x8p.ssdsview.sas& debug=2&libref=OUTLIB&memsel=Mucinex |
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| Key Words | Stability |

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Reviewer's Stability Analysis of Mucinex

Reviewer's Initial analysis

The analyses in this section were later updated as Reviewer's Additional Stability Analysis of Mucinex upon request from CMC reviewer, Dr. Eugenia Nashed on 6/28/02.

Table 1 describes the batches' characteristics and the upper and lower specifications considered in estimating the expiry-dating period.

Table 1. Description of stability analysis for Mucinex

| Test parameter | Temperature | Humidity | Strength | Package | Lower spec | Upper spec |
|----------------|-------------|----------|----------|---------|------------|------------|
| Assay | 25°C | 60% | 600mg | | | |
| Friability | 25°C | 60% | 600mg | | | |
| Hardness | 25°C | 60% | 600mg | | | |

The following tables show linear regression lines on which the estimations of the expiry-dating period are based. The estimates appear in the last columns of these tables. The time unit is month.

Table 3. Estimate of expiry dating period based on assay (600mg, 25°C, 60%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|--|---------|-------------------------|
| $Y = 100.2309 - 0.0053 \times \text{Time}$ | POOLED | |
| | Minimum | |

Table 5. Estimate of expiry dating period based on friability (600mg, 25°C, 60%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|-------------|---------|-------------------------|
| _____ | PB320S | _____ |
| _____ | PB321S | _____ |
| _____ | PB322S | _____ |
| | Minimum | _____ |

*: See Table A-1, Appendix for data listing.

Please note that for the friability, 600mg, the minimum estimate is calculated to be _____. The batches had inconsistent friability measurements: Two of the three batches, PB320S and PB322S, had all observations at _____ while the third batch, PB321S had most observations ranging from _____. See Table A-1 in Appendix.

Table 7. Estimate of expiry dating period based on hardness (600mg, 25°C, 60%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|-------------|---------|-------------------------|
| _____ | PB320S | _____ |
| _____ | PB321S | _____ |
| _____ | PB322S | _____ |
| | Minimum | _____ |

Results from Initial Analysis

Table 8 summarizes the estimates based on assay, friability, and hardness. For friability, the minimum estimate is calculated to be — which might be a result of possibly inconsistent data among the batches. However, without the friability data, with 95% confidence, this drug is expected to remain within the specification limits for at least — months.

Table 8. Estimated expiry-dating period: Summary

| Test parameter | Strength | Condition | Estimated expiry-dating period (in month) |
|----------------|----------|-------------|---|
| Assay | | | |
| Assay | 600mg | 25°C, 60%RH | — |
| Friability | | | |
| Friability | 600mg | 25°C, 60%RH | — |
| Hardness | | | |
| Hardness | 600mg | 25°C, 60%RH | — |
| | | Minimum | — |

**:. To facilitate the CMC reviewer to further examine friability, the data for friability, 600mg are displayed in the Appendix.

Reviewer's Additional Stability Analysis of Mucinex

The additional stability analyses were done using the 600mg tablet data dated 5/8/02. The following points highlight the setups of these analyses:

The data under accelerated condition (40°C, 75%RH) and normal condition (25°C, 60%RH) were analyzed separately with one exception: The data for bottles of 20 and 40 and for both storage conditions were analyzed together. This consideration was based on the fact that there was only one batch for each condition and package. With this combination, four batches were included in the statistical analysis. Dr. Nashed and this reviewer considered such an arrangement was reasonable.

To circumvent difficulty in labeling the mixtures of different temperatures, RH, and package types in report, the storage temperature was indicated as "91," the RH, "92," and the package type, —. The specifications in this additional analysis were the same as those in the initial analysis, except that, now, the specifications for ASSAY were —.

Similar to the initial analysis, the following tables show linear regression lines on which the estimations of the expiry-dating period are based. The estimates appear in the last columns of these tables. The time unit is month.

The graphs for the additional analyses can be found in Figures A-7 to A-21, Appendix.

Table 9. Estimate of expiry dating period based on assay (600mg, Bottle of 2, 25°C, 60%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|-------------|---------|-------------------------|
| | 1E0804S | |
| | 1G0805S | |
| | 1G0806S | |
| | ~MIN~ | |

Table 10. Estimate of expiry dating period based on assay (600mg, Bottle of 2, 40°C, 75%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|-------------|---------|-------------------------|
| | 1E0804S | |
| | 1G0805S | |
| | 1G0806S | |
| | ~MIN~ | |

Table 11. Estimate of expiry dating period based on assay (600mg, Bottles of 20 and 40, 40°C,

| Fitted Line | Batch | Estimated Expiry Period |
|-------------|---------|-------------------------|
| | 1E804FA | |
| | 1E804FR | |
| | 1E804GA | |
| | 1E804GR | |
| | ~MIN~ | |

Table 12. Estimate of expiry dating period based on assay (600mg, Bottle of 100, 25°C, 60%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|---|--------|-------------------------|
| $Y = 98.7389 + 0.0722 \times \text{Time}$ | POOLED | |
| | ~MIN~ | |

Table 13. Estimate of expiry dating period based on assay (600mg, Bottle of 100, 40°C, 75%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|---|--------|-------------------------|
| $Y = 99.1283 - 0.0868 \times \text{Time}$ | POOLED | |
| | ~MIN~ | |

Table 14. Estimate of expiry dating period based on friability (600mg, Bottle of 2, _____)

| Fitted Line | Batch | Estimated Expiry Period |
|-------------|---------|-------------------------|
| _____ | 1E0804S | _____ |
| _____ | 1G0805S | _____ |
| _____ | 1G0806S | _____ |
| | ~MIN~ | |

Table 15. Estimate of expiry dating period based on friability (600mg, Bottle of 2, 40°C, 75%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|-------------|---------|-------------------------|
| _____ | 1E0804S | |
| _____ | 1G0805S | _____ |
| _____ | 1G0806S | _____ |
| | ~MIN~ | _____ |

Table 16. Estimate of expiry dating period based on friability (600mg, Bottles of 20 and 40, 40°C, _____)

| Fitted Line | Batch | Estimated Expiry Period |
|--|--------|-------------------------|
| $Y = 0.0603 + 0.0103 \times \text{Time}$ | POOLED | _____ |
| | ~MIN~ | _____ |

Table 17. Estimate of expiry dating period based on friability (600mg, Bottle of 100, 25°C, 60%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|--|--------|-------------------------|
| $Y = 0.0444 + 0.0111 \times \text{Time}$ | POOLED | _____ |
| | ~MIN~ | _____ |

Table 18. Estimate of expiry dating period based on friability (600mg, Bottle of 100, 40°C, 75%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|-------------|---------|-------------------------|
| _____ | 1E0804A | _____ |
| _____ | 1E0805A | _____ |
| _____ | 1E0806A | _____ |
| | ~MIN~ | |

Table 19. Estimate of expiry dating period based on hardness (600mg, Bottle of 2, 25°C, 60%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|-------------|---------|-------------------------|
| | 1E0804S | |
| | 1G0805S | |
| | 1G0806S | |
| | ~MIN~ | |

Table 20. Estimate of expiry dating period based on hardness (600mg, Bottle of 2, 25°C, 60%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|---|--------|-------------------------|
| $Y = 17.8742 + 0.1635 \times \text{Time}$ | POOLED | |
| | ~MIN~ | |

Table 21. Estimate of expiry dating period based on hardness (600mg, Bottles of 20 and 40, 40°C, 75%RH and 25°C, 60%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|-------------|---------|-------------------------|
| | 1E804FA | |
| | 1E804FR | |
| | 1E804GA | |
| | 1E804GR | |
| | ~MIN~ | |

Table 22. Estimate of expiry dating period based on hardness (600mg, Bottle of 100, 25°C, 60%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|-------------|---------|-------------------------|
| | 1E0804A | |
| | 1E0805A | |
| | 1E0806A | |
| | ~MIN~ | |

Table 23. Estimate of expiry dating period based on hardness (600mg, Bottle of 100, 40°C, 75%RH)

| Fitted Line | Batch | Estimated Expiry Period |
|---|--------|-------------------------|
| $Y = 17.7736 + 0.2610 \times \text{Time}$ | POOLED | |
| | ~MIN~ | |

Results from Additional Analysis

Table 24. Estimated expiry-dating period: Summary of Reviewer's Additional Analyses

| Test parameter | Package | Strength | Condition | Estimated expiry-dating period (in month) |
|----------------|----------------------|----------|-----------------------------|---|
| Assay | Bottle of 2 | 600mg | 25°C, 60%RH | — |
| Assay | Bottle of 2 | 600mg | 40°C, 75%RH | — |
| Assay | Bottles of 20 and 40 | 600mg | 25°C, 60%RH and 40°C, 75%RH | — |
| Assay | Bottle of 100 | 600mg | 25°C, 60%RH | — |
| Assay | Bottle of 100 | 600mg | 40°C, 75%RH | — |
| Friability | Bottle of 2 | 600mg | 25°C, 60%RH | — |
| Friability | Bottle of 2 | 600mg | 40°C, 75%RH | — |
| Friability | Bottles of 20 and 40 | 600mg | 25°C, 60%RH and 40°C, 75%RH | — |
| Friability | Bottle of 100 | 600mg | 25°C, 60%RH | — |
| Friability | Bottle of 100 | 600mg | 40°C, 75%RH | — |
| Hardness | Bottle of 2 | 600mg | 25°C, 60%RH | — |
| Hardness | Bottle of 2 | 600mg | 40°C, 75%RH | — |
| Hardness | Bottles of 20 and 40 | 600mg | 25°C, 60%RH and 40°C, 75%RH | — |
| Hardness | Bottle of 100 | 600mg | 25°C, 60%RH | — |
| Hardness | Bottle of 100 | 600mg | 40°C, 75%RH | — |
| | | | Minimum | |

Table 24 summarizes the estimates based on assay, friability, and hardness—using sponsor's data dated 5/8/02. Note that the shortest estimate is: — which is resulting from the analyses of assay and hardness based on data combining package types (bottles of 20 and 40), and storage conditions (25°C, 60%RH and 40°C, 75%RH). The next to the shortest estimate is: — resulting from the analysis based on friability under condition, 40°C, 75%RH for bottle of 2.

Appendix

Table A-1. Data (dated 1/11/02 with 24-month updated on 5/8/02) listing for FRIABIL 600mg 250C 60%RH

| By-variable (Internal-use variable) | Alpha Level | Number of Sides of Confidence Limits | Lower Spec. Limit | Upper Spec. Limit | Batch | Time (in months) | Measurement |
|-------------------------------------|-------------|--------------------------------------|-------------------|-------------------|--------|------------------|-------------|
| [22111] | 0.050 | 1 | . | / | PB320S | 0 | / |
| [22111] | 0.050 | 1 | . | / | PB320S | 3 | / |
| [22111] | 0.050 | 1 | . | / | PB320S | 6 | / |
| [22111] | 0.050 | 1 | . | / | PB320S | 9 | / |
| [22111] | 0.050 | 1 | . | / | PB320S | 12 | / |
| [22111] | 0.050 | 1 | . | / | PB320S | 18 | / |
| [22111] | 0.050 | 1 | . | / | PB320S | 24 | / |
| [22111] | 0.050 | 1 | . | / | PB321S | 0 | / |
| [22111] | 0.050 | 1 | . | / | PB321S | 3 | / |
| [22111] | 0.050 | 1 | . | / | PB321S | 6 | / |
| [22111] | 0.050 | 1 | . | / | PB321S | 9 | / |
| [22111] | 0.050 | 1 | . | / | PB321S | 12 | / |
| [22111] | 0.050 | 1 | . | / | PB321S | 18 | / |
| [22111] | 0.050 | 1 | . | / | PB321S | 24 | / |
| [22111] | 0.050 | 1 | . | / | PB322S | 0 | / |
| [22111] | 0.050 | 1 | . | / | PB322S | 3 | / |
| [22111] | 0.050 | 1 | . | / | PB322S | 6 | / |
| [22111] | 0.050 | 1 | . | / | PB322S | 9 | / |
| [22111] | 0.050 | 1 | . | / | PB322S | 12 | / |
| [22111] | 0.050 | 1 | . | / | PB322S | 18 | / |
| [22111] | 0.050 | 1 | . | / | PB322S | 24 | / |

Source: Exhibition K and L, vol. 1.
 ***: Page 4-104, vol. 1 (1/11/2002)
 ****: Page 4-219, vol. 1 (5/8/2002, 24-month update)
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Graphs from Initial Analyses



Figure A-2. ASSAY, 600MG

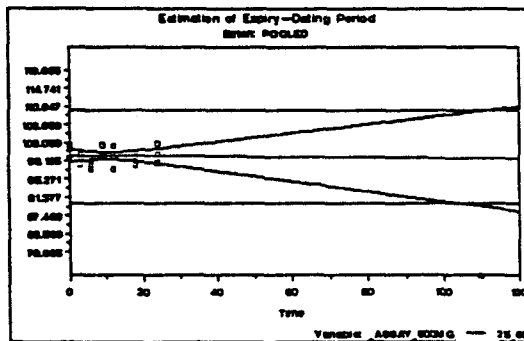


Figure A-4. FRIABIL, 600MG, 25°C, 60%RH

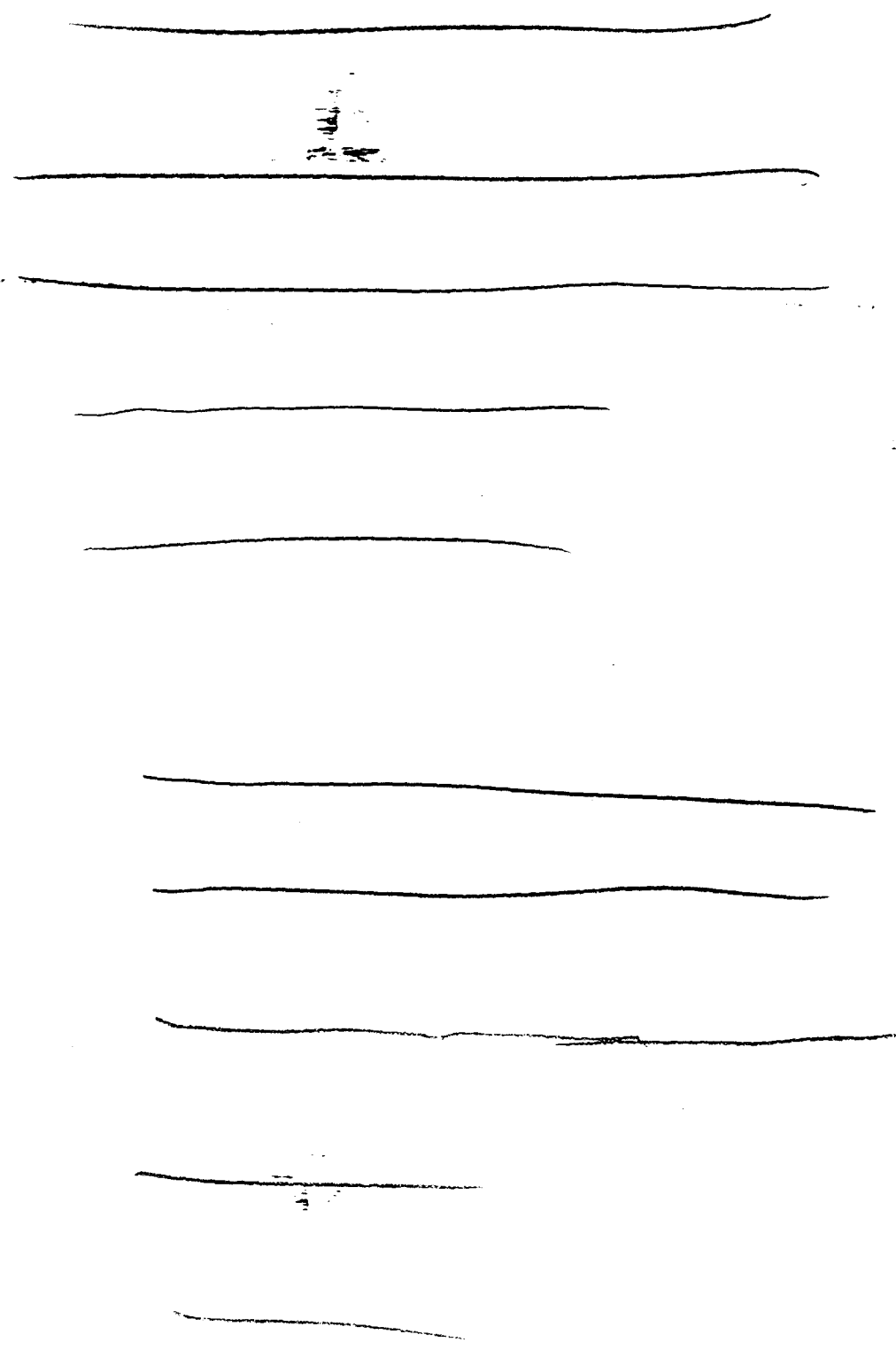
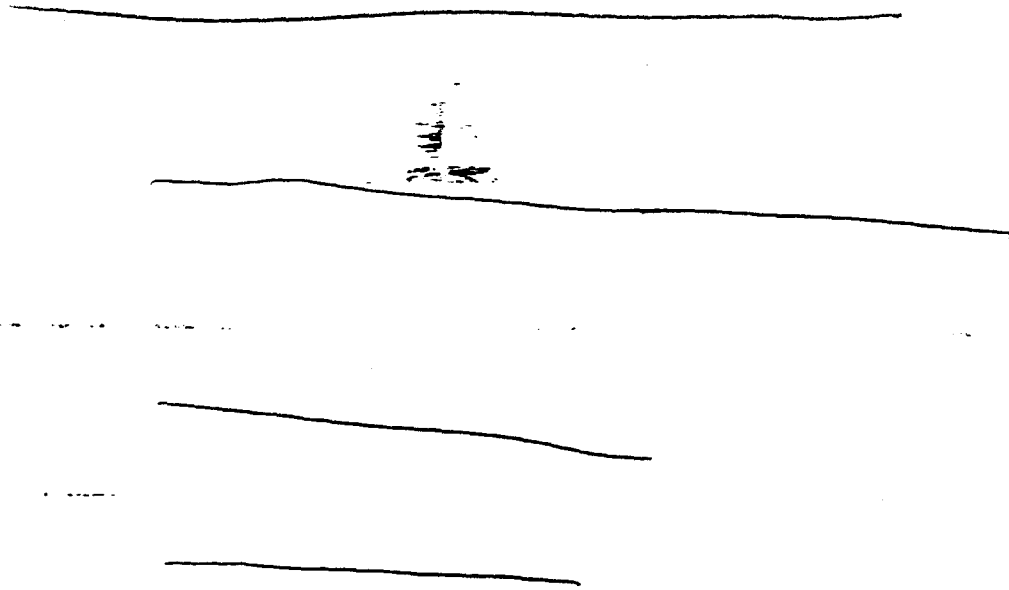


Figure A-6. HARD, 600MG, — , 25°C, 60%RH



Graphs from additional analysis

Figure A-8. Estimate of expiry dating period based on assay (600mg, Bottle of 2, 40°C, 75%RH)

Figure A-7. Estimate of expiry dating period based on assay (600mg, Bottle of 2, 25°C, 60%RH)

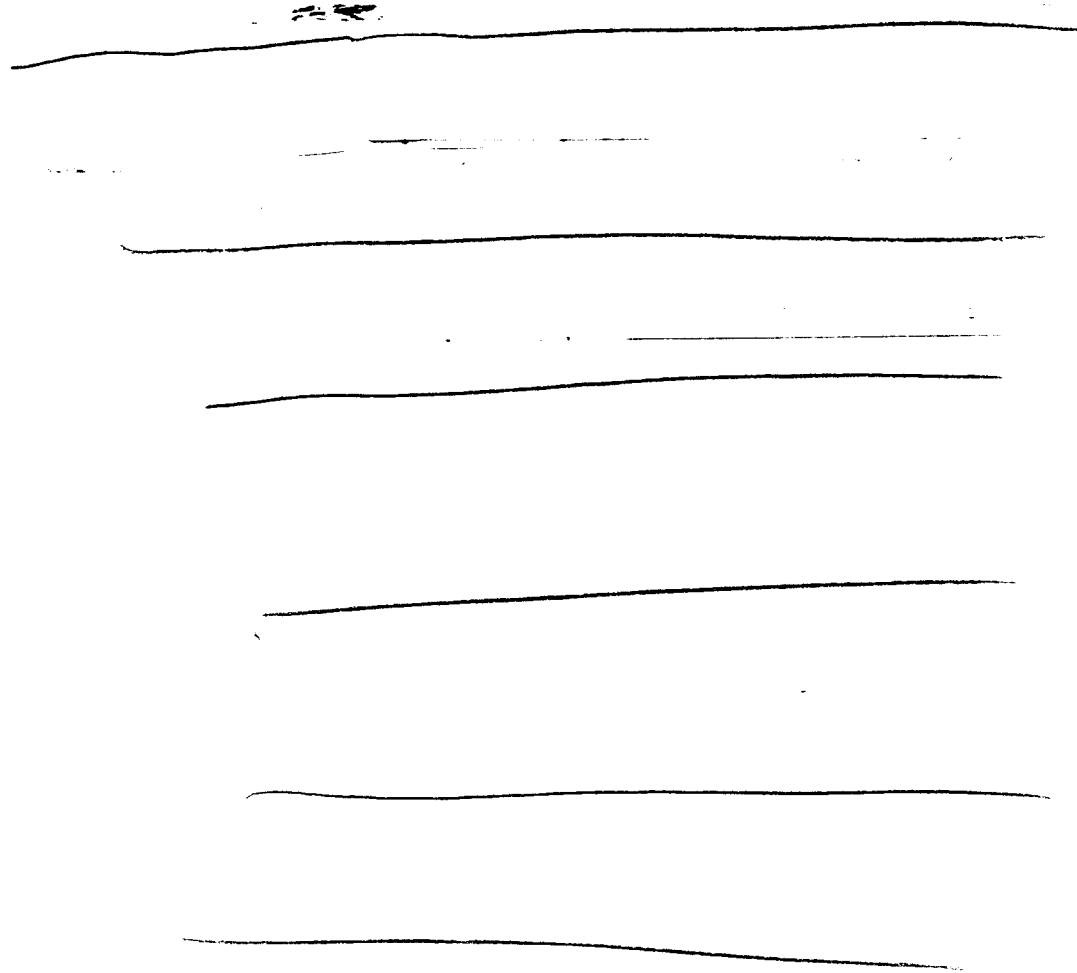


Figure A-9. Estimate of expiry dating period based on assay (600mg. Bottles of 20 and 40,

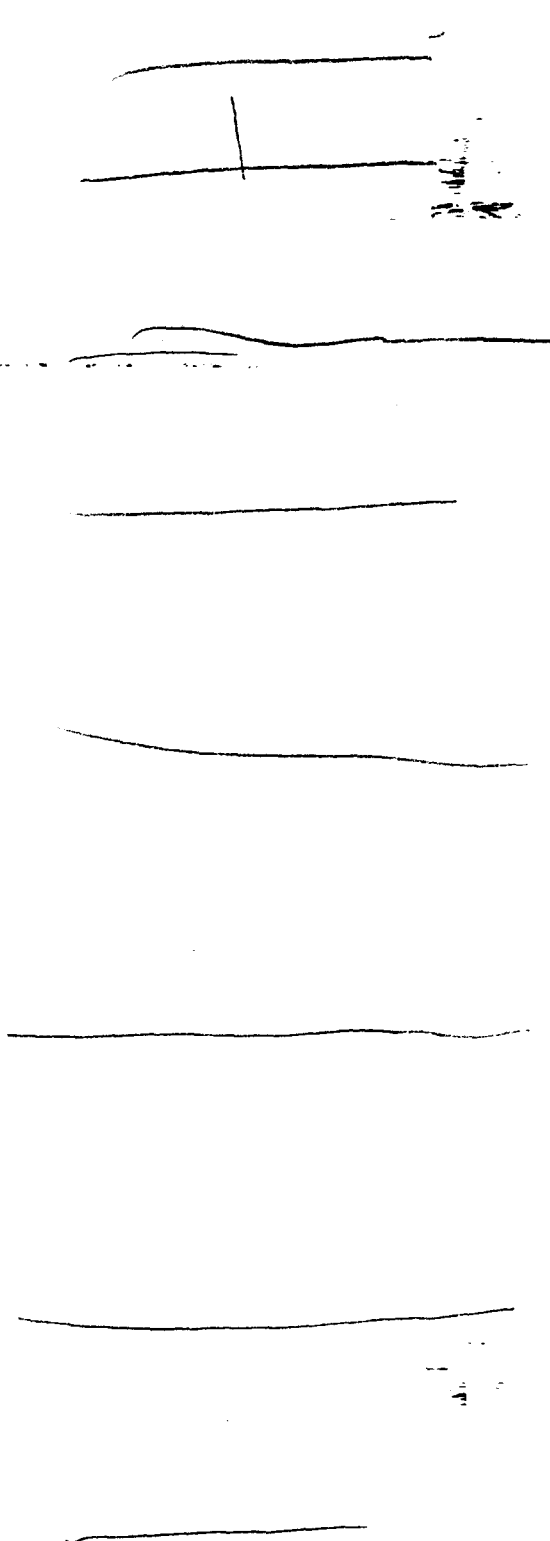


Figure A-10. Estimate of expiry dating period based on assay (600mg, Bottle of 100, 25°C, 60%RH)

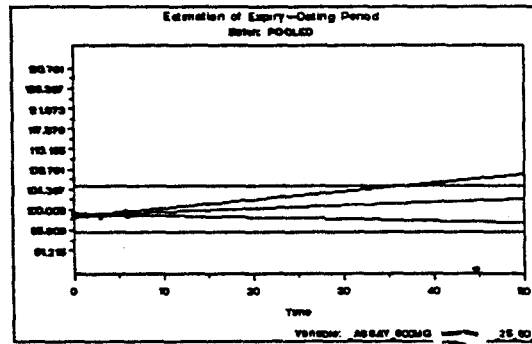


Figure A-11. Estimate of expiry dating period based on assay (600mg, Bottle of 100, 40°C, 75%RH)

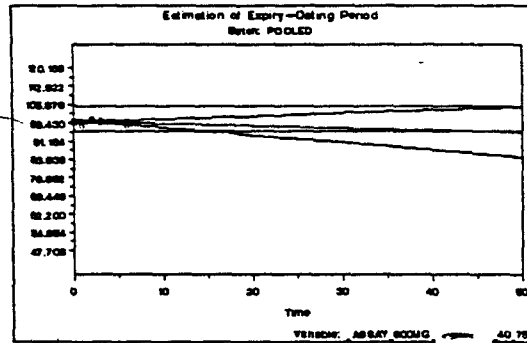


Figure A-12. Estimate of expiry dating period based on friability (600mg, Bottle of 2, 25°C, 60%RH)

Figure A-13. Estimate of expiry dating period based on friability (600mg, Bottle of 2, 40°C, 75%RH)

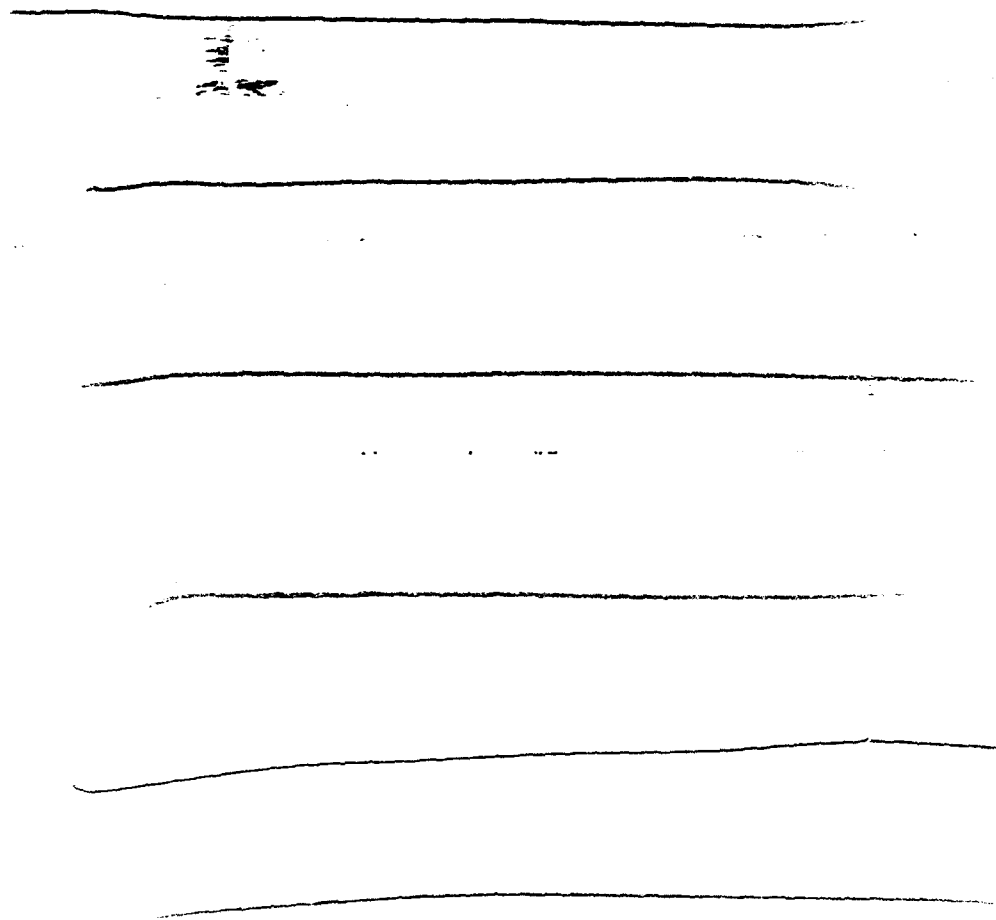


Figure A-14. Estimate of expiry dating period based on friability (600mg, Bottles of 20 and 40, 40°C, 75%RH and 25°C, 60%RH)

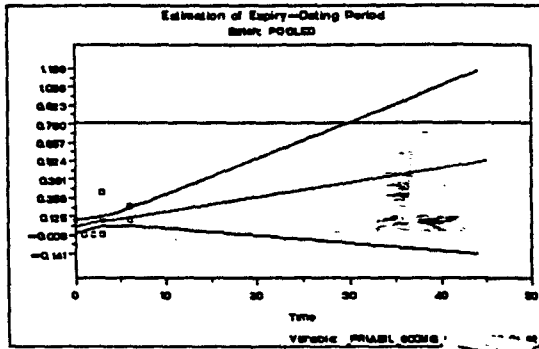


Figure A-15. Estimate of expiry dating period based on friability (600mg, Bottle of 100, 25°C, 60%RH)

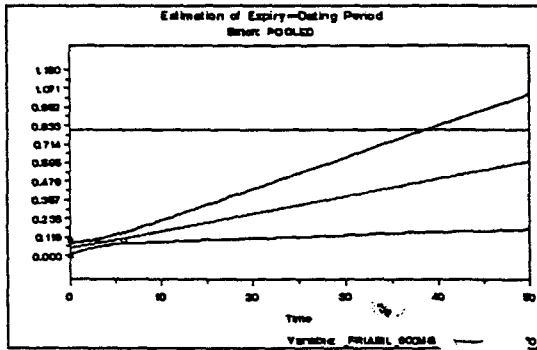


Figure A-16. Estimate of expiry dating period based on friability (600mg, Bottle of 100, 40°C, 75%RH)

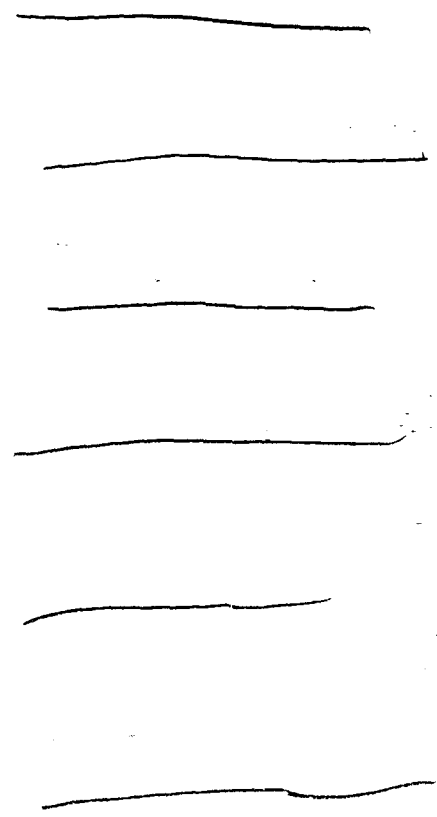


Figure A-17. Estimate of expiry dating period based on hardness (600mg, Bottle of 2, 25°C, 60%RH)

Figure A-19. Estimate of expiry dating period based on hardness (600mg, Bottles of 20 and 40, 40°C, 75%RH and 25°C, 60%RH)

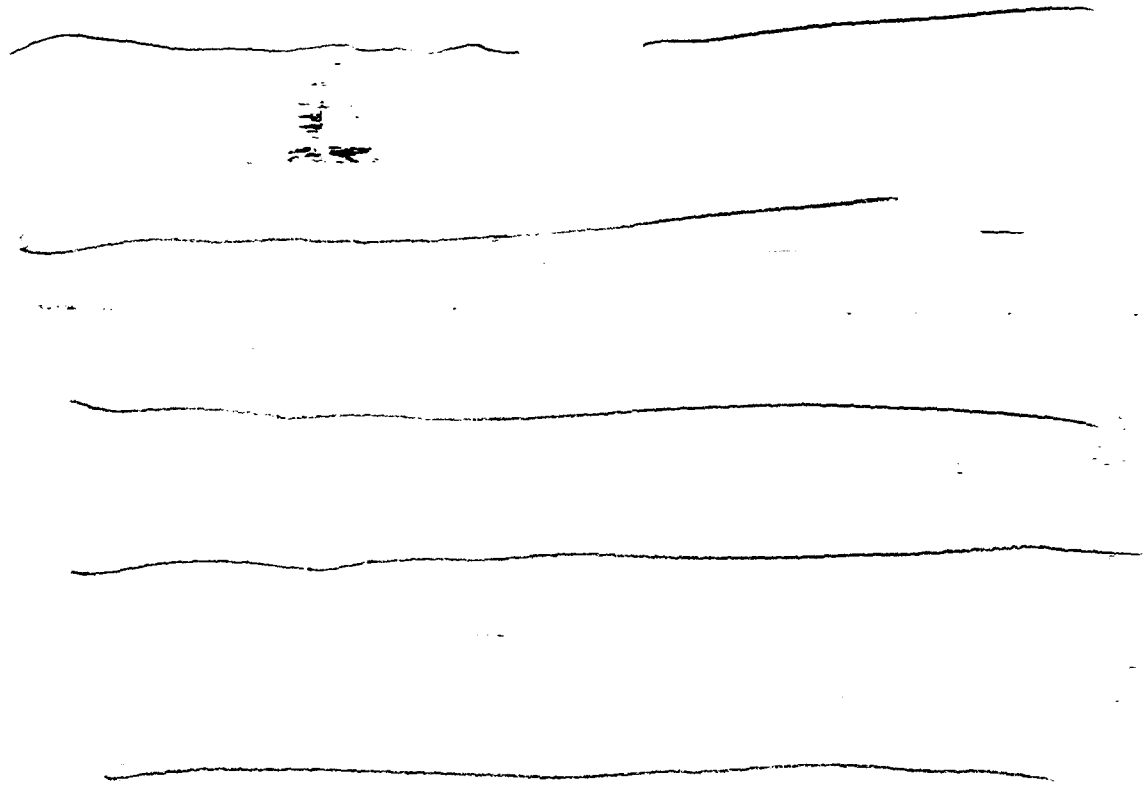


Figure A-18. Estimate of expiry dating period based on hardness (600mg, Bottle of 2, 40°C, 75%RH)

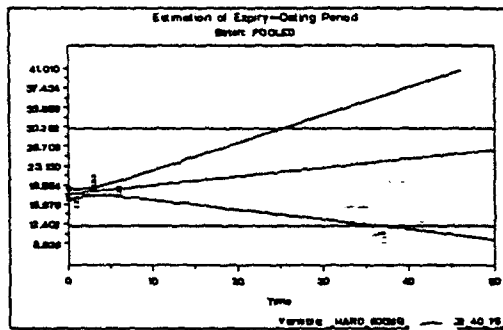


Figure A-20. Estimate of expiry dating period based on hardness (600mg, Bottle of 100, 25°C, 60%RH)

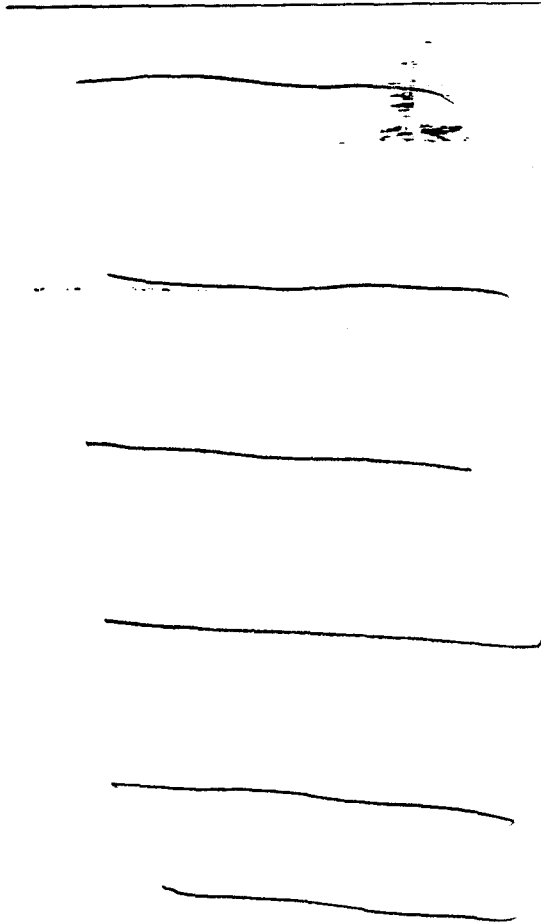
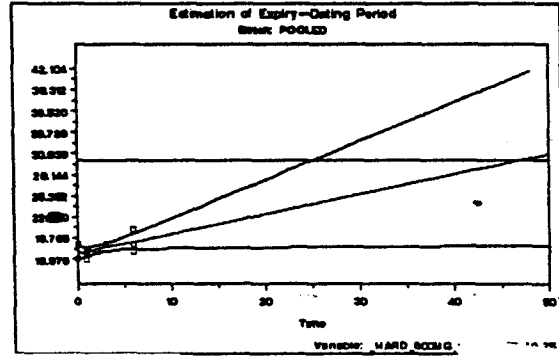


Figure A-21. Estimate of expiry dating period based on hardness (600mg, Bottle of 100, 40°C, 75%RH)



Stability Data

Table A-2 Data (dated 1/11/02 with 24-month updated on 5/8/02)

| TEST | TEMPER RH | STRENGTH PACKAGE | CLLEVEL | CLSIDE | LOWSPEC | UPPSPEC | BATCH | TIME LEVEL |
|---------|-----------|------------------|---------|--------|---------|---------|--------|------------|
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 0 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 3 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 6 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 9 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 12 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 18 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 24 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 0 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 3 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 6 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 9 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 12 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 18 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 24 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 0 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 3 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 6 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 9 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 12 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 18 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 24 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 0 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 3 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 6 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 9 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 12 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 18 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 24 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 0 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 3 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 6 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 9 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 12 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 18 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 24 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 0 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 3 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 6 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 9 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 12 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 18 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | | | PB322S | 24 |
| HARD | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 0 |
| HARD | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 3 |
| HARD | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 6 |
| HARD | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 9 |
| HARD | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 12 |
| HARD | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 18 |
| HARD | 25 | 60 600mg | 0.05 | 2 | | | PB320S | 24 |
| HARD | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 0 |
| HARD | 25 | 60 600mg | 0.05 | 2 | | | PB321S | 3 |

| | | | | | | |
|-------|----|----------|------|---|--------|----|
| HARD | 25 | 60 600mg | 0.05 | 2 | PB321S | 6 |
| HARD | 25 | 60 600mg | 0.05 | 2 | PB321S | 9 |
| HARD | 25 | 60 600mg | 0.05 | 2 | PB321S | 12 |
| HARD | 25 | 60 600mg | 0.05 | 2 | PB321S | 18 |
| HARD | 25 | 60 600mg | 0.05 | 2 | PB321S | 24 |
| HARD | 25 | 60 600mg | 0.05 | 2 | PB322S | 0 |
| HARD | 25 | 60 600mg | 0.05 | 2 | PB322S | 3 |
| HARD | 25 | 60 600mg | 0.05 | 2 | PB322S | 6 |
| HARD | 25 | 60 600mg | 0.05 | 2 | PB322S | 9 |
| HARD | 25 | 60 600mg | 0.05 | 2 | PB322S | 12 |
| HARD | 25 | 60 600mg | 0.05 | 2 | PB322S | 18 |
| HARD | 25 | 60 600mg | 0.05 | 2 | PB322S | 24 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 0 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 3 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 6 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 9 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 12 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 18 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 24 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 0 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 3 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 6 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 9 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 12 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 18 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 0 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 3 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 6 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 9 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 12 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 18 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 0 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 3 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 6 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 9 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 12 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 18 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 0 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 3 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 6 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 9 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 12 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 18 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 0 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 3 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 6 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 9 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 12 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB322S | 18 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 0 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 3 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 6 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 9 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 12 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB320S | 18 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 0 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 3 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 6 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 9 |
| IMPUR | 25 | 60 600mg | 0.05 | 1 | PB321S | 12 |

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|---------|----|----|----|------|---|--------|----|
| ASSAY | 25 | 60 | mg | 0.05 | 2 | PB315S | 6 |
| ASSAY | 25 | 60 | mg | 0.05 | 2 | PB315S | 9 |
| ASSAY | 25 | 60 | mg | 0.05 | 2 | PB315S | 12 |
| ASSAY | 25 | 60 | mg | 0.05 | 2 | PB315S | 18 |
| ASSAY | 25 | 60 | mg | 0.05 | 2 | PB315S | 24 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB304S | 0 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB304S | 3 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB304S | 6 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB304S | 9 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB304S | 12 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB304S | 18 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB304S | 24 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB314S | 0 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB314S | 3 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB314S | 6 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB314S | 9 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB314S | 12 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB314S | 18 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB314S | 24 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB315S | 0 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB315S | 3 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB315S | 6 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB315S | 9 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB315S | 12 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB315S | 18 |
| FRIABIL | 25 | 60 | mg | 0.05 | 2 | PB315S | 24 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB304S | 0 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB304S | 3 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB304S | 6 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB304S | 9 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB304S | 12 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB304S | 18 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB304S | 24 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB314S | 0 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB314S | 3 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB314S | 6 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB314S | 9 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB314S | 12 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB314S | 18 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB314S | 24 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB315S | 0 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB315S | 3 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB315S | 6 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB315S | 9 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB315S | 12 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB315S | 18 |
| HARD | 25 | 60 | mg | 0.05 | 2 | PB315S | 24 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 0 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 3 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 6 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 9 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 12 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 18 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 0 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 3 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 6 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 9 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 12 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 18 |

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|-------|----|----|-----|------|---|--------|----|
| IMPUR | 25 | 60 | img | 0.05 | 1 | PB315S | 0 |
| IMPUR | 25 | 60 | img | 0.05 | 1 | PB315S | 3 |
| IMPUR | 25 | 60 | img | 0.05 | 1 | PB315S | 6 |
| IMPUR | 25 | 60 | img | 0.05 | 1 | PB315S | 9 |
| IMPUR | 25 | 60 | img | 0.05 | 1 | PB315S | 12 |
| IMPUR | 25 | 60 | img | 0.05 | 1 | PB315S | 18 |
| IMPUR | 25 | 60 | img | 0.05 | 1 | PB304S | 0 |
| IMPUR | 25 | 60 | img | 0.05 | 1 | PB304S | 3 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 6 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 9 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 12 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 18 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 0 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 3 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 6 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 9 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 12 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 18 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB315S | 0 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB315S | 3 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB315S | 6 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB315S | 9 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB315S | 12 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB315S | 18 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 0 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 3 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 6 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 9 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 12 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB304S | 18 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 0 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 3 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 6 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 9 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 12 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB314S | 18 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB315S | 0 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB315S | 3 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB315S | 6 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB315S | 9 |
| IMPUR | 25 | 60 | mg | 0.05 | 1 | PB315S | 12 |

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|----------|----|----|-------|------|---|---------|----|
| IMPUR. | 25 | 60 | mg | 0.05 | 1 | PB315S | 18 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB304S | 0 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB304S | 3 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB304S | 6 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB304S | 9 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB304S | 12 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB304S | 18 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB314S | 0 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB314S | 3 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB314S | 6 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB314S | 9 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB314S | 12 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB314S | 18 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB315S | 0 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB315S | 3 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB315S | 6 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB315S | 9 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB315S | 12 |
| IMPURTOT | 25 | 60 | mg | 0.05 | 1 | PB315S | 18 |
| ASSAY | 25 | 60 | 600mg | 0.05 | 2 | 1E0804S | 0 |
| ASSAY | 25 | 60 | 600mg | 0.05 | 2 | 1E0804S | 3 |
| ASSAY | 25 | 60 | 600mg | 0.05 | 2 | 1E0804S | 6 |
| ASSAY | 25 | 60 | 600mg | 0.05 | 2 | 1G0805S | 0 |
| ASSAY | 25 | 60 | 600mg | 0.05 | 2 | 1G0805S | 3 |
| ASSAY | 25 | 60 | 600mg | 0.05 | 2 | 1G0805S | 6 |
| ASSAY | 25 | 60 | 600mg | 0.05 | 2 | 1G0806S | 0 |
| ASSAY | 25 | 60 | 600mg | 0.05 | 2 | 1G0806S | 3 |
| ASSAY | 25 | 60 | 600mg | 0.05 | 2 | 1G0806S | 6 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1E0804S | 0 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1E0804S | 1 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1E0804S | 2 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1E0804S | 3 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1E0804S | 6 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1G0805S | 0 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1G0805S | 1 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1G0805S | 2 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1G0805S | 3 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1G0805S | 6 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1G0806S | 0 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1G0806S | 1 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1G0806S | 2 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1G0806S | 3 |
| ASSAY | 40 | 75 | 600mg | 0.05 | 2 | 1G0806S | 6 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804GA | 0 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804GA | 1 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804GA | 2 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804GA | 3 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804GA | 6 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804GR | 0 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804GR | 3 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804GR | 6 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804FA | 0 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804FA | 1 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804FA | 2 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804FA | 3 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804FA | 6 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804FR | 0 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804FR | 3 |
| ASSAY | 91 | 92 | 600mg | 0.05 | 2 | 1E804FR | 6 |

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|-------|----|----------|------|---|---------|---|
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 0 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 1 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 2 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 3 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 6 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 0 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 1 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 2 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 3 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 6 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 0 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 1 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 2 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 3 |
| ASSAY | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 6 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | 1E0804A | 0 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | 1E0804A | 3 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | 1E0804A | 6 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | 1E0805A | 0 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | 1E0805A | 3 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | 1E0805A | 6 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | 1E0806A | 0 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | 1E0806A | 3 |
| ASSAY | 25 | 60 600mg | 0.05 | 2 | 1E0806A | 6 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0804S | 0 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0804S | 3 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0804S | 6 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1G0805S | 0 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1G0805S | 3 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1G0805S | 6 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1G0806S | 0 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1G0806S | 3 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1G0806S | 6 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0804S | 0 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0804S | 1 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0804S | 2 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0804S | 3 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0804S | 6 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1G0805S | 0 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1G0805S | 1 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1G0805S | 2 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1G0805S | 3 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1G0805S | 6 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1G0806S | 0 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1G0806S | 1 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1G0806S | 2 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1G0806S | 3 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1G0806S | 6 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804GA | 0 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804GA | 1 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804GA | 2 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804GA | 3 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804GA | 6 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804GR | 0 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804GR | 3 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804GR | 6 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804FA | 0 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804FA | 1 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804FA | 2 |

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|---------|----|----------|------|---|---------|---|
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804FA | 3 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804FA | 6 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804FR | 0 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804FR | 3 |
| HARD | 91 | 92 600mg | 0.05 | 2 | 1E804FR | 6 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 0 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 1 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 2 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 3 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 6 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 0 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 1 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 2 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 3 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 6 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 0 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 1 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 2 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 3 |
| HARD | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 6 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0804A | 0 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0804A | 3 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0804A | 6 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0805A | 0 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0805A | 3 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0805A | 6 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0806A | 0 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0806A | 3 |
| HARD | 25 | 60 600mg | 0.05 | 2 | 1E0806A | 6 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0804S | 0 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0804S | 3 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0804S | 6 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1G0805S | 0 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1G0805S | 3 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1G0805S | 6 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1G0806S | 0 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1G0806S | 3 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1G0806S | 6 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0804S | 0 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0804S | 1 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0804S | 2 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0804S | 3 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0804S | 6 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1G0805S | 0 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1G0805S | 1 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1G0805S | 2 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1G0805S | 3 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1G0805S | 6 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1G0806S | 0 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1G0806S | 1 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1G0806S | 2 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1G0806S | 3 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1G0806S | 6 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804GA | 0 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804GA | 1 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804GA | 2 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804GA | 3 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804GA | 6 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804GR | 0 |

| | | | | | | |
|---------|----|----------|------|---|---------|---|
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804GR | 3 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804GR | 6 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804FA | 0 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804FA | 1 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804FA | 2 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804FA | 3 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804FA | 6 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804FR | 0 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804FR | 3 |
| FRIABIL | 91 | 92 600mg | 0.05 | 2 | 1E804FR | 6 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 0 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 1 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 2 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 3 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0804A | 6 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 0 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 1 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 2 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 3 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0805A | 6 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 0 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 1 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 2 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 3 |
| FRIABIL | 40 | 75 600mg | 0.05 | 2 | 1E0806A | 6 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0804A | 0 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0804A | 3 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0804A | 6 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0805A | 0 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0805A | 3 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0805A | 6 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0806A | 0 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0806A | 3 |
| FRIABIL | 25 | 60 600mg | 0.05 | 2 | 1E0806A | 6 |

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/s/

Ted Guo
7/3/02 01:24:26 PM
BIOMETRICS

Lisa A. Kammerman
7/3/02 03:13:59 PM
BIOMETRICS
I concur with review