| BOOK _ TITLE | NO: 11781 TRAVATAN BAC Free , D . 00 | 110/ Fz 1/1 / | PAGE | |
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| _ | · · · · · · · · · · · · · · · · · · · | 1910 lumulations for 1 | PROJECT # | - XX3 // (|
| (cont. from | page. <u>5tar +</u>) | ge un | → of | |
| Puraxe | To oceans TRA | AUATAN RAC FREE 0.00 | 4% wirkpH 5.5, 6.5 a | 1 . 41 85% |
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| o imponentante | ÷ | | - increase engineers of contraction of the contract | gunne francounterware and was |
| | Experimental: | | | |
| uju | Equipment: | | | 140 800 |
| | Mettler AX 205 DR Analyt | tical Balance, Asset No. 51 | 5840, Rm. B134 (referred to as B | Salance 1) |
| | Orion 525A+ pH Meter, As | Asset No. 101205, Rm. B13 sset No. A2309 Rm. B134 | 34 (referred to as Balance 2) | |
| | The Advanced Micro-Osmo | ometer Model 3300, Asset | no. 00103390. Rm. B132 | 4 |
| * * | 5111 Tales, Kill. D134 | | V0.00000, ICIII. D101 | į |
| -acce al | Millipore 0.22 μm Filter Un | nit (1000 mL) | | |
| | Formulations: | | | |
| enen diamentenen | FID Batch 109032 05-40452 | Description | | . Water State Stat |
| | 109032 05-40452 109033 05-40453 | TRAVATAN BAC Fre TRAVATAN BAC Fre | e, 0.004% - pH 5.5 | |
| | 109034 05-40454 | TRAVATAN BAC Fre | e, 0.004% - pH 6.5 e, 0.004% - pH 5.5 w/ 85% of zit | aa baria aaid |
| c | omnounding Dropodyness (s. | | | ic, bone acid |
| Ĩ | ompounding Procedures: (see | e attached batch records wi | th adjunctive data) | 19 |
| <i> </i> / | A. FID 109032 Batch | 1 05-40452 TRAVATAN J | BAC Free, 0.004% - pH 5.5 | Neighnikes |
| W | V | | | • |
| 1/100 | 2. Removed the stir bar. W | lass beaker with a stir bar. (Veighed and added the batch | (Balance 2) (Balan | 4L - L - 1 |
| 1 10 | (Durance 2) | | | the beaker. |
| 7 4- | Added about 50 % of t Stirred for at least 15 min | batch quantity of purified winutes until HCO-40 is disse | vater. As 5-3-05 | -th designate had |
| ' | Weighed and added the l | batch quantity of the follow | ving excinients to the booken. be- | mia aaid |
| 7 | soronoi, propyrene gryed | oi, aliu zinc chioride. Stirred | d the solution to dissolve these in | gredients. |
| | (Balance 1) As 5305 6. QSed to 95% of batch wo | | | 0 |
| | /. Measured the pH. Initia | al pH = 4.010 As 5-3.00 | Balance 2) h | |
| s harmann of armania rectues | Adjusted pH if necessary | y. , | | Made of the Control o |
| è | Amount of 1N F Amount of 1N F | HCL added = NIA 185 NaOH added= 0.405 | 3-05 | |
| or organistics. | | | | er noor awko |
| -16 | 9. Weighed the batch quanti | tity of AL-06221 using a sp | atula. (Balance 1) \$5-3-06 | + |
| | 10. Covered the opening with | n the bottle with the end con h parafilm to minimize eya. | ntaining AL-06221 immersed in poration. Stirred overnight to diss | the solution. |
| 20 minipus mas | | | | Solve the AL- |
| å e | Stirring Start time and day | ate: 3:15 pm 18 5-3-05 ate: 9:00 am As 5-405 | - | |
| is no consideration to | 11. Apen to 100% of patch M | veight with purified water (| (Ralance 2) Final nロー ららんノミ | AS 5-405 |
| | 12. Measured Osmolality. Os | smolality = 283 m Dsm// | 1 AS 5-405 | *** |
| | A A Showing-stown | ŕ | | |
| o an an antiger account on the subject | | E DATA AS 6-2105 | φ • | - - |
| to un concentific encontraction and con- | 0 | 'S' | | |
| an an consideration and the second a | PAGE 3 PASES | | | |
| en un consumigio anterescente effectivo. E to Anterescente de inscripcio escripcio della vici | | | | |
| to ut acceptante entre entre especial de la constante especial del constante especial de la constante especial del consta | PAGE 3 PASES REF LN 11781 | | + + + | cont. on page 20 |

| воок _ | NO: 11781 | PAGE | NO: 20 |
|-----------------------------------|---|---|--|
| TITLE _ | TRAVATAN BAC Free, 0.004%, Formulations for PET | PROJECT # _ | 22 5719 |
| (cont. from | page. 19) AS 5-3-05 | w v | |
| A110.00 | agenties in the second in the | | Animhmeniko A Maharanga san |
| | B. FID 109033 Batch 05-40453 TRAVATAN BAC Free, 0.00 | | • |
| | 1. Tare weighed a clean glass beaker with a stir bar. (Balance 2) | 5-3-05 | e o for an enconference en uniforme una une |
| | 2. Removed the stir bar. Weighed and added the batch quantity of H | iCO-40 directly in the | beaker. |
| | 3. Added about 50 % of batch quantity of purified water. #55-3-05 | | www.poo. (Fig. pooler with Fig. |
| * | 4. Stirred for at least 15 minutes until HCO-40 is dissolved. As 5-3-2 5. Weighed and added the batch quantity of the following excipients | s to the beaker: boric: | acid, |
| AND CONTROL | sorbitol, propylene glycol, and zinc chloride. Stirred the solution | to dissolve these ingre | dients. |
| | 6. QSed to 95% of batch weight with purified water. (Balance 2) As 5.3.05 7. Measured the pH. Initial pH = 4.076 As 5.3.05 | 5-3-05 | |
| to to the dimension of the second | 0 A 1' 4 1 II 'C | | erh. voji drava ta diskrikulovovi koji vovok dravata drava kiji de urbaka mji, n. v. j |
| + + | 8. Adjusted pH if necessary. Amount of IN HCL added = N/A As 5-3-3-3 | | 1 |
| \mathcal{L} | Amount of IN NaOH added= 1.493 | | sandanana ĝaran ano |
| 1/1 | 9. Weighed the batch quantity of AL-06221 using a spatula. (Balan | nce 1) As 5-3-05 | a । तीव क्या |
| <i>S</i> y | (d) The spatula was placed in the bottle with the end containing AL- | 06221 immersed in the | solution. |
| 5/1 | 10. Covered the opening with parafilm to minimize evaporation. Stir | red overnight to dissol | ve the AL- |
| | 06221. Stirring Start time and date: 3:15 pm As 5-3-05 | | |
| | Stirring Stop time and date: 9:00am AS 5-4-05 | 6.553 € | Duz 2. Are |
| | 11. OSed to 100% of batch weight with purified water. (Balance 2) F | Final pH = 278 × 0s. / | 7 // 7. |
| | 12. Measured Osmolality. Osmolality = 278 mOsm/lig Ar 5-4-05 | | militaris esperimentaris |
| | | | |
| | C. FID 109034 Batch 05-40454 TRAVATAN BAC Free, 0.00 | 4% - pH 5.5 w/ 85% o | fzinc, |
| | boric acid | | * * |
| | 1. Tare weighed a clean glass beaker with a stir bar. (Balance 2) | 5-3-05 | st to comit de digita de deben ada de la describación de la describac |
| . 4 | 2 Removed the stir bar. Weighed and added the batch quantity of fit | CO-40 directly in the b | eaker. |
| | (Balance 2) 195 5-305 3. Added about 50 % of batch quantity of purified water. As 5-305 | | |
| | 4 Stirred for at least 15 minutes until HCO-40 is dissolved. #\$ 573 | c 5 | The state of the s |
| | 5 Weighed and added the batch quantity of the following excipients | to the beaker: boric a | cid, |
| NUA#Y | sorbitol, propylene glycol, and zinc chloride. Stirred the solution to (Balance 1) As 5-3-05 | o dissolve tilese fligied | , |
| | 6 OSed to 95% of hatch weight with purified water. (Balance 2) | 5-3-05 | ÷ |
| - | 7. Measured the pH. Initial pH = $4./03$ $3.3-03$ | | the restriction of the second |
| 1 | 8. Adjusted pH if necessary. Amount of 1N HCL added = N/A | | ulin ugo |
| . 1)/ | Amount of 1N NaOH added = 0.775 As 5-3-05 | | |
| To Mark | | 1) AS 5-3-05 | NAMA A A A A A A A A A A A A A A A A A A |
| 1 | Weighed the batch quantity of AL-06221 using a spatula. (Balance The spatula was placed in the bottle with the end containing AL-0 | 6221 immersed in the | solution. |
| 52.7 | 10. Covered the opening with parafilm to minimize evaporation. Stirro | ed overnight to dissolv | e the AL- |
| | 06221 | | • |
| mande announcedanns | Stirring Start time and date: 3:15 pm 45 5-3.05 Stirring Stop time and date: 7:00 am Az 5-4-05 | | Sassassashaanaan |
| de de | 11 OSed to 100% of batch weight with purified water. (Balance 2) Fi | inal pH = 5.579 A | 5 5-4-65 |
| · , | 12. Measured Osmolality. Osmolality = 25 7 m cm/kg A 5 5-4-0 | · - | |
| · | , | - ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | |
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| FITLE TRANSPARAN BAC Free , 0.004% For | mulation for A | =7 | PROJE | CT # <u>225</u> 5/ | 9 |
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