

LOW COMPETITION APPROVALS THIS MONTH

COMBINED REPORT FOR NOVEMBER 2025



LOW COMPETITION APPROVALS



06TH NOV – 12TH NOV, 2025

Final Approvals

| Sr. No | Brand Name | Generic Name | Para IV Filers Yet to Be Approved | Approved Company Name | No. Of Final Approvals | Probable Generic Developers ¹ |
|--------|---|-------------------|-----------------------------------|-----------------------|------------------------|--|
| 1. | Forane 99.9% Liquid; Inhalation | Isoflurane | PREMIUM CONTENT | Shandong | 4 th | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |
| 2. | Azulfidine 500mg Tablet | Sulfasalazine | PREMIUM CONTENT | Rising | 4 th | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |
| 3. | Selzentry 150 and 300 mg Tablet | Maraviroc | PREMIUM CONTENT | Rhodes Pharms | 4 th | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |
| 4. | Voltaren 25 mg Tablet, Delayed Release | Diclofenac Sodium | PREMIUM CONTENT | Umedica | 4 th | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |

¹ Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

Research Delta Advisors

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584

LOW COMPETITION APPROVALS



| Sr. No | Brand Name | Generic Name | Para IV Filers Yet to Be Approved | Approved Company Name | No. Of Final Approvals | Probable Generic Developers ¹ |
|------------------------|--|---|-----------------------------------|-----------------------|-----------------------------------|--|
| 5. | Imitrex Statdose Eq 4mg Base/0.5ml (Eq 8mg Base/ml) Eq 6mg Base/0.5ml (Eq 12mg Base/ml) Injectable; Subcutaneous | Sumatriptan Succinate | PREMIUM CONTENT | Alembic | 1 st , 3 rd | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 6. | Cipro Hc Eq 0.2% Base;1% Suspension/Drops;Otic | Ciprofloxacin Hydrochloride; Hydrocortisone | PREMIUM CONTENT | Cosette Pharms | 1 st | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 7. | Xyrem 0.5gm/ml Solution, Oral | Sodium Oxybate | PREMIUM CONTENT | Ascent | 2 nd | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 8. | Jynarque 15 mg, 30 mg, 45 mg, 60 mg, 90 mg Tablet | Tolvaptan | PREMIUM CONTENT | Apotex | 2 nd | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 9. | Jentaduetto 2.5MG;850MG 2.5MG;1GM Tablet | Linagliptin and Metformin Hydrochloride | PREMIUM CONTENT | MSN | 4 th | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |

Research Delta Advisors

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584

LOW COMPETITION APPROVALS



There are no Low Competition Tentative Approvals this week

Research Delta Advisors

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584

LOW COMPETITION APPROVALS



13TH NOV–19TH NOV, 2025

Final Approvals

| Sr. No | Brand Name | Generic Name | Para IV Filers Yet to Be Approved | Approved Company Name | No. Of Final Approvals | Probable Generic Developers ² |
|------------------------|---|-----------------|-----------------------------------|-----------------------|-----------------------------------|--|
| 1. | Omnipaque 300 64.7% Solution; Injection, Oral, Rectal | Iohexol | PREMIUM CONTENT | Amneal | 1 st | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 2. | Dexilant 30 mg Capsule, Delayed Release | Dexlansoprazole | PREMIUM CONTENT | Alembic | 4 th | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 3. | Dexilant 60 mg Capsule, Delayed Release | Dexlansoprazole | PREMIUM CONTENT | Alembic | 4 th | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 4. | Diastat, Diastat Acudial 2.5mg/0.5ml (5mg/ml) 10mg/2ml (5mg/ml) | Diazepam | PREMIUM CONTENT | Navinta | 1 st , 2 nd | PREMIUM CONTENT |

² Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

Research Delta Advisors

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584

LOW COMPETITION APPROVALS



| Sr. No | Brand Name | Generic Name | Para IV Filers Yet to Be Approved | Approved Company Name | No. Of Final Approvals | Probable Generic Developers ² |
|------------------------|----------------------------------|--------------|-----------------------------------|-----------------------|------------------------|--|
| | 20mg/4ml (5mg/ml) Gel; Rectal | | | | | |
| PREMIUM CONTENT | | | | | | |

Tentative Approvals

| Sr. No | Brand Name | Generic Name | Para IV Filers Yet to Be Approved | Approved Company Name | No. Of Final Approvals | Probable Generic Developers ² |
|------------------------|---|--------------|-----------------------------------|-----------------------|------------------------|--|
| 1. | Verzenio 50 mg, 100 mg, 150 mg and 200 mg Tablet | Abemaciclib | PREMIUM CONTENT | Qilu | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 2. | Eliquis 2.5 mg and 5 mg Tablet | APIXABAN | PREMIUM CONTENT | Unichem | 3 | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 3. | Tarpeyo 4 mg; Delayed-release Capsules | Budesonide | PREMIUM CONTENT | Zydus | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |

Research Delta Advisors

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584

LOW COMPETITION APPROVALS



| Sr. No | Brand Name | Generic Name | Para IV Filers Yet to Be Approved | Approved Company Name | No. Of Final Approvals | Probable Generic Developers ² |
|------------------------|--|---------------------------|-----------------------------------|-----------------------|------------------------|--|
| 4. | Crexont 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, 87.5 mg/350 mg; Extended-release Capsules | Carbidopa and Levodopa | PREMIUM CONTENT | Sandoz | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 5. | Kyprolis 10 mg/vial; Powder, Intravenous | Carfilzomib | PREMIUM CONTENT | Hainan | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 6. | Kyprolis 30mg/vial, powder, intravenous | Carfilzomib | PREMIUM CONTENT | Hainan | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 7. | Kyprolis 60 mg/Vial; Powder, Intravenous | Carfilzomib | PREMIUM CONTENT | Hainan | 1 | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 8. | Valtoco 10 mg/spray; Nasal Spray | Diazepam | PREMIUM CONTENT | Padagis | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 9. | Valtoco 5 mg/spray and 7.5 mg/spray; Nasal Spray | Diazepam | PREMIUM CONTENT | Padagis | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |

Research Delta Advisors

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584

LOW COMPETITION APPROVALS



| Sr. No | Brand Name | Generic Name | Para IV Filers Yet to Be Approved | Approved Company Name | No. Of Final Approvals | Probable Generic Developers ² |
|------------------------|---|-----------------------|-----------------------------------|-----------------------|------------------------|--|
| 10. | Xtandi 40 mg; Capsule | Enzalutamide | PREMIUM CONTENT | Cipla | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 11. | Lynparza 100 mg and 150 mg Tablet | Olaparib | PREMIUM CONTENT | Zydus | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 12. | Januvia 25, 50 and 100 mg Tablet | Sitagliptin Phosphate | PREMIUM CONTENT | Laurus Labs | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 13. | Bridion 100mg/1ml Solution; Intravenous | Sugammadex Sodium | PREMIUM CONTENT | Fresenius Kabi | 4 | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 14. | Gemtesa 75 mg Tablet | Vibegron | PREMIUM CONTENT | MSN | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |
| 15. | Trintellix 5,10,15,20 mg Tablet | Vortioxetine | PREMIUM CONTENT | Macleods | None | PREMIUM CONTENT |
| PREMIUM CONTENT | | | | | | |

² Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

Research Delta Advisors

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584

LOW COMPETITION APPROVALS



20TH NOV–26TH NOV, 2025

Final Approvals

| Sr. No | Brand Name | Generic Name | Para IV Filers Yet to Be Approved | Approved Company Name | No. Of Final Approvals | Probable Generic Developers ³ |
|--------|---------------------------|------------------|-----------------------------------|-----------------------|------------------------|--|
| 1. | Keveyis 50mg Tablet | Dichlorphenamide | PREMIUM CONTENT | Rising | 2 nd | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |

³ Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

Research Delta Advisors

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584

LOW COMPETITION APPROVALS



Tentative Approvals

| Sr. No | Brand Name | Generic Name | Para IV Filers Yet to Be Approved | Approved Company Name | No. Of Final Approvals | Probable Generic Developers ³ |
|--------|--|--|-----------------------------------|-----------------------|------------------------|--|
| 1. | Rinvoq 15 mg Tablet, Extended Release | Upadacitinib | PREMIUM CONTENT | Sandoz | None | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |
| 2. | Rinvoq 30 mg Tablet, Extended Release | Upadacitinib | PREMIUM CONTENT | Sandoz | None | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |
| 3. | Rinvoq 45 mg Tablet, Extended Release | Upadacitinib | PREMIUM CONTENT | Sandoz | None | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |
| 4. | Janumet Xr 500mg/50mg, 100mg/1gm Tablet, Extended Release | Sitagliptin Phosphate and Metformin Hydrochloride | PREMIUM CONTENT | MSN | None | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |
| 5. | Xeljanz Xr Eq 22mg Base Tablet, Extended Release | Tofacitinib Citrate | PREMIUM CONTENT | Biocon | 1 | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |

³ Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

Research Delta Advisors

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584

LOW COMPETITION APPROVALS



27TH NOV-03RD DEC, 2025

Final Approvals

| Sr. No | Brand Name | Generic Name | Para IV Filers To Be Approved | Approved Company Name | No. Of Final Approvals | Probable Generic Developers ⁴ |
|--------|---|------------------------------|-------------------------------|---------------------------|-----------------------------------|--|
| 1. | Tazorac 0.05% Cream, Topical | Tazarotene | PREMIUM CONTENT | Long Grove Pharms | 3 rd | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |
| 2. | Dalvance EQ 500mg base/vial Powder; Intravenous | Dalbavancin Hydrochloride | PREMIUM CONTENT | Fresenius Kabi, Kindos | 2 nd , 3 rd | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |
| 3. | Vibra-Tabs Suitability Petition Eq 50mg Base Tablet | Doxycycline Hyclate | PREMIUM CONTENT | Strides Pharma | 4 th | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |

⁴ Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

Research Delta Advisors

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584

LOW COMPETITION APPROVALS



Tentative Approvals

| Sr. No | Brand Name | Generic Name | Para IV Filers To Be Approved | Approved Company Name | No. Of Final Approvals | Probable Generic Developers ⁴ |
|--------|--|--|-------------------------------|-------------------------------|------------------------|--|
| 1. | Janumet Xr 500mg/50mg, 100mg/1gm Tablet, Extended Release | Sitagliptin Phosphate and Metformin Hydrochloride | PREMIUM CONTENT | Zhejiang Jiuzhou Biopharma | None | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |
| 2. | Nurtec ODT 75 mg Orally Disintegrating Tablets | Rimegepant Sulfate | PREMIUM CONTENT | Changzhou Pharma | None | PREMIUM CONTENT |
| | PREMIUM CONTENT | | | | | |

⁴ Probable Generic Developers will also contain companies who might not be the ANDA holders but will be developing for other companies.

Research Delta Advisors

G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023 | Tel: +91.9909919584